Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0672012	01/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Co Dept Of Health & Human Services	2377 N Stemmons Freeway Suite 003, Dallas, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An entrance conference was held on 01/22/19 with the general laboratory supervisor, QA/QC coordinator, LRN principle investigator, and laboratory section supervisor. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 01/22/19 through 01/25/19, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1240 Preanalytic Systems 493.1250 Analytic Systems 493.1403 Laboratory Director Moderate Complexity 493.1409 Technical Consultant 493.1441 Laboratory Director High Complexity 493.1447 Technical Supervisor An exit conference was held on 01/25/19 with the general laboratory supervisor, QA/QC coordinator, LRN principle investigator, laboratory director, and laboratory section supervisor. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to ensure minimal contamination of patient specimens with the HIV-1 NAAT testing as evidenced by: A. In direct observation of testing personnel #16 on 1-25-2019 @ 1015, the testing person for NAAT testing put following specimen tubes in a white refrigerator next to the testing area without adding new caps on the tubes to minimize contamination: Test date 1/25/2019 a. HIV002210 to HIV002216 (1 vacutainer tube) b. HIV001780 (f) (1 vacutainer tube) c. HIV002218 to 002227 (9 vacutainer tubes) d. HIV002284 (1

	vacutainer tubes) e. HIV002285 (1 vacutainer tubes) f. HIV88 (1 vacutainer tubes) g. HIV002293 to 002311 (18 vacutainer tubes) h. HIV002312 toHIV002331 (20 vacutainer tubes) i. HIV002332 to HIV002351 (20 vacutainer tubes) B. In interview with testing personnel #16 @1010 she stated that after they pool the specimens of 20 for testing if one is tested positive they will retest the specimens to try and find out which one is positive for HIV by testing the samples again. c. The laboratory performs 73,500 HIV NAAT tests per year.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and staff interview, it was revealed the laboratory failed to have procedure used to perform or documentation of a competency assessment of the 4 of 4 general supervisors (GS-1, GS-2, GS-3, GS-4). Findings: 1. A review of the laboratory's policies revealed the laboratory failed to have a policy of when and how a competency assessment was to be performed on the general supervisor. 2. Review of personnel records for GS-1 revealed the last documented annual competency assessment was performed on 01/15 /2015. Review of personnel records for GS-2 revealed the last documented annual competency assessment was performed on 07/25/2015. The competency assessment was performed for the title of "Microbiologist" and not as one for a general supervisor. Review of personnel files for GS-3 revealed a hire date of 09/05/2017 and an initial training for Influenza on 01/2018. There was no documentation of semiannual performance for influenza (due 07/2018). Note there was no other documentation of initial training for other select agent testing (Bacillus, Brucella, Tularesnis, Pestis, Psuedomallei, Zika). Review of personnel records for GS-4 revealed there were no documented annual competency assessments since the employee was hired in April 2009. 3. During an interview on 01/23/2019 at 10:30 am, the laboratory director stated that he was aware that he failed to evaluate and document the annual performances of the general supervisors. He stated that he did not always have time to perform the annual assessments. This confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, laboratory's procedures, and interview, the laboratory failed to have a procedure in place and to twice annually verify the accuracy of anal and nasopharyneal swabs for gonorrhea and chlamydia testing in 2018 as evidenced by: 1. The laboratory couldn't produce documentation to show that they have twice annually verified the accuracy of anal and nasopharyneal swabs in 2018. The laboratory was not enrolled in proficiency testing (PT) for these

	two specimen types in 2018. 2. In review of the laboratory's procedures, the laboratory did not have procedure in place to verify twice annual accuracy of anal and nasopharyneal swabs. 3. In interview with the laboratory's QA manager on 1-24-2019 @1325, "We only do PT testing on what CAP sends us (urines only) We don't do twice a year accuracy of aptima anal/nasopharyneal swabs."
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, manufacturer's instructions, patient test records, and laboratory's client service manual, the laboratory failed to meet the requirements of preanalytic systems, as evidenced by: 1. The laboratory failed to ensure patient test requisitions solicited the time of collection for wet mount specimens collected in the clinic and analyzed in the stat laboratory for 8 of 8 patients on 01/24/2019 (random sampling). Refer to D5305. 2. The laboratory failed to ensure urine Aptima gonorrhea (GC) and chlamydia (Chl) samples were within temperature specifications 2-30 degrees C for transport and receiving in the laboratory. Refer to D5311, I. 3. The laboratory failed to implement in their procedure a patient gram stain slide labeling policy. Refer to D5311, II. 4. The laboratory failed to ensure patient gram stain slides received into the stat laboratory for analysis were labeled with patient name or unique patient identifier for 7 of 7 patients on 01/23/2019 (random sampling). Refer to D5311, III. 5. The laboratory failed to define in their written policy the stability of wet mount specimens to ensure integrity of specimens when received and analyzed in the stat laboratory. Refer to D5311, IV. 6. The laboratory failed to make available the manual for their clients and have up to date information (specimen handling requirements) on what tests that laboratory performs. Refer to D5317.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, and in interview with staff, the laboratory failed to ensure patient test requisitions solicited the time of collection for wet mount specimens collected in the clinic and analyzed in the stat laboratory for 8 of 8 patients on 01/24/2019 (random sampling). Findings included: 1. Review of "WET MOUNT PROCEDURE" did not include patient wet mount specimen stability or required documented information on patient test requisitions prior to analysis. Refer to D5311, IV. The wet mount specimens were collected by providers in the sexually transmitted disease (STD) clinic and walked over to the stat laboratory for microscopic analysis. 2. Review of patient "Order Requisition Report" for wet mount test (filled by collecting provider) and wet mount test result sheets (partially filled by collecting provider) from 01/24/2019 revealed the following: Patient #888400 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #885961 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985061 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #969376 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985062 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #979193 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985068 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985066 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. The laboratory did not ensure collection date/time were solicited on patient order requisition forms for patient testing. 3. During an interview on 01/24/2019 at 10:45 am, one of the providers of the STD clinic was asked about the blank collection date /time on patient order requisition forms and on the test result sheets, she stated the nurses should be stamping the date/time of collection when delivering to the stat laboratory for testing. The provider also pointed out on the order requisition form at the bottom where it says "Authorization-Please Sign and Date" is the name of the ordering provider and a date/time, she stated that is the collection date/time. The date /time by the provider's name did not indicate on the form whether this was the collection date/time. The "Collection Date/Time:" on the top right corner of the order requisition report for all patients was consistently blank.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Aptima Urine Samples: I. Based on direct observation, manufacturer's instructions, laboratory's policy, and interview, the laboratory failed to ensure urine Aptima gonorrhea (GC) and chlamydia (Chl) samples were within temperature specifications

2-30 degrees C for transport and receiving in the laboratory as evidenced by: 1.In review of the manufacturer's instructions for the aptima GC and Chl states, " store processed urine specimens at 2 degrees C to 30 degrees C and assay within 30 days after transfer" 2. In direct observation on 1-24-2019 @0935 with the laboratory manager, aptima GC/Chl specimens from a nearby Texas county health department had specimens shipped via Fedex to the laboratory in a Styrofoam container with a ice pack on top of the specimens. The urine specimen were cold to the touch. The laboratory did not take any type of temperature reading to ensure that the specimens came into the laboratory within the 2-30 degrees C requirements. The following specimens were received from the nearby Texas county health department: CC 01960-01978 date received 1-24-19 @0935. 3. In direct observation on 1-24-2019 @0945 with the laboratory manager, aptima GC/Chl specimen from a nearby jail had specimens carried from a courier with an ice pack on top of the specimens. The urine specimens were cold to the touch. The laboratory did not take any type of temperature reading to ensure the specimen came into the laboratory with the 2-30 degree C requirements. The following specimens were received from the nearby jail: JNC 01953-01959 date received 1-24-2019 @0930 4. In review of laboratory's policy for Aptima GC and Chl stated the same as the manufacturer's instructions "". It did not have a procedure for taking temperature on specimens. 5. In interview with the Laboratory manager 1-24-2019 @0948 he stated, "We don't take the temperature when we receive it in the lab, we don't have a temperature gun to take temperatures." 6. The laboratory performs 93,336 aptima combo Gc/Chl per year. 33867 II. Based on direct observation, laboratory's policy, patient test records, and in interview with staff, the laboratory failed to implement in their procedure a patient gram stain slide labeling policy. Findings included: 1. Review of the laboratory's policy for gram stain did not include patient gram stain slide labeling. The stat sexually transmitted disease (STD) clinic practice was providers collected a specimen from urethral, cervix, rectum, or throat. The specimen is collected by provider via swab and then smeared on a slide. The slide is then walked over to the stat lab for examination of gram negative diplococci (GND) (intracellular or extracellular). 2. During a tour of the stat laboratory on 01/24/2019 at 2:30 pm, there were 7 patient gram stain slides observed and only labeled with the patient's first name and last name initials and first initial of the provider who collected the specimen. The slides were analyzed for GND on 01/23 /2019. Review of patient test records (Daily N. gonorrhea Gram Stain Log-in) for the above slides observed were for Patient #985014, Patient #971447, Patient #973160, Patient #985021, Patient #985038, Patient #985045, Patient #961169, Patient #985017. The laboratory's procedure manual did not include labeling instructions for patient gram stain slides to ensure positive identification. 3. During an interview on 01 /24/2019 at 2:30 pm, Testing Person - 13 confirmed the above findings. During an interview on 01/24/2019 at 3:00 pm, the laboratory director was unable to provide a policy for labeling patient gram stain slides. III. Based on direct observation, laboratory's policy, patient test records, and in interview with staff, the laboratory failed to ensure patient gram stain slides received into the stat laboratory for analysis were labeled with patient name or unique patient identifier for 7 of 7 patients on 01/23 /2019 (random sampling). Findings included: 1. Review of the laboratory's policy for gram stain did not include patient gram stain slide labeling. The stat sexually transmitted disease (STD) clinic practice was providers collected a specimen from urethral, cervix, rectum, or throat. The specimen is collected by provider via swab and then smeared on a slide. The slide is then walked over to the stat lab for examination of gram negative diplococci (GND) (intracellular or extracellular). 2. During a tour of the stat laboratory on 01/24/2019 at 2:30 pm, there were 7 patient gram stain slides observed and only labeled with the patient's first name and last name initials and first initial of the provider who collected the specimen. The slides were analyzed for GND

	on 01/23/2019. Review of patient test records (Daily N. gonorrhea Gram Stain Log-in) for the above slides observed were for Patient #985014, Patient #971447, Patient #973160, Patient #985021, Patient #985038, Patient #985045, Patient #961169, Patient #985017. The gram stain slides received into the laboratory did not include patient name or unique patient identifier. 3. During an interview on 01/24/2019 at 2:30 pm, Testing Person - 13 confirmed the above findings. During an interview on 01/24/2019 at 3:00 pm, the laboratory director was unable to provide a policy for labeling patient gram stain slides. IV. Based on review of the laboratory's policy, patient test requisitions, and in interview with staff, the laboratory failed to define in their written policy the stability of wet mount specimens to ensure integrity of specimens when received and analyzed in the stat laboratory. Findings included: 1. Review of "WET MOUNT PROCEDURE" did not include defined patient wet mount specimen stability or required documented information on patient test requisitions prior to analysis. The wet mount specimens were collected by providers in the sexually transmitted disease (STD) clinic and walked over to the stat laboratory for microscopic analysis. 2. Review of patient "Order Requisition Report" for wet mount test (filled by collecting provider) and wet mount test result sheets (partially filled by collecting provider) from 01/24/2019 revealed the following: Patient #888400 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #885961 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985061 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #969376 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985062 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #979193 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985068 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. Patient #985066 order requisition report "Collection Date/Time:" was blank; test result sheet "Time Collected:" was blank. The laboratory did not ensure collection date/time were solicited on patient order requisition forms for patient testing and did not have a defined stability of this specimen type. 3. According to laboratory records, the annual volume was 959 wet mount tests. 4. During an interview on 01/24/2019 at 10:45 am, Testing Person - 14 was asked what was the expected timeframe from time of collection to analysis for wet mount test, she stated, "5 minutes." The laboratory did not have a written policy defining the stability for wet mount specimens.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's client service manual, and interview, the laboratory failed to make available the manual for their clients and have up to date information (specimen handling requirements) on what tests that laboratory performs as evidenced by: 1. In interview with the Quality Assurance (QA) Manager on 1-23-2019 @ 1425 stated he didn't think they had a client service manual, but later was able to find the documents on the computer. The document was written in 2016. In

	questioning further after he found the manual, the QA manager stated that he didn't think that his clients served by the laboratory had the manual. He only sent out memos or talk with the laboratory's on the phone if they had questions concerning specimen collection. 2. In review of the laboratory's client service manual, the manual did not have the following new tests listed in it that have been added by the laboratory after 2016: Cepheid Xpert MTB-RIF Hologic Aptima HIV-1 RNA Kinyoun smear Quantiferon TB Biorad Bioplex Syphillis IgG/IgM Biorad Genius HIV 1/2 supplemental Biorad GS HIV combo ag/ab EIA Those new tests did not have following listed: patient preparation specimen collection requirements specimen labeling, specimen source specimen storage and preservation conditions for transport specimen acceptability and rejection 3. In the exit conference on 1-25-2019 with the Laboratory Director and his staff, he stated that he was aware that it was not updated and that in was created in 2016 to met regulatory requirements.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, manufacturer's instructions, patient test records, and laboratory's client service manual, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems, as evidenced by: 1. The laboratory failed to ensure patient test requisitions solicited the time of collection for wet mount specimens collected in the clinic and analyzed in the stat laboratory for 8 of 8 patients on 01/24/2019 (random sampling). Refer to D5305. 2. The laboratory failed to ensure urine Aptima gonorrhea (GC) and chlamydia (Chl) samples were within temperature specifications 2-30 degrees C for transport and receiving in the laboratory. Refer to D5311, I. 3. The laboratory failed to implement in their procedure a patient gram stain slide labeling policy. Refer to D5311, II. 4. The laboratory failed to ensure patient gram stain slides received into the stat laboratory for analysis were labeled with patient name or unique patient identifier for 7 of 7 patients on 01/23/2019 (random sampling). Refer to D5311, III. 5. The laboratory failed to define in their written policy the stability of wet mount specimens to ensure integrity of specimens when received and analyzed in the stat laboratory. Refer to D5311, IV. 6. The laboratory failed to make available the manual for their clients and have up to date information (specimen handling requirements) on what tests that laboratory performs. Refer to D5317.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the laboratory's procedure, manufacturer's instructions for GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test, laboratory quality control/patient records, temperature logs, and maintenance records, the laboratory failed to meet the requirements of the analytic systems, as evidenced by: 1. The laboratory failed to have their staff follow their procedures with the HIV-1 NAAT testing. Refer to D5401, I. 2. The laboratory failed to ensure written policies were consistent with one another and with the laboratory's practice for changing gram stain reagents. Refer to D5401, II. 3. The laboratory failed to follow its own written policy to use a calibrated nephelometer to confirm the required McFarland standard for MGIT drug susceptibility testing. Refer to D5401, III. 4. The laboratory failed to follow its own written procedure and manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test. Refer to D5401, IV. 5. The laboratory failed to follow their own written policy to ensure that the specified ATCC organism was utilized for quality control testing. Refer to D5401, V. 6. The laboratory did not have procedures for the HIV-1 quantitative testing that started in December 2018. Refer to 5403, I. 7. The laboratory failed to implement written policies and procedures for preparing their own potassium hydroxide (KOH) and saline for wet mount tests. Refer to D5403, II. 8. The laboratory failed to implement QC procedures for reagin plasma reagin (RPR) card test and Biorad BioPlex 2200 analyzer. Refer to D5403, III. 9. The laboratory failed to follow manufacturer's instructions for the Aptima combo urine gonorrhea and chlamydia testing. Refer to D5411, I. 10. The laboratory failed to follow gram stain manufacturer's instructions for staining patient slides for 8 of 8 patients 01/23/2019 (random sampling). Refer to D5411, II. 11. The stat laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 166 days of 166 of QC and 69 of 69 patients from 05/2018 through 12/2018. Refer to D5411, III. 12. The main laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 102 of 102 days of QC from 06/2018 through 10/2018 and 01/2019 and 22 of 22 patients from 01 /2019 (random sampling of patients and QC). Refer to D5411, IV. 13. The laboratory failed to follow manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the BD DrySlide Oxidase test. Refer to D5411, V. 14. The laboratory failed to monitor room temperature where aptima reagents are stored in the hallway. Refer to D5413, I. 15. The laboratory failed to monitor and document temperature of the stat laboratory in which reagents were stored. Refer to D5413, II. 16. The laboratory failed to monitor specimen collection tube storage and specimen blood collection temperature requirements for the Quantiferon TB Gold specimen collection tubes. Refer to D5413, III. 17. The laboratory failed to monitor room temperature as required for the Quantiferon TB Gold ELISA (Enzyme-linked immunosorbent assay) test. Refer to D5413, IV. 18. The laboratory failed to monitor the humidity for the BacTec MGIT 960 mycobacterial detection system. Refer to D5413, V. 19. The laboratory failed to define a temperature range for the phlebotomy room, in which collection supplies were stored, to ensure temperature did not exceed manufacturer instructions for 12 of 12 months in 2018. Refer to D5413, VI. 20. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes according to manufacturer's requirements for storage. Refer to D5413, VII. 21. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Refer to D5413, VIII. 22. The laboratory failed monitor and document temperature for the storage of BD blood collection tubes and swab sets according to

	manufacturer's requirements for storage. Refer to D5413, IX. 23. The laboratory failed to label gram stain reagent secondary containers with identity (including lot number) and poured/expiration dates. Refer to D5415, I. 24. The laboratory failed to ensure vials of mycobacteriology ATCC organisms were labeled with a preparation date and an expiration date specified by the manufacturer. Refer to D5415, II. 25. The laboratory failed to have documentation of the open date 6 of 6 bottles of Kinyoun and Auramine Rhodamine staining reagents. Refer to D5415, III. 26. The laboratory failed follow manufacturer's instructions to document the preparation date and revised expiration date for 3 of 3 prepared Bio Rad GS HIV Combo Ag/Ab EIA (Enzyme Immunosorbant Assay) reagents. Refer to D5415, IV. 27. The laboratory failed to ensure prepared reagents of saline stored in secondary containers were labeled with identification, concentration, poured dates, preparation dates, and expiration dates. Refer to D5415, V. 28. The laboratory failed to ensure alcohol reagent was not used past its expiration date. Refer to D5417, I. 29. The laboratory failed to ensure that Quantiferon TB Gold blood collection tubes were not expired prior to testing. Refer to D5417, II. 30. The laboratory failed to ensure blood collection containers did not exceed their expiration date. Refer to D5417, III. 31. The laboratory failed to ensure reagents, quality control (QC), calibration materials, and blood collection containers did not exceed their expiration date. Refer to D5417, IV. 32. The laboratory failed to have documentation of performing verification studies on the Evolis (Serial Number 9163701015) before testing for GS HIV Combo Ag/Ab EIA testing. Refer to D5421. 33. The laboratory failed to have documentation of performing all required daily (26 of 158 testing days), weekly (12 of 72 weeks), and monthly (5 of 18 months) maintenance. Refer to D5429. 34. The stat laboratory failed to implement an IQCP for syphilis health check when QC was tested less frequent than required. Refer to D5445. 35. The laboratory failed to follow their quality assessment plan for Cepheid Gene xpert MTB/RIF test. Refer to D5447. 36. The stat laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 166 of 166 days from 05/2018 through 12/2018. Refer to D5449, I. 37. The stat laboratory failed to include negative and positive control material every day of patient testing for syphilis health check for 7 of 7 days from 07/2018 through 12/2018 (random sampling). Refer to D5449, II. 38. The main laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 102 of 102 days in 2018 and 2019 (random sampling from 06/2018 through 10 /2018 and 01/2019). Refer to D5449, III. 39. The stat laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 3 of 3 lot numbers in 2018 (random sampling 05/2018 through 12/2018). Refer to D5469, I. 40. The main laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 2 of 2 lot numbers in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01 /2019). Refer to D5469, II. 41. The laboratory failed to establish the criteria for acceptability and that statistical parameters (standard deviation, mean) for each lot number were defined and available for BioPlex 2200 Syphilis Total control material current lot (effective 10/22/2018). Refer to D5469, III. 42. The laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response. Refer to D5477. 43. The laboratory failed to have a system in place that twice a year defines the relationship between using two different panther instruments while testing anal /nasophargnal swabs and urine specimens for gonorrhea and chlamydia. Refer to D5775. 44. The laboratory failed to document corrective action when the temperature range exceeded manufacturer's requirements for the storage of BD blood collection tubes for 2 of 40 days in 2018 (July 2018, September 2018). Refer to D5785.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's procedure, the laboratory failed to have their staff follow their procedures with the HIV-1 NAAT testing as evidenced by: 1.In review of the laboratory procedures "NAAT pooling Procedures" under High Risk pool (20 specimens pool) states under step 3, "Set pipet to 50 ul and add 50 ul from each specimen to its assigned pool test tube. Continue until all specimens are added into the correct pool test" 2. In direct observation on 1-25-2019 @0955 with testing personnel #16, the testing person added 100ul of each patient to 20 patient pool samples, pool numbers 103, 104, 105, 106. The patients were: pool 103 HIV002210 to HIV002216 HIV001780(F) HIV002218 to HIV 002285 pool 104 88 HIV002293 to HIV002311 pool 105 HIV002312 to HIV002331 pool 106 HIV002332 to HIV002351 3. In interview with testing personnel #16 after she added the sample the surveyor ask how much patient sample she added to the 20 patient pool, she stated that yeah when I do a pool of 20 I add 100 ul of patient sample to the pool. 33867 II. Based on direct observation, review of the laboratory's procedure manual, and in interview with staff, the laboratory failed to ensure written policies were consistent with one another and with the laboratory's practice for changing gram stain reagents. Findings included: 1. Review of the "GRAM STAIN CONTROL CONTROL [sic]" policy stated, "II. Procedure: A. Reagents in staining wells are changed daily after each day's use." The policy was signed and dated by the laboratory director 04/08/2009. The policy did not include whether it was no longer in-use or discontinued. Review of "Gram Stain Procedure" policy stated (page 3), "Procedure: 1) The Gram Iodine and decolorizer are changed daily after each day's use. The Gram crystal violet and safranin are changed weekly." At the bottom of the policy it stated, "Revision Date: May 01, 2013." The written policies were not consistent with one another. 2. During a tour of the stat laboratory on 01/24/2019 at 10:30 am, gram stain reagents were observed to be stored in secondary containers for staining patient slides. The first container to the left contained the crystal violet, followed by three containers of deionized water, followed by a container of iodine, followed by one container of deionized water, followed by two containers of decolorizer, followed by one container of deionized water, followed by a container of safranin, followed by two containers of deionized water (none were labeled with identity, lot number, pour/expiration date). During an interview on 01/24/2019 at 10: 30 am, Testing Person - 14 was asked how often were the gram stain reagents changed, she stated the water was changed daily and the other reagents (crystal violet, iodine, safranin) were changed weekly. The laboratory was not following either written policy and the laboratory did not ensure their written policies were consistent with the laboratory's practice. 39812 III. Based on review of laboratory policy and confirmed by staff interview, the laboratory failed to follow its own written policy to use a calibrated nephelometer to confirm the required McFarland standard for MGIT drug susceptibility testing. Findings included: 1. Review of laboratory policies revealed the following: a. Review of the laboratory policy titled "SOP.TB-P7B MGIT PZA Drug Susceptibility Testing" (Approved by the laboratory director 01/2018) in the section titled "Solid Media Isolate" stated, "Confirm the 0.5 McFarland density

using the calibrated nephelometer ... ...IMPORTANT: Ensure that the final test inoculum is at or near a 0.5 McFarland standard before proceeding to the inoculation of the SIRE drug tubes. Failure to proceed with an inoculum at a 0.5 McFarland standard could result in erroneous results." b. Review of the laboratory policy titled "SOP.TB-P7A MGIT S.I.R.E Drug Susceptibility Testing" (Approved by the laboratory director 06/2018) in the section titled "Solid Media Isolate" stated, "Adjust suspension to a 0.5 McFarland standard by using the BD PhoenixSpec Nephelometer ... ... IMPORTANT: Ensure that the final test inoculum is at or near a 0.5 McFarland standard before proceeding to the inoculation of the SIRE drug tubes. Failure to proceed with an inoculum at a 0.5 McFarland standard could result in erroneous results." 2. In an interview on 01/24/2019 at 1030 hours in the mycobacteriology section of the laboratory, testing person #10 stated the facility does NOT use a nephelometer to determine the McFarland standard. This confirmed the above findings. Word Key: MGIT= Mycobacterial Growth Indicator Tube PZA=Pyrazinamide S.I.R.E= Streptomycin, Isoniazid, Rifampin and Ethambutol IV. Based on review of laboratory policy, manufacturer's instructions for GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test and laboratory quality control/patient records, and confirmed in staff interview, the laboratory failed to follow its own written procedure and manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test. Findings included: 1. Review of the laboratory policy titled "Cultures for the Isolation of Neisseria Gonorrhea" (April 29, 2013) in the section titled "Quality Control" stated, 'Positive and negative control strains should be tested routinely. A culture of N. gonorrhoeae (e. g., American Type Culture Collection, ATCC #19424) may be used as the positive control while a culture of Neisseria meningitidis (e.g., ATCC #13077) may be used as the negative control." 2. Review of the manufacturer's instructions for GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test (102846 Rev L 2011-12) in the section titled "Controls" stated, "Positive and negative control strains should be tested routinely in each laboratory according to local regulations. A culture of N. gonorrhoeae (e. g., American Type Culture Collection, ATCC #19424) may be used as the positive control while a culture of Neisseria meningitidis (e.g., ATCC #13077) may be used as the negative control." 3. Review of the laboratory record titled "Daily Urethral GC Cultures Worksheet" (Created March 2018) listed the following under "Quality Control Information": "Accuprobe; Positive Control; N. gonorrhoeae ATCC: 43069; Negative Control; N. meningiditis ATCC: 13090" Per laboratory policy and manufacturer's instructions, N. gonorrhoeae ATCC 19424 should be used as the positive control. Per laboratory policy and manufacturer's instructions, N. meningiditis ATCC 13077 should be used as the negative control. 4. Review of laboratory quality control/patient testing records from 01/18/2019 through 01/25/2019 revealed 2 of 4 days in which the laboratory performed the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification testing and failed to utilize the CORRECT ATCC organisms for quality control testing. The following patients were tested using the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test. 01/18/2019 Patient 964838 Patient 984789 Patient 970419 Patient 780002 01/22/2019 Patient 973348 Patient 984868 Patient 983261 Patient 984876 5. The above findings were confirmed on 01/25/2019 at 1230 hours in a staff interview. V. Based on review of laboratory policy, laboratory quality control records (2017 and 2018), direct observation, and confirmed in staff interview, the laboratory failed to follow their own written policy to ensure that the specified ATCC organism was utilized for quality control testing. Findings included: 1. Review of laboratory policies and quality control records revealed the following ATCC organisms were used for quality control testing: a. Gram Stain Staphylococcus epidermis ATCC 14990 Escherichia coli ATCC 43069

	b. Oxidase Neisseria gonorrhoeae ATCC 43069 Proteus mirabilis ATCC 43071 c. Thayer-Martin media Staphylococcus epidermidis ATCC 12228 Proteus mirabilis ATCC 43071 d. BD BacTec MGIT Liquid Culture Analysis Mycobacterium fortuitum ATCC 6841 Mycobacterium kansasii ATCC 12478 Mycobacterium tuberculosis ATCC 27294 e. BD BacTec MGIT PZA Drug Susceptibility Mycobacterium tuberculosis ATCC 35822 Mycobacterium tuberculosis ATCC 27294 f. BD BacTec MGIT S.I.R.E Drug Susceptibility Mycobacterium tuberculosis ATCC 35822 Mycobacterium tuberculosis ATCC 27294 g. Accuprobe Mycobacterium Tuberculosis Culture Identification Test Mycobacterium avium ATCC 25291 Mycobacterium gordonae ATCC 35759 Mycobacterium kansasii ATCC 12478 Mycobacterium scrofulaceum ATCC 35785 Mycobacterium tuberculosis ATCC 27294 h. Accuprobe Neisseria Gonorrhoae Culture Identification Test Neisseria gonorrhoeae ATCC 43069 Neisseria meningitidis ATCC 13077 2. During a tour of the mycobacteriology section of the laboratory on 01/25/2019 at 1230 hours, the following small vials of preserved quality control microbiology organism pellets were observed in the freezer in a container labeled "TB stocks": 2 vials labeled TBS 2 vials labeled TBR 1 vial labeled GO 2 vials labeled KA 1 vial labeled CH 1 vial labeled SC 1 vial labeled FO 1 vial labeled AV 1 vial labeled PZAR 3. In an interview on 01/25 /2019 at 1230 hours in the mycobacteriology section of the laboratory, Testing person #10 was asked where the ATCC commerically prepared organisms were stored. Testing person #10 stated that the laboratory does NOT have any commercially prepared ATCC organisms for quality control testing. Testing person #10 was asked how did the laboratory verify that the organisms used for quality control were the ATCC specified on the quality control documents. Testing person #10 stated that the laboratory keeps an inventory of organisms that are subbed periodically to sustain growth but the ATCC was unknown. The laboratory failed to ensure that the specified ATCC organisms was utilized for quality control testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's procedures and interview, the laboratory did not have procedures for the HIV-1 quantitative testing that started in December 2018 as

	evidenced by: 1. In review of the laboratory's procedures, the laboratory could not provide a procedure for HIV-1 RNA quantitative testing to the surveyor. 2. In interview with the QA manager on 1-24-2019 stated that the laboratory did not have a procedure for HIV-1 RNA quantitative testing. 3. Since December 2018, the laboratory has performed 9 patient tests. 33867 II. Based on direct observation, review of the laboratory's policy, and interview with staff, the laboratory failed to implement written policies and procedures for preparing their own potassium hydroxide (KOH) and saline for wet mount tests. Findings included: 1. During a tour of the stat laboratory on 01/24/2019 at 10:30 am, KOH 10% was observed to be stored in a glass container and premade saline tubes (6 X 12 tubes) were observed in a blue rack (made 01/23/2019 and expiration 04/23/2019). 2. During an interview on 01/24/2019 at 10: 30 am, Testing Person - 13 (TP-13) was asked how were the KOH and saline solution prepared by the laboratory, she stated for the making the KOH they use 10 grams of KOH and 100 mL deionized water and for making the saline they use "9.9 grams to 1000 mL deionized water." She stated the stability for KOH and saline was 6 months. 3. Review of the laboratory's procedure manual did not include preparation of KOH and saline solutions used for patient wet mounts, including defined stability. 4. During an interview on 01/24/2019 at 10:30 am, TP-13 was asked whether there was a written procedure for preparing KOH and saline solutions, she stated no. III. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the laboratory failed to implement QC procedures for reagin plasma reagin (RPR) card test and Biorad BioPlex 2200 analyzer. Findings included: 1. Review of "Section I. Rapid Plasma Reagin (RPR) 18mm Card Test" policy did not include qualitative control procedures for the RPR card test. Review of "Section I. Rapid Plasma Reagin (RPR) 18mm Card Test" policy did not include establishing criteria of acceptability of control material for quantitative RPR card test. Review of the laboratory's policy did not include establishing criteria for acceptability, including statistical parameters for each lot number for BioPlex 2200 Syphilis Total control material. 2. Review of ASI RPR CARD TEST FOR SYPHILIS manufacturer's instructions (package insert) stated, "Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures ..." The laboratory did not document qualitative QC results every day of patient testing. Refer to D5449, III. Review of Biorad BioPlex 2200 Syphilis Total control material manufacturer's instructions (package insert) stated, "ASSIGNMENT OF VALUES: The mean values were derived from replicate analyses and should fall within the corresponding standard deviation. It is recommended that an individual laboratory use the limits provided only as guides." The laboratory did not include manufacturer's instructions in their written policies /procedures. The laboratory did not follow manufacturer's instructions for establishing their criteria for acceptability. Refer to D5469 II, III. 3. The laboratory's written policies and procedures for RPR card test and Bioplex 2200 analyzer did not include: RPR qualitative control procedures; criteria to determine acceptable control results for quantitative RPR card test and BioPlex 2200 Syphilis Total.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
I. Based on review of the manufacturer's package inserts, and interview, the laboratory failed to follow manufacturer's instructions for the Aptima combo urine gonorrhea and chlamydia testing as evidenced by: 1. In review of the manufacturer's package inserts Aptima Combo 2 assay (panther system) rev.005 pg 14 states" If a specimen tube contains bubbles in the space between the liquid and the cap, centrifuge the tube for 5 minutes at 420 RCF to eliminate bubbles." 2. In an interview with testing personnel in charge of the Aptima Panther system on 1-25-2019 @1320 he demonstrated that they open the lid of the specimen and use a sterile polyester tip applicator to get rid of the bubble. after the surveyor showed him the package insert that stated to centrifuge the specimens instead of using the applicator, he stated, "I have never heard of spinning the specimens down." 3. The laboratory perform 93,336 aptima combo for CT/GC 33867 II. Based on direct observation, review of manufacturer's instructions, laboratory's policy, patient test records, and in interview with staff, the laboratory failed to follow gram stain manufacturer's instructions for staining patient slides for 8 of 8 patients 01/23/2019 (random sampling). Findings included: 1. Review of Gram Stain Remel manufacturer's instructions for "Procedure" stated, "1. Make a thin smear of the material for study on a glass slide. Allow the slide to air-dry completely or use a slide warmer. Fix the slide by passing 3 or 4 times through the flame of a Bunsen burner or flood the smear with methanol and allow it to evaporate. 2. Place the slide on a staining rack and overlay with Gram Crystal Violet for 1 minute. 3. Wash thoroughly with water and overlay with Gram Iodine mordant for 1 minute. 4. Flood with Gram Decolorizer until the solvent flows colorless from the slide (10-30 seconds). 5. Rinse with water and overlay with Gram Safranin for 30 seconds. 6. Rinse with water and allow to dry." 2. Review of laboratory's "Gram Stain Procedure" stated, "Preparation of Smear: Heat fix the smear briefly by passing it over a flame several times. The slide should feel warm but not hot. Staining: 1. Dip the slide in crystal violet for approximately 5 seconds, then rinse in the three bath of tap water. 2. Dip slide in Gram's iodine for approximately 5 seconds, then rinse in tap water. 3. Rinse the slide in the decolorizing solution until the purple color no longer runs from the thinnest part of the smear. The length of decolorizing depends on the composition of the decolorizing reagent and the thickness of the smear. For 50% acetone and 50% ethanol solution, decolorize approximately 5 seconds. 4. Place the slide in safranin for approximately 20 seconds, then rinse in water. 5. Dry smear, blot the slide gently on blotting paper (do not rub the slide)." The laboratory's policy was not consistent with manufacturer's instructions for crystal violet and iodine time (1-minute vs 5 seconds), dipping the slide in water after the iodine instead of the decolorizer, safranin time (30 seconds vs 20 seconds). 3. During a tour of the stat laboratory on 01/24/2019 at 10:30 am, gram stain reagents were observed to be stored in secondary containers for staining patient slides. The first container to the left contained the crystal violet, followed by three containers of deionized water, followed by a container of iodine, followed by one container of deionized water, followed by two containers of decolorizer, followed by one container of deionized water, followed by a container of safranin, followed by two containers of deionized water (none were labeled with identity, lot number, pour/expiration date). The water followed by the iodine was not according to manufacturer's instructions, decolorizer should be after the iodine. 4. During an interview on 01/24/2019 at 10:30 am, Testing Person - 14 was asked how she stained patient slides, she stated she heat fixes the slide about 5 seconds, dips the slide in each reagent and water until color disappears, about 5 seconds each. The laboratory did not follow Remel gram stain manufacturer's instructions for staining patient slides. 5. Review of patient test records for gram stain slides on 01/23/2019 (random sampling) revealed the following patient's urethral gram negative diplococci

results: Patient #985014 Patient #971447 Patient #973160 Patient #985021 Patient #985038 Patient #985045 Patient #961169 Patient #985017 Laboratory records revealed the annual patient volume was 87,886 bacteriology tests. III. Based on direct observation, review of manufacturer's instructions, laboratory's policy, quality control (QC) records, patient records, and in interview with staff, the stat laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 166 days of 166 of QC and 69 of 69 patients from 05/2018 through 12/2018. Findings included: 1. Review of Macro-Vue RPR Card Tests manufacturer's instructions (package insert) stated, "PROCEDURES AND RESULTS ...Materials Required But not Provided: ...Saline (0.9%) for use in quantitative testing ..." and "8 mm Quantitative Card Test: For each specimen to be tested, place 0.05 mL of 0.9% saline onto circles, numbered 2 to 5 ..." 2. Review of "LABORATORY PROCEDURE MACRO-VUE RPR CARD TESTS 18 MM CIRCLE QUALITATIVE AND QUANTITATIVE For the Serologic Detection of Syphilis" stated, "IV. PROCEDURES ...Materials Required But not Provided: ... Saline (0.9%) for use in quantitative testing ..." and "18 mm Circle Quantitative Card Test: 1. For each specimen to be tested, place 0.05 mL of 0.9% saline onto circles, numbered 2 to 5..." 3. During a tour of the stat laboratory on 01/24/2019 at 10:45 am, observed in the small Summit refrigerator was a yellow top cup labeled "recv'd 1/16 /19" and "Saline, exp 2/16/19." On the counter, where RPR testing occurred, was a yellow top cup labeled "in use 1/22/19." During an interview on 01/24/2019 at 10:45 am, TP-13 stated the yellow top cup was saline that is produced "downstairs" (main laboratory) used for RPR testing. During the tour on 01/24/2019 at 10:50 am, TP-14 was observed to perform the RPR test procedure, she pipetted 50 microliters of saline and dispensed on the card, pipetted 50 microliters of plasma and dispensed to the card and mixed with a dispenstir, dispensed suspension drops, and placed card on the rotator (7 to 8 minutes). The saline used in stat laboratory was "fetal bovine serum saline" and was produced by the main laboratory. The saline was not 0.9% saline as required by Macro-Vue RPR Card Tests. The laboratory's policy did not include using "fetal bovine serum saline" for RPR quantitative testing. 4. Review of "BD MACRO-VUE-STAT LABORATORY RPR QUALITY CONTROL LOG SHEET" records from 05/2018 through 12/2018 revealed the laboratory performed quantitative RPR QC for 166 days using "fetal bovine serum saline" in the procedure. Review of "Syphilis Serology Log" from 05/2018 through 12/2018 included patients tested for quantitative RPR, as follows (random sampling): 05/10/2018 - Patient #8 (result: 1:2); Patient #9 (result: 1:4); Patient #12 (result: 1:4) 06/11/2018 - Patient #6 (result: 1:128) 07/05/2018 - Patient #2 (result: 1:4); Patient #5 (result: 1:4) 08/03/2018 - Patient #3 (result: 1:128); Patient #6 (result: 1:2); Patient #7 (result: 1:64) 09/24/2018 - Patient #2 (result: 1:4); Patient #6 (result: >1:512); Patient #7 (result: 1:4) 10/19/2018 - Patient #1 (result: 1:16); Patient #3 (result: >1:512); Patient #4 (result: >1:512) 11/05 /2018 - Patient #3 (result: 1:32); Patient #6 (result: 1:16); Patient #7 (result: 1:4) 12/19 /2018 - Patient #2 (result: 1:64); Patient #3 (result: 1:16); Patient #4 (result: 1:128) Comparison studies between 0.9% saline and fetal bovine serum saline were performed in 1998. The manufacturer of RPR card tests used in studies was not indicated. The highest titer included was 1:16. The laboratory's patient testing included titers beyond 1:16 and did not include titer's beyond that in their studies. IV. Based on direct observation, review of manufacturer's instructions, laboratory's policy, quality control (QC) records, patient records, and in interview with staff, the main laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 102 of 102 days of QC from 06/2018 through 10/2018 and 01/2019 and 22 of 22 patients from 01 /2019 (random sampling of patients and QC). Findings included: 1. Review of ASI RPR CARD TEST FOR SYPHILIS manufacturer's instructions (package insert)

	stated, "Additional Materials Required: ...Saline (0.9% NaCl Solution)." 2. Review of "SECTION I. Rapid Plasma Reagin (RPR) 18 mm Card Test" included 0.9% saline with fetal bovine serum in their written procedure. This was not in accordance with ASI RPR CARD TEST FOR SYPHILIS manufacturer's instructions. 3. During an interview on 01/25/2019 at 9:15 am, Testing Person - 7 confirmed the main laboratory used the fetal bovine serum saline for RPR quantitative testing. 4. Review of "RPR QUALITY CONTROL LOG SHEET" records from 06/2018 through 10/2018 and 01 /2019 revealed the laboratory performed daily quantitative RPR QC and patient testing with "fetal bovine serum saline" in the procedure. Review of "DAILY WORKSHEET SYPHLIS SEROLOGY -STD CLINIC" from 01/2019 included patients tested for quantitative RPR, as follows (random sampling): 01/18/2019 - Patient #808529 (result: 1:1024), Patient #984875 (result: 1:2), Patient #983684 (result: 1:32), Patient #905166 (result: 1:256), Patient #984871 (result: 1:128), Patient #784240 (result: 1:1024), Patient #866803 (result: 1:32), Patient #973067 (result: 1: 32), Patient #984876 (result: 1:64), Patient #984874 (result: 1:4), Patient #902516 (result: 1:1024), Patient #743686 (result: 1:1). 01/23/2019 - Patient #831290 (result: 1: 128), Patient #984943 (result: 1:256), Patient #96217 (result: 1:2), Patient #981764 (result: 1:16), Patient #984246 (result: 1:8), Patient #981745 (result: 1:1), Patient #965915 (result: 1:32), Patient #973435 (result: 1:256), Patient #984956 (result: 1:64), Patient #974752 (result: 1:1). QC records from 06/2018 through 10/2018 and 01/2019 revealed the laboratory performed quantitative QC for 102 days. Comparison studies between 0.9% saline and fetal bovine serum saline were performed in 1998. The manufacturer of RPR card tests used in studies was not indicated. The highest titer included was 1:16. The laboratory's patient testing included titers beyond 1:16 and did not include titer's beyond that in their studies. 5. During an interview on 01/25/2019 at 10:56 am, the laboratory director reviewed and confirmed the above findings. 39812 V. Based on review of manufacturer's instructions for the BD DrySlide Oxidase test (2010/06), laboratory quality control records, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the BD DrySlide Oxidase test. Findings included: 1. Review of the manufacturer's instructions for the BD DrySlide Oxidase test (2010/06) stated the following: "Perform the oxidase test following the above procedure with the test organisms listed below. Escherichia coli ATCC 25922 Neisseria sicca ATCC 9913 Pseudomonas aeruginosa ATCC 27853 Quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent NCCLS guidance and CLIA regulations for appropriate Quality Control practices." 2. Review of the laboratory record titled "Oxidase-Gram Stain Quality Control" revealed the laboratory utilized Neisseria gonorrhoeae ATCC 43069 and Proteus mirabilis ATCC 43071 for quality control testing. The laboratory failed to follow manufacturer's instructions. 3. Review of laboratory quality control/patient testing records from 01/18 /2019 through 01/25/2019 revealed 2 of 4 days in which the laboratory performed the BD DrySlide Oxidase testing and failed to utilize the correct ATCC organisms for quality control testing. The following patients were tested using the BD DrySlide Oxidase test: 01/18/2019 Patient 964838 Patient 984789 Patient 970419 Patient 780002 01/22/2019 Patient 973348 Patient 984868 Patient 983261 Patient 984876 4. The above findings were confirmed on 01/25/2019 at 1230 hours in a staff interview. Word Key BD= Becton Dickinson ATCC= American Type Culture Collection
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
I. Based on direct observation, manufacturer's labels, and interview, the laboratory failed to monitor room temperature where aptima reagents are stored in the hallway as evidenced by: 1. In direct observation on 1-24-2019 @1311 the following regents were not being monitored for room temperature: 9-boxes of Hologic Aptima combo 2 lot #244327AH exp: 3-25-20 manufacturer's label stated, "store at 15-30 degrees C" 8- boxes of Hologic Aptima combo 2 lot#247394AH exp: 3-15-20 manufacturer's label stated, " store at 15-30 degrees C" 10- 260 ml aptima oil lot # 7010704 exp: 11-15-2020 manufacturer's label stated, " store at 15-30 degrees C" 10- bottles of aptima Na Bicarbonate buffer lot# 245364 manufacturer's label stated " store at 15-30 degrees C" 5- bottles of 10mM Hepes lot#2X25224CH exp11-15-2020 manufacturer's label stated, " store at 15-30 degrees C" 10-aptima wash solution lot #245397 manufacturer's label stated, "store at 15-30 degrees C" 11- aptima RNA qualitative assay lot# 235831GH manufacturer's label stated "store at15-30 degrees C' 7- HIV qualitative assay 221599H exp: 7-15-2019 manufacturer's label stated "store at 15-30 degrees C" 7-luminmeter 236058H exp: 8-15-2019 manufacturer's label stated " store at 15-30 degrees C" 2. In interview with the with testing personnel in charge of the Aptima Panther system on 1-24-2019 @1310 he stated, "We don't take the room temperature in the hallway." 33867 II. Based on direct observation, review of manufacturer's instructions, temperature logs, and in interview with staff, the laboratory failed to monitor and document temperature of the stat laboratory in which reagents were stored. Findings included: 1. Review of Remel crystal violet, iodine, decolorizer and safranin package inserts "Storage" requirements stated, "Store product in its original container at 20-25C until used." 2. During a tour of the stat laboratory on 01/24/2019 at 10:30 am, the following was observed to be stored in the stat laboratory near the gram stain station: Remel Gram Crystal Violet (1 gallon), Lot #42435, expiration date 02/28/2019 Remel Gram Iodine (1 gallon), Lot #438423, expiration date 07/18/2019 Remel Gram Safranin (1 gallon), Lot #441796 Remel Gram Decolorizer (1 gallon), Lot #464389, expiration date 03/05/2020 There were no thermometer devices near the gram stain reagents to monitor and document temperature. 3. Review of temperature records for the stat laboratory only included temperature monitoring and documentation of temperature for the syphilis health check test kit storage and test area (4 - 30C and 20-26C) and for RPR test area (23-29C). The storage and test area of syphilis was on the opposite side of the gram stain storage area. During the tour of the stat laboratory on 01/24/2019 at 10:30 am, thermometer devices were observed to be stored in the syphilis testing area. 4. During an interview on 10/24/2019 at 10:30 am, Testing Person - 13 confirmed the stat laboratory was not monitoring and documenting temperature the area in which gram stain reagents were stored. 40420 VI. Based on direct observation, review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to define a temperature range for the phlebotomy room, in which collection supplies were stored, to ensure temperature did not exceed manufacturer instructions for 12 of 12 months in 2018. Findings: 1. Review of BD Vacutainer Evacuated Blood Collection System instructions page 3 stated "Storage ...Store tubes

at 4-25C (39-77F)." Review of manufacturer's instructions for Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab stated: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." Review of manufacturer's instructions for Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens state: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." 2. During a tour of the phlebotomy room (room 341) on 01 /24/2019 at 10:30 am, the following were observed to be stored in a storage cabinet: 38 BD SST tubes, Lot #8198909, expiration date 07/31/2019 142 BD K2EDTA tubes, Lot # 8215727, expiration date 12/31/19 7 BD Serum tubes, Lot #8229700, expiration date 08/31/2020 88 BD Acid Solution A tubes, Lot #7067687, expiration date 03/31 /2019 100 BD Acid Solution A tubes, Lot #8099551, expiration date 04/30/2020 50 Aptima Unisex Swab Collection Kits for Endocervical and Male Urethral Swab, Lot #230218H, expiration date 01/31/2019 50 Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens, Lot #32687H, expiration date 10/31/2019 1 Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens, Lot #31828H, Expiration date 01/31/2019 The laboratory failed to define a temperature range to ensure temperatures did not exceed manufacturer's instructions for blood collection tubes, swab kits and urine collection kits. 3. Review of temperature charts from January 2018-December 2018 revealed the laboratory did not define a temperature range of the phlebotomy room (room 341). 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings. VII. Based on direct observation, review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to monitor and document temperature for the storage of BD blood collection tubes according to manufacturer's requirements for storage. Findings: 1. Review of BD Vacutainer Evacuated Blood Collection System instructions page 3 stated "Storage ...Store tubes at 4-25C (39-77F)." 2. During a tour of the third floor storage room (room 343) on 01/24/2019 at 11:03 am, the following blood collection tubes were observed to stored: 200 BD K2EDTA tubes, Lot #8249529, expiration date 1/31/2020 200 BD Serum Blood Collection tubes, lot #8156727, expiration date 6/30/2020 100 BD Serum Blood Collection tubes, lot #8215657, expiration date 8/31/2020 100 BD Serum Blood Collection tubes, lot #8099576, expiration date 4/30/2020 292 BD SST tubes, lot #8306507, expiration date 10/31/2019 292 BD SST tubes, lot #8198909, expiration date 7/31/2019 100 BD Acid Solution A tubes, lot #7180819, expiration date 7/31 /2019 100 BD Acid Solution A tubes, lot #7097973, expiration date 4/30/2019 100 BD Acid Solution A tubes, lot #7157578, expiration date 6/30/2019 There was no thermometer in the storage room. The laboratory failed to monitor and document temperature to ensure the temperature was within range for blood collection tubes according to manufacturer's instructions. 3. During an interview on 01/24/2019 at 11:15 am, Clerk I was asked if temperature was monitored or documented in the storage room and she stated "no." 4. During the exit interview on 01/25/2019 at 4:05 pm, the lab director confirmed the above findings. VIII. Based on direct observation, review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Findings: 1. Review of BD Vacutainer Evacuated Blood Collection System I instructions page 3 stated "Storage ...Store tubes at 4-25C (39-77F)." Review of manufacturer's instructions for UTM w/Minitip Flocked Swab stated: "Storage Universal Transport Medium-UTM The product should be stored in its original container at 2C to 25C until used. Do not overheat. Do not incubate, or freeze prior to use. Improper storage will result in a loss of efficacy. Swab The product should be stored at 2C to 30C until used." Review of manufacturer's instructions for Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab stated: "Kit

Storage Requirements Store collection kit at room temperature (15C to 30C)." 2. During a tour of the first floor sexually transmitted disease (STD) clinic supply room on 1/24/19 at 11:38 am, the following blood collection tubes and swab sets were observed to be stored: 2000 BD K2EDTA tubes, Lot #8011513, expiration date 5/31/2019 700 BD Serum Blood Collection tubes, Lot #8156727, expiration date 6/30/2020 29 UTM w/Minitip Flocked Swab sets, Lot #138435, expiration date 12/31/2019 350 Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab, Lot #238555H, expiration date 8/31/2019 50 Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab, Lot #238554H, expiration date 8/31/2019 There was no thermometer in the storage room. The laboratory failed to monitor and document temperature to ensure the temperature was within range for blood collection tubes and swab sets according to manufacturer's instructions. 3. During an interview on 01/24/2019 at 1:38 pm, the nurse from the STD clinic stated that temperatures were not monitored or documented in the storage room for the clinic. 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings. IX. Based on direct observation, review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Findings: 1. Review of BD Vacutainer Evacuated Blood Collection System instructions page 3 stated "Storage ...Store tubes at 4-25C (39-77F)." Review of manufacturer's instructions for UTM w/Minitip Flocked Swab stated: "Storage Universal Transport Medium-UTM The product should be stored in its original container at 2C to 25C until used. Do not overheat. Do not incubate, or freeze prior to use. Improper storage will result in a loss of efficacy. Swab The product should be stored at 2C to 30C until used." Review of manufacturer's instructions for Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab stated: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." 2. During a tour of a treatment room in the sexually transmitted disease (STD) clinic (room 101) on 01/24/209 at 1:25 pm, the following blood collection tubes and swab sets were observed to be stored: 69 BD Serum tubes, Lot # 8156727, expiration date 6/30/2020 110 K2EDTA tubes, Lot #8011513, expiration date 5/31/19 8 Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab, Lot # 238564HA, expiration date 11/30/2019 5 UTM w/Minitip Flocked Swab, Lot #138435, expiration date 12/31/19 There was no thermometer in the treatment room. The laboratory failed to monitor and document temperature to ensure the temperature was within range for blood collection tubes and swab sets according to manufacturer's instructions. 3. During an interview on 01/24/2019 at 1:25 pm, the nurse from the STD clinic stated that there were a total of 8 treatment rooms in the clinic and all 8 rooms were stocked the same way with the same blood collection tubes and swab sets. She also stated that the temperatures were not monitored or documented in any of the 8 treatment rooms. 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings. 39812 III. Based on direct observation, laboratory policy, manufacturer's instructions and staff interview, the laboratory failed to monitor specimen collection tube storage and specimen blood collection temperature requirements for the Quantiferon TB Gold specimen collection tubes. Findings included: 1. A tour of the laboratory on 01/23/2019 at 1400 hours revealed the following boxes and lot numbers Quantiferon TB Gold collection tubes on the storage rack directly in front of the elevators: a. One box (100 count) Quantiferon TB Gold collection tubes Lot number=56005122 Expiration date=2019-04-30 b. Two boxes (100 count) Quantiferon TB Gold Plus collection tubes Lot number=56004724 Expiration date=2019-01-31 c. Three boxes (100 count) Quantiferon TB Gold Plus collection tubes Lot number=56009147 Expiration

	date=2019-10-31 2. The manufacturer's instruction for Quantiferon TB Gold blood collection tubes (Rev. 01 06/2016) stated, "The blood collection tubes supplied should be stored at 4 C to 25 C ... ...Tube temperature should be between 17-25 C (63-77 F) at the time of blood tube filling." 3. The laboratory's policy titled "Quantiferon TB Gold ELISA" (Approved by the laboratory director, Effective date May 2017) in the section titled "Specimen Collection" stated the following: "b. Blood collection must occur at room temperature (17 - 25 C) and specimen tubes can be stored between temperature (4 - 25 C), however must be brought to room temperature prior to collection." 4. The manufacturer's instructions for Quantiferon TB Gold Plus (08 /2017) in the section titled "Storage and Handling" stated the following: "Store blood collection tubes at 4 to 25 C (40 to 77 F)." The manufacturer's instructions further stated, "Blood collection tubes should be at room temperature 17 - 25 C (62.6 - 77 F) at the time of blood collection." As of the survey date, the laboratory had NOT started testing using the Quantiferon TB Gold Plus ELISA test kit. 5. In an interview on 01/23 /2019 at 1210 hours in the laboratory hallway, the laboratory was asked if there were any other places in the facility where collection tubes were stored or where patient specimens were collected. General Supervisor (GS) #2 stated that TB Gold tubes were stored and collected in the TB (Tuberculosis) clinic and in the HIV (Human Immunodeficiency Virus) clinic. A tour of the HIV clinic on 01/23/2019 at 1416 hours, revealed 7 pre-made bags of various collection tubes, which included Quantiferon TB Gold collection tubes, were stored in the area. A tour of the TB clinic revealed TB tubes were stored in a locked filing cabinet. GS #2 nor the clinic nurse had a key to open the filing cabinet. The General Supervisor (GS) #1 was asked to provide documentation of temperature readings for all areas where Quantiferon collection tubes were stored or where specimens were collected. No documentation was provided. GS #1 stated areas were NOT monitored for temperature. IV. Based on direct observation, review of laboratory policy and staff interview, the laboratory failed to monitor room temperature as required for the Quantiferon TB Gold ELISA (Enzyme-linked immunosorbent assay) test. Findings included: 1. A tour of the bacteriology section of the laboratory on 01/23/2019 at 1315 hours revealed the laboratory did NOT have a thermometer in the area to monitor room temperature readings. The Quantiferon TB Gold ELISA test was performed in this area. 2. The laboratory's policy titled "Quantiferon TB Gold ELISA" (Approved by the laboratory director, Effective date May 2017) in the section titled "Reagent Preparations" stated the following: "1. All plasma specimens, and reagents, except for Conjugate 100X Concentrate, must be brought to room temperature (17 - 25?C) before use. Allow at least 60 minutes for equilibration." 3. In an interview on 01/23/2019 at 1320 hours in the bacteriology area of the laboratory, GS #1 was asked to provide documentation of room temperature monitoring of the area. No documentation was provided. This confirmed the above findings. V. Based on direct observation, review of BacTec MGIT 960 operator's manual and staff interview, the laboratory failed to monitor the humidity for the BacTec MGIT 960 mycobacterial detection system. Findings included: 1. A tour of the mycobacteriology area of the laboratory on 01/23/2019 at 1330 hours, revealed the laboratory utilized a BacTec MGIT 960 instrument (Serial Number MG1375) for mycobacterial detection and susceptibility testing. 2. The BacTec MGIT 960 operator's manual (2003/09) in the section titled "Environmental Requirements" stated, "Humidity 30%-80% RH (relative humidity)." 3. In an interview 01/25/2019 at 1230 hours in the mycobacteriology area, testing person #10 was asked to provide documentation of monitoring humidity in the area. No documentation was provided. This confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
I. Based on direct observation, photos of work station, laboratory's policy, and in interview with staff, the laboratory failed to label gram stain reagent secondary containers with identity (including lot number) and poured/expiration dates. Findings included: 1.During a tour of the stat laboratory on 01/24/2019 at 10:30 am, gram stain reagents were observed to be stored in secondary containers for staining patient slides. The first container to the left contained the crystal violet, followed by three containers of deionized water, followed by a container of iodine, followed by one container of deionized water, followed by two containers of decolorizer, followed by one container of deionized water, followed by a container of safranin, and followed by two containers of deionized water. The secondary containers observed were not labeled with identity, lot number, pour/expiration dates. (Photo taken of this observation is attached to this survey kit). A secondary glass container of alcohol used for heat fixing the gram stain slides was observed to not be labeled with identity (lot number) or pour/expiration date. 2. Review of the "GRAM STAIN CONTROL CONTROL [sic]" policy stated, "II. Procedure: A. Reagents in staining wells are changed daily after each day's use." The policy was signed and dated by the laboratory director 04/08 /2009. The policy did not include whether it was no longer in-use or discontinued. Review of "Gram Stain Procedure" policy stated (page 3), "Procedure: 1) The Gram Iodine and decolorizer are changed daily after each day's use. The Gram crystal violet and safranin are changed weekly." At the bottom of the policy it stated, "Revision Date: May 01, 2013." During an interview on 01/24/2019 at 10:30 am, Testing Person - 14 was asked how often were the gram stain reagents changed, she stated the water was changed daily and the other reagents (crystal violet, iodine, safranin) were changed weekly. The written policies were not consistent with one another and the laboratory was not following either policy (Refer to D5401). 3. During a tour of the stat laboratory on 01/24/2019 at 10:30 am, the following was observed to be stored in the stat laboratory near the gram stain station, the gram stain reagents primary containers: Remel Gram Crystal Violet (1 gallon), Lot #42435, expiration date 02/28 /2019 Remel Gram Iodine (1 gallon), Lot #438423, expiration date 07/18/2019 Remel Gram Safranin (1 gallon), Lot #441796 Remel Gram Decolorizer (1 gallon), Lot #464389, expiration date 03/05/2020 Fisher Scientific Reagent Alcohol (3 - 1 gallon), Lot #136758, expiration date 02/2017 (for heat fixing) 4. During the exit conference on 01/25/2019 at 4:00 pm, the laboratory staff confirmed the above findings. The laboratory did not label secondary containers in which gram stain reagents were used for patient slide staining. 39812 II. Based on review of laboratory policy, laboratory quality control records (2017 and 2018), direct observation, and confirmed in staff interview, the laboratory failed to ensure vials of mycobacteriology ATCC organisms were labeled with a preparation date and an expiration date specified by the manufacturer. Findings included: 1. Review of laboratory policies and quality control records revealed the following ATCC organisms were used for mycobacteriology quality control testing: a. BD BacTec MGIT Liquid Culture Analysis Mycobacterium fortuitum ATCC 6841 Mycobacterium kansasii ATCC 12478 Mycobacterium tuberculosis ATCC 27294 b. BD BacTec MGIT PZA Drug Susceptibility Mycobacterium tuberculosis ATCC 35822 Mycobacterium tuberculosis ATCC 27294

c. BD BacTec MGIT S.I.R.E Drug Susceptibility Mycobacterium tuberculosis ATCC 35822 Mycobacterium tuberculosis ATCC 27294 d. Accuprobe Mycobacterium Tuberculosis Culture Identification Test Mycobacterium avium ATCC 25291 Mycobacterium gordonae ATCC 35759 Mycobacterium kansasii ATCC 12478 Mycobacterium scrofulaceum ATCC 35785 Mycobacterium tuberculosis ATCC 27294 2. During a tour of the mycobacteriology section of the laboratory on 01/25 /2019 at 1230 hours, the following small vials of preserved quality control microbiology organism pellets were observed in the freezer in a container labeled "TB stocks": 2 vials labeled TBS 2 vials labeled TBR 1 vial labeled GO 2 vials labeled KA 1 vial labeled CH 1 vial labeled SC 1 vial labeled FO 1 vial labeled AV 1 vial labeled PZAR None of the frozen vials were labeled with a preparation date or a manufacturer expiration date. 3. In an interview on 01/25/2019 at 1230 hours in the mycobacteriology section of the laboratory, testing person #10 was asked what was the corresponding ATCC number for the frozen specimens. Testing person #10 stated that the laboratory keeps an inventory of organisms that are subbed periodically to sustain growth. Testing person #10 was asked if the ATCC, preparation date and manufacturer's expiration date of the subcultured quality control organisms could be verified. The laboratory could NOT provide verification of the specific ATCC number, preparation date, and expiration date for the organisms currently utilized for mycobacteriology quality control testing. This confirmed the above findings. III. Based on direct observation and staff interview, it was revealed that the laboratory failed to have documentation of the open date 6 of 6 bottles of Kinyoun and Auramine Rhodamine staining reagents. Findings included: 1. During a tour of the mycobacteriology section of the laboratory on 01/23/2019 at 1330 hours, the following bottles of staining reagents in use were observed: a. 1 bottle Remel TB Auramine Rhodamine stain; Lot number 450545; Expiration date 2019/05/07 b. 1 bottle Remel TB Decolorizer; Lot number 462129; Expiration date 2020/02/01 c. 1 bottle Remel TB Potassium Permanganate; Lot number 444640; Expiration date 2019 /03/10 d. 1 bottle Alpha Tec Kinyoun Carbofusion; Lot number 34686; Expiration date 01-2019 e. 1 bottle Alpha Tec Decolorizer; Lot number 036514; Expiration date 2021-03-03 f. 1 bottle Alpha Tec Methylene Blue Counterstain; Lot number 035758; Expiration date 2019-05-28 The laboratory failed to document the date each bottle was opened and put into use. 2. The above findings were confirmed by testing person #10 in an interview on 01/23/2019 at 1400 in the mycobacteriology section of the laboratory. IV. Based on direct observation, review of manufacturer's instructions, and staff interview, it was revealed that the laboratory failed follow manufacturer's instructions to document the preparation date and revised expiration date for 3 of 3 prepared Bio Rad GS HIV Combo Ag/Ab EIA (Enzyme Immunosorbant Assay) reagents. Findings included: 1. Observed during a tour of the serology section of the laboratory on 01/25/2019 at 1430 hours were 2 Bio Rad GS HIV Combo Ag/Ab EIA testing kits (Lot number 150NJJ-10; Expiration date 06-14-2019) which contained the following components: a. Conjugate 1 b. Conjugate 2 c. Conjugate 2 Diluent d. Substrate Buffer e. Chromogen f. Stopping Solution g. Wash Solution Concentrate Also, observed were prepared reagents (Working Conjugate 2, Working TMB Solution, and Working Wash Solution) from the BioRad GS HIV Combo Ag/Ab EIA test kit. None of the containers for these prepared reagents were labeled with preparation date and new expiration date. 2. Review of the manufacturer's instructions for Bio Rad GS HIV Combo Ag/Ab EIA (Revised September 2016) in the section titled "Reagent Preparation and Storage" stated the following: a. "Working Conjugate 2 Solution For the 40mL Lyophilized Conjugate vial, add 40 mL of Conjugate Diluent. Working Conjugate 2 solution is stables for 15 hours at room temperature, and for 4 weeks if stored at 2-8?C ....Note the Concentrate lot number and date and time of preparation of the Working Conjugate 2 Solution. Prepare a user log to record

	the time and temperature of Working Conjugate 2 Solution storage, to ensure that the recommended limits are not exceed." b. "Working TMB Solution Prepare a 1:1 dilution for each strip to be tested by mixing 100 uL of Chromogen to 1 mL of Substrate Buffer .....Note Chromagen lot number, date and time of preparation, and date and time of expiration (8 hours from preparation) on container." c. "Working Wash Solution Prepare working wash solution by adding one part Wash Solution Concentrate (30X) to 29 parts of water (e.g., 120 mL of Wash Concentration Solution to 3480 mL of water) ....The diluted Wash Solution can be stored at room temperature for up to four weeks in a plastic container. Note the lot number, date prepared, and expiration date on the container." 3. In an interview on 01/25/2019 at 1445 hours in the serology section of the laboratory, testing person #8 was asked if the prepared date and new expiration date was recorded on the reagent containers. Testing person #8 stated, No, we use up all of the reagents up every day." This confirmed the above findings. 40420 V. Based on direct observation and confirmed in interview, the laboratory failed to ensure prepared reagents of saline stored in secondary containers were labeled with identification, concentration, poured dates, preparation dates, and expiration dates. Findings: 1. During a tour of the serology lab on 01/24/2019 at 3:16 pm, the surveyor observed the following in the refrigerator: 2 Bottles (secondary containers) labeled: "Saline Exp date 6/6/19" The laboratory failed to label the secondary container with the saline lot numbers, concentration, and poured dates. Note: This saline was poured from a primary container of saline from the laboratory's bulk located in their storage room. Bottle (tertiary container) labeled: "Saline w/serum Exp 6/6/19 RPR Saline Date added 1/7/19 Exp date 3/8/19 RPR Saline: 250 mL of Saline 5 mL of fetal calf serum" The laboratory failed to label the tertiary container with lot numbers of the serum and saline. Note: the saline solution was obtained from the secondary container of saline and mixed with fetal calf serum. Bottle (tertiary container) labeled: "Saline Exp date 6/6/19 RPR Saline Date added 1/24/19 RPR Saline: 250 mL of Saline 5 mL of fetal calf serum" The laboratory failed to label the tertiary container with the prepared name and the lot numbers of the serum and saline. Bottle (quaternary container) labeled: "1/22/19 taken from stock bottle" The laboratory failed to label the quaternary container with the prepared name, lot numbers of the serum and saline, and expiration dates. Note: this solution was poured from the tertiary containers for daily use. Bottle (quaternary container) labeled: "taken from stock bottle" The laboratory failed to label the quaternary container with the prepared name, lot numbers of the serum and saline, pour date, and expiration dates. 2. During an interview on 01/24/19 at 3:46 pm, Testing Person-7 (TP-7) stated that the two unlabeled bottles were the "daily" working saline solution with serum bottles. They are poured off from the "made up" saline serum bottles. 3. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on direct observation and in interview with staff, the laboratory failed to ensure alcohol reagent was not used past its expiration date. Findings included: 1. During a tour of the state laboratory on 01/24/2019 at 10:30 am, the flammable

	cabinet contained Fisher Scientific Reagent Alcohol (3 - 1 gallon), Lot #136758, expiration date 02/2017. The alcohol was used for heat fixing the gram stain slides. The secondary glass container of alcohol was observed to not be labeled with identity (lot number) or pour/expiration date. 2. Laboratory records revealed the annual patient volume was 87,886 bacteriology tests. 3. During an interview on 01/24/2019 at 10:30 am, Testing Person 13 and 14 confirmed the Fisher Scientific alcohol from the flammable cabinet was poured into the secondary glass container for heat fixing the gram stain slides. The laboratory did not ensure reagents were not used past their expiration dates for processing patient gram stain slides. 39812 II. Based on direct observation, patient records and confirmed in staff interview, the laboratory failed to ensure that Quantiferon TB Gold blood collection tubes were not expired prior to testing. Findings included: 1. A tour of the bacteriology section of the laboratory on 01 /24/2019 at 1500 hours revealed the following 4 of 12 tubes tested for Quantiferon TB Gold assay on this day were expired: 2 tubes; Lot number A1709376; Expiration date 2018-12-31 2 tubes; Lot number A1709377; Expiration date 2018-12-31 2. A review of patient records revealed the following patients were tested using expired collection tubes: Patient #984935 Patient #984742 3. The above findings were confirmed by GS #1 on 01/24/2019 at 1510 40420 III. Based on direct observation and confirmed in interview, the laboratory failed to ensure blood collection containers did not exceed their expiration date. Findings: 1. During a tour of the sexually transmitted disease (STD) clinic storage room on 01/23/2019 at 4:10 pm, an open and expired bag of BD Mircotainer Serum Separator Tubes, Lot # 4181362, expiration date 09/2015 was found on the shelf. 2. During an interview on 01/23/2019 at 4:20 pm, the nurse from the STD clinic confirmed the above findings. 3. During a tour of the third floor laboratory (Room 341) on 01/24/2019 at 10:30 am, the following blood collection tubes were found to exceed their expiration date: 9 tubes of Quantiferon TB Antigen, Lot #A1709376, expiration date 12/31/18 9 tubes of Quantiferon Mitogen, Lot #A170937K, expiration date 12/31/18 4. During an interview on 01/24/19 at 11:00 am, the phlebotomist confirmed the above findings. IV. Based on direct observation and confirmed in interview, the laboratory failed to ensure reagents, quality control (QC), calibration materials, and blood collection containers did not exceed their expiration date. Findings: 1. During a tour of the serology lab on 01/24/2019 at 2:00 pm, the following were observed to exceed their expiration dates: Lead Care Blood Test Kit, Lot #CFCSUB lot 4, expiration date 11/24/2017 43 BD Mircotainer Serum Separator Tubes, Lot #2048787, expiration date 04/2013 2. During a second tour of the serology lab on 01/24/2019 at 3:16 pm, the following were observed to exceed their expiration dates: BioPlex 2200 Detector QC Solutions, Lot #300655, expiration date 06/30/2018 BioPlex 2200 Detector Calibration Kit, Lot # 300754, expiration date 12/29/2018 BioPlex 2200 Detector Rhodamine Solution, Lot # 300278, expiration date 03/31/2018 10 bottles Syphilis Positive Control QC Connect, Lot #514807, expiration date 01/2017 2 boxes BioPlex 2200 HIV Ag-Ab Calibrator Set, Lot #50386, expiration date 11/30/2018 3. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records from 07/2018 through 09/2018, laboratory patient records and confirmed in staff interview, it was revealed the laboratory failed to have documentation of performing verification studies on the Evolis (Serial Number 9163701015) before testing for GS HIV Combo Ag/Ab EIA testing. Findings included: 1. Review of the maintenance records for the Bio Rad Evolis (Serial Number 9163700998) microplate processor for automated HIV EIA testing revealed the instrument was out of service from August 09, 2018 through September 7, 2018. 2. Review of patient records from August 09, 2018 through September 7, 2018 revealed 3496 of 3496 HIV Combo Ag/Ab EIA tests were performed on the laboratory's other Bio Rad Evolis (Serial Number 9163701015) which is used for Quantiferon TB Gold testing. The following is a random sample of those patients tested: 08/14/2018 Patient HIV21044 through Patient HIV21060 Patient HIV21147 through Patient HIV21213 08/20/2018 Patient HIV21980 through Patient HIV22061 08/24/2018 Patient HIV22868 through Patient HIV22881 Patient HIV22889 through Patient HIV22937 08/28/2018 Patient HIV23151 through Patient HIV23233 09/05/2018 Patient HIV23954 through Patient HIV24029 09/06/2018 Patient HIV24069 through Patient HIV24149 2. The laboratory was asked to provide documentation of verification studies for accuracy, precision, reportable ranges, and patient reference ranges for the Bio Rad Evolis (Serial Number 9163701015) for the HIV Combo Ag/Ab EIA test. No documentation was provided. 3. In an interview on 01/25/2019 at 1530 hours in the conference room, GS #2 stated that he thought validation studies had been performed on the instrument but he could not locate the documents. This confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, manufacturer's instructions, laboratory maintenance and quality control (QC) records from 08/2017 through 12/2018 for the BioRad Evolis instrument and staff interview, the laboratory failed to have documentation of performing all required daily (26 of 158 testing days), weekly (12 of 72 weeks), and monthly (5 of 18 months) maintenance. Findings included: 1. A tour on 01/25/2019 at 1230 hours of the bacteriology section of the laboratory revealed the laboratory utilized BioRad Evolis instrument (Serial Number 9163701015) for Quantiferon TB Gold ELISA testing. 2. The manufacturer's instructions for the BioRad Evolis instrument (89788C June 2009) in the section titled "Maintenance" stated the following: "a. Daily Maintenance Procedures Start Up Check /Refill System Liquid Container Check/Empty Liquid Waste Container Check for Bubbles in Pipettor Tubing After Worklist Run Check/Empty Tip Waste End of Day Check for/Clean Liquid Spills Check Vacuum and Internal Waste Trap Bottles Clean the Pipettor Head b. Weekly Maintenance Perform the MNTC Washer Clean.asy procedure Clean/Disinfect Internal Work Areas and Access Compartments Clean /Disinfect External Instrument Surfaces Disinfect Sample and Reagent Racks

Disinfect Plate Carriers Disinfect Tip Ejection Slide c. Monthly Procedures Maintenance Procedures Disinfect the System Liquid Container and Pipettor Perform the MNTC Washer Disinfect.asy procedure Clean the Plate Transport Area and Room Temperature Incubators Performance Evaluation Procedures PE Plate Transport Check.asy PE Photometer Verification Procedure PE Kit Procedures Perform the Fluidics Performance Evaluation Panel If PE Kit is unavailable, PE Washer Aspirate Check.asy PE Washer Dispense Check.asy PE Pipettor Check.asy" 3. The laboratory policy titled "Quantiferon TB Gold ELISA" (Approved by the Laboratory Director May 2017) stated the following: "8.3 Evolis Start-up 23. Log all daily maintenance performed on the EVOLIS instrument onto the Combined Maintenance and PE Log document located on the side of the instrument. 9. Evolis Maintenance 9.1 Daily Maintenance 9.1.1 Check/Refill System Liquid Container 9.1.2 Check/Empty Liquid Waste Container 9.1.3 Pipettor Tubing Inspection 9.1.4 Check/Empty Tip Waste 9.1.5 Check for/Clean Liquid Spills 9.1.6 Check Vacuum and Internal Waste Trap Bottles 9.1.7 Clean the Pipettor Head 9.2 Weekly Maintenance 9.2.1 Perform the MNTC Washer Clean procedure 9.2.2 Clean/Disinfect Internal Work Areas and Access Compartments 9.2.3 Clean/Disinfect External Instrument Surfaces 9.2.4 Disinfect Sample and Reagent Racks 9.2.5 Disinfect Plate Carriers 9.2.6 Disinfect Tip Ejection Slide and the Tip Eject Chute 9.3 Monthly Maintenance 9.3.1 Disinfect the System Liquid Container, Pipettor and Wash Modules 9.3.2 Disinfect Washer Module 9.3.3 Rinse System Liquid Lines and Prepare Fresh Systm Liquid 9.3.4 Clean the Plate Transport Area and Room Temperature Incubators 9.3.5 Inspect Pipettor System 9.3.6 Inspect Reagent Rack 9.4 Performance Evaluation Check 9.4.1 PE Plate Transport Check 9.4.2 PE Photometer Verification 9.4.3 PE Photometer Verification Procedure 9.4.4 Fluidics Performance Evaluation Panel" 4. Review of the daily QC log for Quantiferon TB Gold testing and the Combined Maintenance and PE log from 08/ 2017 through 12/2018 revealed 26 of 158 testing days when daily maintenance was NOT documented. The following are days when quality control results were documented but NO daily maintenance was documented: August 8, 2017 August 9, 2017 August 10, 2017 August 11, 2017 September 6, 2017 September 7, 2017 September 8, 2017 October 17, 2017 October 26, 2017 October 31, 2017 November 10, 2017 December 14, 2017 December 29, 2017 January 22, 2018 February 16, 2018 February 19, 2018 March 7, 2018 March 20, 2018 July 11, 2018 August 5, 2018 August 28, 2018 September 13, 2018 October 5, 2018 October 17, 2018 November 9, 2018 November 30, 2018 5. Review of the Combined Maintenance and PE log from 08/2017 through 12/2018 revealed 12 of 72 weeks when weekly maintenance was NOT documented. The following are weeks with NO weekly maintenance documented: September 4-8, 2017 September 25-29, 2017 November 6-10, 2017 December 18-22, 2017 January 1-5, 2018 January 8-12, 2018 February 5-9, 2018 February 19-23, 2018 February 26-March 2, 2018 September 3-7, 2018 October 22-26, 2018 November 19-23, 2018 6. Review of the Combined Maintenance and PE log from 08/2017 through 12/2018 revealed 5 of 18 months when monthly maintenance was NOT documented. The following are months with NO monthly maintenance documented: September 2017 February 2018 March 2018 April 2018 July 2018 7. The laboratory tests an annual volume of 4,734 Quantiferon TB Gold tests. The following is a random review of patients based on review of patient test records (08 /2017-12/2018) for Quantiferon TB Gold testing when required maintenance was not performed/documented: Date tested: October 27, 2017 Patient #810; Patient #811; Patient #812; Patient #813; Patient #814; Patient #815 Date tested: September 13, 2018 Patient # 670, Patient #671; Patient #672; Patient #673; Patient #674; Patient #675; Patient #676 Date tested: October 5, 2018 Patient # 696, Patient #697; Patient #698; Patient #699; Patient #700; Patient #702; Patient #702 Date tested: October 17, 2018 Patient # 707, Patient #708; Patient #709; Patient #710 Word Key:

	TB=Tuberculosis ELISA=Enzyme Linked Immunosorbent Assay PE=Performance Evaluation MNTC= Maintenance
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the stat laboratory failed to implement an IQCP for syphilis health check when QC was tested less frequent than required. Findings included: 1. Review of the laboratory's policy for syphilis health check test stated (page 8 of 25), "VI. QUALITY CONTROL: If you are not running the Syphilis Health Check under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, quality control must be performed in compliance with those regulations." 2. According to Syphilis Health Check manufacturer, the test can be categorized as waived when using "Fingerstick Whole Blood Specimens ONLY" or can be categorized as moderate complexity when using plasma for testing. The manufacturer's instructions (package insert) for Syphilis Health Check QC procedures were applicable to waived-status testing, analyze external QC "Each new lot; Each new shipment ...; Each new operator ...; Monthly ...; Whenever problems (storage, operator, or other) are identified." The manufacturer stated, "If your local or state regulations require more frequent testing of quality control material, quality control must be performed in compliance with those regulations." The laboratory performed patient Syphilis Health Check testing on plasma daily and had not performed an IQCP. 3. Review of "Diagnostics Direct Syphilis Health Check Quality Control Sheet" dated from 06/25/2018 through 01/07 /2019 revealed QC (negative and positive) was not tested everyday of patient testing, as follows (random sampling): 07/20/2018 (Kit #09107) - Patient #2: Negative; and there was no external QC documented. 08/03/2018 (Kit #09107) - Patient #4: Negative; Patient #8: Positive; Patient #9: Positive; and there was no external QC documented. 08/15/2018 (Kit #09107) - Patient #1: Negative; Patient #2: Negative, Patient #5: Positive; Patient #10: Negative; and there was no external QC documented. 09/06/2018 (Kit #12048) - Patient #1: Positive; Patient #8: Negative; and there was no external QC documented. 10/06/2018 (Kit #12048) - Patient #6: Negative; and there was no external QC documented. 11/01/2018 (Kit #12048) - Patient #3: Negative; Patient #4: Positive; and there was no external QC documented. 12/19/2018 (Kit #12048) - Patient #11: Positive; Patient #14: Negative; and there was no external QC documented. 4. During an interview on 01/24/2019 at 3:30 pm, Testing Person - 13 confirmed external QC was not performed every day of patient testing for Syphilis Health Check and was unsure if an IQCP was done. During an interview on 01/25/2019 at 1:03 pm, the laboratory director confirmed an IQCP had not been performed to lessen the frequency of external QC on the Syphilis Health Check test.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Plan (IQCP), laboratory records, and interview, the laboratory failed to follow their quality assessment plan for Cepheid Gene xpert MTB/RIF test as evidenced by: 1. In review of the laboratory's IQCP plan, their section 5 Quality assessment monitoring plan states: "Routine data collection and monitoring of QC data will occur weekly, QC data will be addressed during QA meetings organized by the Quality/Compliance Group and Laboratory Director." "Statistics on patient testing will be concurrently compiled and analyzed on a weekly basis and reviewed by the Quality/Compliance group to identify trends that may indicate problems with cartridge or control lots, specimen collection practices, or other factors." 2. In a request by the laboratory surveyor for these records on 1-23-2019 @1451 the QA manager stated, "We do not have the QC analysis, we stopped on May 1,2018." 3. The laboratory could not provide these records from May 1st 2018 to the time of the survey. 4. In interview with the QA manager on 1-23-2019 @1452 he states that they only had the rest of the stats up until 1-17-2018. The laboratory could not provide stats on patient testing since 1-17-2018 to the time of the survey.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the stat laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 166 of 166 days from 05/2018 through 12/2018. Findings included: 1. Review of "LABORATORY PROCEDURE MACRO-VUE RPR CARD TESTS 18 MM CIRCLE QUALITATIVE AND QUANTITATIVE For the Serologic Detection of Syphilis" stated, "Qualitative The Control ++ should show characteristic clumping: the Control - should show the smooth, grayish appearance of unclumped particles. The Control + should show minimal-to-moderate clumping which should be less than for the reactive control (Control ++). Any control exhibiting any deviation from these results should be rerun ..." This was consistent and verbatim with BD Macro-Vue RPR Card Test Liquid Control manufacturer's instructions. 2. Review of Macro-Vue RPR Card Tests manufacturer's instructions (package insert) stated, "Quality Control: Quality control requirements must be performed in accordance with

applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to the pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices." The laboratory used BD Macro-Vue RPR Card Test Liquid Control material and it included "Reactive Control Serum Positive" (Control ++), "Moderately Reactive Control Serum Weakly Positive" (Control +), and "Negative Control Serum Negative Control" (Control -). 3. Review of "BD MACRO-VUE-STAT LABORATORY RPR QUALITY CONTROL LOG SHEET" records from 05/2018 through 12/2018 revealed the laboratory performed QC everyday of patient testing but only documented quantitative QC results, not qualitative (positive /negative) for 166 days, as follows (sampling of days): 05/2018 - BD Controls included "R" Lot #16181, "R" Lot #16182, "NR" Lot #16183 (expiration date 02 /2019) and a sampling of results of the 22 documented days: 05/01/2018 - "R" 1:4; "R" R(1:); "NR" NR 05/02/2018 - "R" 1:4; "R" R(1:); "NR" NR 05/03/2018 - "R" 1:4; "R" R(1:); "NR" NR 05/04/2018 - "R" 1:4; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 06/2018 - BD Controls included "R" Lot #16181, "R" Lot #16182, "NR" Lot #16183 (expiration date 02/2019) and a sampling of results of the 21 documented days: 06/01/2018 - "R" 1:8; "R" R(1:); "NR" NR 06/04/2018 - "R" 1:4; "R" R(1:); "NR" NR 06/05/2018 - "R" 1:8; "R" R(1:); "NR" NR 06/06/2018 - "R" 1:8; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 07/2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 21 documented days: 07/02/2018 - "R" 1:8; "R" R(1:); "NR" NR 07/03/2018 - "R" 1:4; "R" R(1:); "NR" NR 07/05/2018 - "R" 1:8; "R" R(1:); "NR" NR 07/06/2018 - "R" 1:8; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 08/2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 21 documented days: 08/01/2018 - "R" 1:4; "R" R(1:); "NR" NR 08/02/2018 - "R" 1:8; "R" R(1:); "NR" NR 08/03/2018 - "R" 1:8; "R" R(1:); "NR" NR 08/06/2018 - "R" 1:4; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 09/2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 19 documented days: 09 /04/2018 - "R" 1:4; "R" R(1:); "NR" NR 09/05/2018 - "R" 1:4; "R" R(1:); "NR" NR 09 /06/2018 - "R" 1:4; "R" R(1:); "NR" NR 09/07/2018 - "R" 1:4; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 10/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 23 documented days: 10/01/2018 - "R" 1:8; "R" R(1:); "NR" NR 10/02/2018 - "R" 1:4; "R" R(1:); "NR" NR 10/03/2018 - "R" 1:4; "R" R(1:); "NR" NR 10/04/2018 - "R" 1:4; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 11/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 20 documented days: 11/01/2018 - "R" 1:4; "R" R(1:); "NR" NR 11/02/2018 - "R" 1:4; "R" R(1:); "NR" NR 11/05/2018 - "R" 1:4; "R" R(1:); "NR" NR 11/06/2018 - "R" 1:8; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. 12/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 19 documented days: 12/03/2018 - "R" 1:4; "R" R(1:); "NR" NR 12/04/2018 - "R" 1:4; "R" R(1:); "NR" NR 12/05/2018 - "R" 1:4; "R" R(1:); "NR" NR 12/06/2018 - "R" 1:4; "R" R(1:); "NR" NR Qualitative QC results were not documented, only quantitative. Laboratory controls key: "R" in first column = Reactive Control Serum Positive; "R" in middle column = Moderately Reactive Control Serum Weakly Positive; "NR" = Negative Control Serum Negative Control. 4. According to records, the laboratory's annual volume was 44,552 syphilis serology tests. The laboratory performed and reported both qualitative (reactive/non-reactive) and quantitative (titer) tests/results of patients. 5. During an interview on 01/24/2019 at 10:45 am, Testing Person - 14 (TP-14) was asked whether qualitative QC was performed for RPR card test, she stated yes. It was pointed out to TP-14 that QC documentation provided for RPR QC did not include documentation for the qualitative QC (positive/negative). She reviewed and confirmed that the qualitative RPR QC was not documented. II. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the stat laboratory failed to include negative and positive control material every day of patient testing for syphilis health check for 7 of 7 days from 07/2018 through 12/2018 (random sampling). Findings included: 1. Review of the laboratory's policy for syphilis health check test stated (page 8 of 25), "VI. QUALITY CONTROL: If you are not running the Syphilis Health Check under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, quality control must be performed in compliance with those regulations." 2. According to Syphilis Health Check manufacturer, the test can be categorized as waived when using "Fingerstick Whole Blood Specimens ONLY" or can be categorized as moderate complexity when using plasma for testing. The manufacturer's instructions (package insert) for Syphilis Health Check QC procedures were applicable to waived-status testing, analyze external QC "Each new lot; Each new shipment ...; Each new operator ...; Monthly ...; Whenever problems (storage, operator, or other) are identified." The manufacturer stated, "If your local or state regulations require more frequent testing of quality control material, quality control must be performed in compliance with those regulations." The laboratory performed patient Syphilis Health Check testing on plasma daily. 3. Review of "Diagnostics Direct Syphilis Health Check Quality Control Sheet" dated from 06/25/2018 through 01/07/2019 revealed QC (negative and positive) was not tested everyday of patient testing, as follows (random sampling): 07/20/2018 (Kit #09107) - Patient #2: Negative; and there was no external QC documented. 08/03/2018 (Kit #09107) - Patient #4: Negative; Patient #8: Positive; Patient #9: Positive; and there was no external QC documented. 08/15/2018 (Kit #09107) - Patient #1: Negative; Patient #2: Negative, Patient #5: Positive; Patient #10: Negative; and there was no external QC documented. 09/06/2018 (Kit #12048) - Patient #1: Positive; Patient #8: Negative; and there was no external QC documented. 10/06/2018 (Kit #12048) - Patient #6: Negative; and there was no external QC documented. 11/01/2018 (Kit #12048) - Patient #3: Negative; Patient #4: Positive; and there was no external QC documented. 12/19/2018 (Kit #12048) - Patient #11: Positive; Patient #14: Negative; and there was no external QC documented. 4. During an interview on 01/24/2019 at 3:30 pm, Testing Person - 13 confirmed external QC was not performed every day of patient testing for Syphilis Health Check and was unsure if an IQCP was done. During an interview on 01/25/2019 at 1:03 pm, the laboratory director confirmed an IQCP had not been performed to lessen the frequency of external QC on the Syphilis Health Check test. III. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the main laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 102 of 102 days in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01/2019). Findings included: 1. Review of "Section I. Rapid Plasma Reagin (RPR) 18mm Card Test" policy did not include qualitative control procedures for the RPR card test. 2. Review of ASI RPR CARD TEST FOR SYPHILIS manufacturer's instructions (package insert) stated, "Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures ..." The laboratory used ASI RPR/VDRL CONTROL SERUM SET and it included "REACTIVE CONTROL; WEAK REACTIVE

	CONTROL; NON-REACTIVE CONTROL." 3. Review of "RPR QUALITY CONTROL LOG SHEET" records revealed from 06/2018 through 10/2018 and 01 /2019 the laboratory performed QC everyday of patient testing but only documented quantitative QC results, not qualitative (positive/negative) for 102 days, as follows (sampling of days): 06/2018 - ASI Controls included "R" Lot #R7M09RD, "RMIN" Lot #R7M09RE, "NR" Lot #R7M09RB (expiration date 11/2019) and a sampling of results of the 16 documented days: 06/04/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 06 /05/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 06/06/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR 06/07/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR Qualitative QC results were not documented, only quantitative. 07/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 04/30 /2019) and a sampling of results of the 22 documented days: 07/02/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 07/03/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 07/04/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR 07/05/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR Qualitative QC results were not documented, only quantitative. 08/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 19 documented days: 08/06/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/07/2018 - "R" 1: 8; "RMIN" (1:2); "NR" NR 08/08/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/09 /2018 - "R" 1:8; "RMIN" (1:2); "NR" NR Qualitative QC results were not documented, only quantitative. 09/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 18 documented days: 09/04/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/05/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/06/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/07/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR Qualitative QC results were not documented, only quantitative. 10/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 17 documented days: 10/01/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/02/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/03 /2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/04/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR Qualitative QC results were not documented, only quantitative. 01/2019 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 10 documented days: 01/14/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR 01/15/2019 - "R" 1: 8; "RMIN" (1:2); "NR" NR 01/16/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR 01/17 /2019 - "R" 1:8; "RMIN" (1:2); "NR" NR Qualitative QC results were not documented, only quantitative. Laboratory's controls key: "R" in first column = Reactive Control; "RMIN" in middle column = Weak Reactive Control; "NR" = Non-Reactive Control. 4. According to records, the laboratory's annual volume was 44,552 syphilis serology tests. The laboratory performed and reported both qualitative (reactive/non-reactive) and quantitative (titer) tests/results of patients. 5. During an interview on 01/25/2019 at 10:30 am, Testing Person - 7 (TP-7) confirmed qualitative QC was performed and only quantitative results were documented on the logs. During an interview on 01/25/2019 at 10:57 am, laboratory director reviewed and confirmed the laboratory was not documenting qualitative QC results for RPR card test.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the stat laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 3 of 3 lot numbers in 2018 (random sampling 05/2018 through 12/2018). Findings included: 1. Review of "LABORATORY PROCEDURE MACRO-VUE RPR CARD TESTS 18 MM CIRCLE QUALITATIVE AND QUANTITATIVE For the Serologic Detection of Syphilis" stated, "Quantitative Procedure: Refer to the quantitative procedure outlined in the package insert of the Macro-Vue RPR 18 mm Circle Card Test Kit. VI. RESULTS Each laboratory must establish an acceptable reactivity pattern for each lot number of control material." 2. Review of BD Macro-Vue RPR Card Test Liquid Control manufacturer's instructions (package insert) stated, "Quantitative Procedure: ...RESULTS Each laboratory must establish an acceptable reactivity pattern for each lot number of control material." The laboratory used Macro-Vue RPR Card Test Liquid Controls and it included "Reactive Control Serum Positive" (Control ++), "Moderately Reactive Control Serum Weakly Positive" (Control +), and "Negative Control Serum Negative Control" (Control -). 3. Review of "BD MACRO-VUE-STAT LABORATORY RPR QUALITY CONTROL LOG SHEET" records from 05/2018 through 12/2018 revealed the laboratory did not include defined criteria for day-to-day acceptability, as follows: 05/2018 - BD Controls included "R" Lot #16181, "R" Lot #16182, "NR" Lot #16183 (expiration date 02/2019) and a sampling of results of the 22 documented days: 05/01/2018 - "R" 1:4; "R" R(1:1); "NR" NR 05/02/2018 - "R" 1:4; "R" R(1:1); "NR" NR 05/03/2018 - "R" 1:4; "R" R(1:1); "NR" NR 05/04/2018 - "R" 1:4; "R" R(1:1); "NR" NR 06/2018 - BD Controls included "R" Lot #16181, "R" Lot #16182, "NR" Lot #16183 (expiration date 02/2019) and a sampling of results of the 21 documented days: 06/01/2018 - "R" 1:8; "R" R(1:1); "NR" NR 06/04/2018 - "R" 1:4; "R" R(1:1); "NR" NR 06/05/2018 - "R" 1:8; "R" R(1:1); "NR" NR 06/06/2018 - "R" 1:8; "R" R(1:1); "NR" NR At the bottom of the log for 06/2018 was documented "*New Lot Kit lot 16445, Exp 4/4/19; LN: 16422, 16423, 16424." There was no date when the new lot was implemented for use and no established acceptable criteria for new lot of control material. 07/2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 21 documented days: 07/02/2018 - "R" 1:8; "R" R(1:1); "NR" NR 07/03/2018 - "R" 1:4; "R" R(1:1); "NR" NR 07/05 /2018 - "R" 1:8; "R" R(1:1); "NR" NR 07/06/2018 - "R" 1:8; "R" R(1:1); "NR" NR 08 /2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 21 documented days: 08 /01/2018 - "R" 1:4; "R" R(1:1); "NR" NR 08/02/2018 - "R" 1:8; "R" R(1:1); "NR" NR 08/03/2018 - "R" 1:8; "R" R(1:1); "NR" NR 08/06/2018 - "R" 1:4; "R" R(1:1); "NR" NR 09/2018 - BD Controls included "R" Lot #16422, "R" Lot #16423, "NR" Lot #16424 (expiration date 04/04/2019) and a sampling of results of the 19 documented days: 09/04/2018 - "R" 1:4; "R" R(1:1); "NR" NR 09/05/2018 - "R" 1:4; "R" R(1:1); "NR" NR 09/06/2018 - "R" 1:4; "R" R(1:1); "NR" NR 09/07/2018 - "R" 1:4; "R" R(1:

1); "NR" NR 10/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 23 documented days: 10/01/2018 - "R" 1:8; "R" R(1:1); "NR" NR 10/02/2018 - "R" 1:4; "R" R(1:1); "NR" NR 10/03/2018 - "R" 1:4; "R" R(1:1); "NR" NR 10/04/2018 - "R" 1:4; "R" R(1:1); "NR" NR New lot of control material was documented in 10/2018. There was no date when the new lot was implemented for use and no established acceptable criteria for new lot of control material. 11/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 20 documented days: 11/01/2018 - "R" 1:4; "R" R(1:1); "NR" NR 11/02/2018 - "R" 1:4; "R" R(1:1); "NR" NR 11/05/2018 - "R" 1:4; "R" R(1:1); "NR" NR 11/06/2018 - "R" 1:8; "R" R(1:1); "NR" NR 12/2018 - BD Controls included "R" Lot #16719, "R" Lot #16720, "NR" Lot #16721 (expiration date 06/21/2019) and a sampling of results of the 19 documented days: 12/03/2018 - "R" 1:4; "R" R(1:1); "NR" NR 12/04/2018 - "R" 1:4; "R" R(1:1); "NR" NR 12/05/2018 - "R" 1:4; "R" R(1:1); "NR" NR 12/06/2018 - "R" 1:4; "R" R(1:1); "NR" NR Laboratory's controls key: "R" in first column = Reactive Control Serum Positive; "R" in middle column = Moderately Reactive Control Serum Weakly Positive; "NR" = Negative Control Serum Negative Control. The logs for QC did not include established criteria for acceptability. 4. According to records, the laboratory's annual volume was 44,552 syphilis serology tests. The laboratory performed and reported both qualitative (reactive/non-reactive) and quantitative (titer) tests/results of patients. 5. During an interview on 01/24/2019 at 10:45 am, Testing Person - 14 (TP-14) was asked what was the acceptability for quantitative control material for RPR card test, she stated it was 1:4 to 1:8 for "twice positive control" (Reactive Control Serum Positive) and 1:1 for "control one time positive" (Moderately Reactive Control Serum Weakly Positive). TP-14 stated acceptability criteria for control material had not been established. II. Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) records, and in interview with staff, the main laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 2 of 2 lot numbers in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01/2019). Findings included: 1. Review of "Section I. Rapid Plasma Reagin (RPR) 18mm Card Test" policy did not include establishing criteria of acceptability of control material for quantitative RPR card test. 2. Review of ASI RPR CARD TEST FOR SYPHILIS manufacturer's instructions (package insert) stated, "Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures ..." The laboratory used ASI RPR/VDRL CONTROL SERUM SET and it included "REACTIVE CONTROL; WEAK REACTIVE CONTROL; NON-REACTIVE CONTROL." 3. Review of "RPR QUALITY CONTROL LOG SHEET" records revealed from 06/2018 through 10/2018 and 01/2019 the laboratory did not include defined criteria for day-to-day acceptability, as follows: 06/2018 - ASI Controls included "R" Lot #R7M09RD, "RMIN" Lot #R7M09RE, "NR" Lot #R7M09RB (expiration date 11/2019) and a sampling of results of the 16 documented days: 06/04/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 06/05/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 06/06/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR 06/07/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR 07/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 04/30/2019) and a sampling of results of the 22 documented days: 07/02/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 07/03/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 07/04/2018 - "R" 1:8; "RMIN" (1:1); "NR" NR 07/05/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 19 documented days: 08/06

/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/07/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/08/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 08/09/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 18 documented days: 09/04/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/05/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/06/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 09/07/2018 - "R" 1:8; "RMIN" (1:2); "NR" NR 10/2018 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 17 documented days: 10/01/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/02/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/03/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 10/04/2018 - "R" 1:4; "RMIN" (1:1); "NR" NR 01/2019 - ASI Controls included "R" Lot #R7F03RA, "RMIN" Lot #W7F03RA, "NR" Lot #N7D04RAE (expiration date 06/2019) and a sampling of results of the 10 documented days: 01/14/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR 01/15/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR 01/16/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR 01/17/2019 - "R" 1:8; "RMIN" (1:2); "NR" NR Laboratory's controls key: "R" in first column = Reactive Control; "RMIN" in middle column = Weak Reactive Control; "NR" = Non-Reactive Control. The logs for QC did not include established criteria for acceptability for each lot. 4. According to records, the laboratory's annual volume was 44,552 syphilis serology tests. The laboratory performed and reported both qualitative (reactive/non-reactive) and quantitative (titer) tests/results of patients. 5. During an interview on 01/25/2019 at 10:30 am, Testing Person - 7 (TP-7) was asked what was the acceptability for quantitative control material for RPR card test, he stated "+/- 1 titer." During an interview on 01/25/2019 at 10:57 am, laboratory director reviewed and confirmed the laboratory had not established criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test with each new lot. III. Based on review of laboratory's policy, manufacturer's instructions, quality control (QC) data, and in interview with staff, the laboratory failed to establish the criteria for acceptability and that statistical parameters (standard deviation, mean) for each lot number were defined and available for BioPlex 2200 Syphilis Total control material current lot (effective 10/22/2018). Findings included: 1. Review of the laboratory's policy did not include establishing criteria for acceptability, including statistical parameters for each lot number for BioPlex 2200 Syphilis Total control material. 2. Review of Biorad BioPlex 2200 Syphilis Total control material manufacturer's instructions (package insert) stated, "ASSIGNMENT OF VALUES: The mean values were derived from replicate analyses and should fall within the corresponding standard deviation. It is recommended that an individual laboratory use the limits provided only as guides." The laboratory analyzed "CTRL -" and "CTRL + 1" levels everyday of patient testing on BioRad BioPlex 2200 analyzer for Syphilis Total QC. 3. Review of Biorad BioPlex 2200 Syphilis Total control set "ASSIGNMENT OF VALUES" provided by manufacturer revealed the following: CTRL - (Lot #50526, expiration date 05/01/2019): Mean 0.2; Standard Deviation (SD) 0.20 CTRL + 1 (Lot #50527, expiration date 05/01/2019): Mean 2.9; SD 0.44 4. Review of analyzer Syphilis Total QC statistical parameters (sampling from 01/17/2019, 01/18/2019, 01/22/2019, 01/24/2019) used by the laboratory for day-to-day acceptability revealed the following: Level 1 (CTRL - Lot #50526): Mean 0.2; 2 SD Range 0.0 - 0.6 AI Level 2 (CTRL + 1 Lot #50527): Mean 2.9; 2 SD Range 2.0 - 3.8 AI The QC statistical parameters used by the laboratory were consistent with those provided by the manufacturer (Assignment of Values). The laboratory did not establish their own criteria for acceptability including statistical parameters for each lot. The above mentioned lot was in effect 10/22/2018. 5. During an interview on 01/25/2019 at 2:10 pm, Testing Person - 7 was asked how QC ranges were established for new lot of Biorad Syphilis Total control material, he stated he input the values that

	come with the QC (provided by the manufacturer) by calling the manufacturer support for how-to enter procedure. During an interview on 01/25/2019 at 2:25 pm, General Supervisor - 1 was asked how QC ranges were established for new lot of Biorad Syphilis control material, he stated there is a disk with new lot of control material and those values would be entered in the analyzer. During an interview on 01/25/2019 at 3:45 pm, General Supervisor - 2 stated the QC ranges, may have been pre-set. The laboratory was unable to provide documentation of statistical parameters established for criteria acceptability of Syphilis Total QC on the BioPlex 2200 analyzer.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observations, review of manufacturer's instructions, review of microbiology media quality control documentation for 2017 and 2018, and confirmed in staff interview, the laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response. Findings included: 1. A tour of the laboratory facility on 01/23/2019 at 1330 hours revealed the laboratory utilized Thayer Martin and Lowenstein Jensen microbiology media as part of the microbiology testing. 2. Review of manufacturer's instructions revealed the following: a. Review of the Thayer Martin manufacturer's instructions (Revised March 31, 2008) stated, "Testing for control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported. Control Organism: (CLSI recommended organisms) Neisseria gonorrhoeae ATCC 43069 Staphylococcus epidermidis ATCC 12228 Proteus mirabilis ATCC 43071" b. Review of Lowenstein (LJ) medium manufacturer' instructions (Revised August 30, 2011) stated, "Testing for control organisms should be performed in accordance with established laboratory quality control procedures. If aberrant quality control results are noted, patient results should not be reported. CONTROL: Mycobacterium fortuitum ATCC 6841 Mycobacterium intracellulare ATCC 13950 Mycobacterium kansasii ATCC 12478 Mycobacterium scrofulaceum ATCC 19981 Mycobacterium tuberculosis ATCC 25177" 3. Review of the microbiology media quality control documentation for 2017 and 2018 revealed the laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response with the specified ATCC quality control organism for every batch of media received. The following lot numbers (from 06/26/2018 through 01/18/2019) of Thayer-Martin media were documented as received by the laboratory without documentation of QC testing with the organisms specified by the manufacturer: Lot numbers 358001; 364276; 372029; 403499; 322448; 432172; 455297; 463688 No documentation of LJ media lot numbers or quality control was provided. 4. During an interview on 01/23/2019 at 1400 hours in the conference room, testing person #10 stated that the laboratory accepted manufacturer quality control. This confirmed the above findings.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, and interview, the laboratory failed to have a system in place that twice a year defines the relationship between using two different panther instruments while testing anal/nasophargnal swabs and urine specimens for gonorrhea and chlamydia as evidenced by: 1. In interview on 1-24-2019 @0919 with the QA manager he stated, "We are still doing the comparison study for the panther system." 2. In review of the laboratory's records, the laboratory did not have documentation to show that a second comparison study done in 2018 between the two panther instruments #00143 and #00869.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to document corrective action when the temperature range exceeded manufacturer's requirements for the storage of BD blood collection tubes for 2 of 40 days in 2018 (July 2018, September 2018). Findings: 1. Review of BD Vacutainer Evacuated Blood Collection System instructions page 3 stated "Storage ...Store tubes at 4-25C (39-77F)." Review of manufacturer's instructions for Aptima Unisex Swab Collection Kit for Endocervical and Male Urethral Swab stated: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." Review of manufacturer's instructions for Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens state: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." 2. During a tour of the phlebotomy room (room 341) on 01/24/2019 at 10:30 am, the following were observed to be stored in a storage cabinet: 38 BD SST tubes, Lot #8198909, expiration date 07/31/2019 142 BD K2EDTA tubes, Lot # 8215727, expiration date 12/31/19 7 BD Serum tubes, Lot #8229700, expiration date 08/31 /2020 88 BD Acid Solution A tubes, Lot #7067687, expiration date 03/31/2019 100 BD Acid Solution A tubes, Lot #8099551, expiration date 04/30/2020 50 Aptima Unisex Swab Collection Kits for Endocervical and Male Urethral Swab, Lot #230218H, expiration date 01/31/2019 50 Aptima Urine Specimen Collection Kits for Male and Female Urine Specimens, Lot #32687H, expiration date 10/31/2019 1 Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens, Lot #31828H, Expiration date 01/31/2019 The laboratory failed to define a temperature range to ensure temperatures did not exceed manufacturer's instructions for blood collection tubes, swab kits and urine collection kits. 3. Review of the phlebotomy

	room (room 341) temperature logs for July 2018 and September 2018 revealed the temperature exceeded the manufacturer's required temperature for the following days: July 20, 2018/7:52 am: 79F September 12, 2018/8:12 am: 78F The laboratory failed to define a temperature range and ensure the temperature was within range for blood collection tubes according to manufacturer's instructions. There was no corrective action documented for the temperature exceeding the acceptable range per manufacturer's requirements. 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, manufacturer's instructions for GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test, laboratory quality control/patient records, temperature logs, and maintenance records, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems, as evidenced by: 1. The laboratory failed to have their staff follow their procedures with the HIV-1 NAAT testing. Refer to D5401, I. 2. The laboratory failed to ensure written policies were consistent with one another and with the laboratory's practice for changing gram stain reagents. Refer to D5401, II. 3. The laboratory failed to follow its own written policy to use a calibrated nephelometer to confirm the required McFarland standard for MGIT drug susceptibility testing. Refer to D5401, III. 4. The laboratory failed to follow its own written procedure and manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test. Refer to D5401, IV. 5. The laboratory failed to follow their own written policy to ensure that the specified ATCC organism was utilized for quality control testing. Refer to D5401, V. 6. The laboratory did not have procedures for the HIV-1 quantitative testing that started in December 2018. Refer to 5403, I. 7. The laboratory failed to implement written policies and procedures for preparing their own potassium hydroxide (KOH) and saline for wet mount tests. Refer to D5403, II. 8. The laboratory failed to implement QC procedures for reagin plasma reagin (RPR) card test and Biorad BioPlex 2200 analyzer. Refer to D5403, III. 9. The laboratory failed to follow manufacturer's instructions for the Aptima combo urine gonorrhea and chlamydia testing. Refer to D5411, I. 10. The laboratory failed to follow gram stain manufacturer's instructions for staining patient slides for 8 of 8 patients 01/23/2019 (random sampling). Refer to D5411, II. 11. The stat laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 166 days of 166 of QC and 69 of 69 patients from 05/2018 through 12/2018. Refer to D5411, III. 12. The main laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 102 of 102 days of QC from 06/2018 through 10/2018 and 01/2019 and 22 of 22 patients from 01/2019 (random sampling of patients and QC). Refer to D5411, IV. 13. The laboratory failed to follow manufacturer's instructions for utilizing the correct ATCC organisms for quality

control testing for the BD DrySlide Oxidase test. Refer to D5411, V. 14. The laboratory failed to monitor room temperature where aptima reagents are stored in the hallway. Refer to D5413, I. 15. The laboratory failed to monitor and document temperature of the stat laboratory in which reagents were stored. Refer to D5413, II. 16. The laboratory failed to monitor specimen collection tube storage and specimen blood collection temperature requirements for the Quantiferon TB Gold specimen collection tubes. Refer to D5413, III. 17. The laboratory failed to monitor room temperature as required for the Quantiferon TB Gold ELISA (Enzyme-linked immunosorbent assay) test. Refer to D5413, IV. 18. The laboratory failed to monitor the humidity for the BacTec MGIT 960 mycobacterial detection system. Refer to D5413, V. 19. The laboratory failed to define a temperature range for the phlebotomy room, in which collection supplies were stored, to ensure temperature did not exceed manufacturer instructions for 12 of 12 months in 2018. Refer to D5413, VI. 20. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes according to manufacturer's requirements for storage. Refer to D5413, VII. 21. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Refer to D5413, VIII. 22. The laboratory failed monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Refer to D5413, IX. 23. The laboratory failed to label gram stain reagent secondary containers with identity (including lot number) and poured/expiration dates. Refer to D5415, I. 24. The laboratory failed to ensure vials of mycobacteriology ATCC organisms were labeled with a preparation date and an expiration date specified by the manufacturer. Refer to D5415, II. 25. The laboratory failed to have documentation of the open date 6 of 6 bottles of Kinyoun and Auramine Rhodamine staining reagents. Refer to D5415, III. 26. The laboratory failed follow manufacturer's instructions to document the preparation date and revised expiration date for 3 of 3 prepared Bio Rad GS HIV Combo Ag/Ab EIA (Enzyme Immunosorbant Assay) reagents. Refer to D5415, IV. 27. The laboratory failed to ensure prepared reagents of saline stored in secondary containers were labeled with identification, concentration, poured dates, preparation dates, and expiration dates. Refer to D5415, V. 28. The laboratory failed to ensure alcohol reagent was not used past its expiration date. Refer to D5417, I. 29. The laboratory failed to ensure that Quantiferon TB Gold blood collection tubes were not expired prior to testing. Refer to D5417, II. 30. The laboratory failed to ensure blood collection containers did not exceed their expiration date. Refer to D5417, III. 31. The laboratory failed to ensure reagents, quality control (QC), calibration materials, and blood collection containers did not exceed their expiration date. Refer to D5417, IV. 32. The laboratory failed to have documentation of performing verification studies on the Evolis (Serial Number 9163701015) before testing for GS HIV Combo Ag/Ab EIA testing. Refer to D5421. 33. The laboratory failed to have documentation of performing all required daily (26 of 158 testing days), weekly (12 of 72 weeks), and monthly (5 of 18 months) maintenance. Refer to D5429. 34. The stat laboratory failed to implement an IQCP for syphilis health check when QC was tested less frequent than required. Refer to D5445. 35. The laboratory failed to follow their quality assessment plan for Cepheid Gene xpert MTB/RIF test. Refer to D5447. 36. The stat laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 166 of 166 days from 05/2018 through 12/2018. Refer to D5449, I. 37. The stat laboratory failed to include negative and positive control material every day of patient testing for syphilis health check for 7 of 7 days from 07/2018 through 12/2018 (random sampling). Refer to D5449, II. 38. The main laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 102 of 102 days in 2018 and 2019 (random sampling from 06/2018 through 10

	/2018 and 01/2019). Refer to D5449, III. 39. The stat laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 3 of 3 lot numbers in 2018 (random sampling 05/2018 through 12/2018). Refer to D5469, I. 40. The main laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 2 of 2 lot numbers in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01 /2019). Refer to D5469, II. 41. The laboratory failed to establish the criteria for acceptability and that statistical parameters (standard deviation, mean) for each lot number were defined and available for BioPlex 2200 Syphilis Total control material current lot (effective 10/22/2018). Refer to D5469, III. 42. The laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response. Refer to D5477. 43. The laboratory failed to have a system in place that twice a year defines the relationship between using two different panther instruments while testing anal /nasophargnal swabs and urine specimens for gonorrhea and chlamydia. Refer to D5775. 44. The laboratory failed to document corrective action when the temperature range exceeded manufacturer's requirements for the storage of BD blood collection tubes for 2 of 40 days in 2018 (July 2018, September 2018). Refer to D5785.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing reports, and interview, the laboratory did not have units of interpretation or value on test reports for the HIV-1 quantitative testing that started in December 2018 as evidenced by: 1. In review of 9 patient records from December to the time of the survey the following patient test reports sent to the doctors did not have the units of interpretation or value on the test reports: a. patient created date of 1/10/2019 resulted on 1/11/2019 = 5.22 (no units of interpretation or value) in the comments b. patient created date of 1/09/2019 resulted on 1/11/2019 = 3.88 (no units of interpretation or value) in the comments c. patient created date of 1/01/2019 resulted on 1/11/2019 = 3.62 (no units of interpretation or value) in the comments d. patient created date of 1/10/2019 resulted on 1/10/2019 = 5.69 (no units of interpretation or value) in the comments e. patient created date of 1 /04/2019 resulted on 1/09/2019 = 4.99 (no unit of interpretation or value) in the comments 2. In an interview with the QA manager on 1-25-2019 he confirmed the finding.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, patient test records, CMS 209 form, laboratory personnel records, and quality control records, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure requirements for moderate complexity preanalytic systems were met. Refer D6007. 2. The Laboratory Director failed to ensure that 1 of 8 Testing Persons (TP-6) received the appropriate training in moderate complexity testing prior to patient testing. Refer to D6029. 3. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 8 of 8 Testing Persons (TP-5, TP-6, TP-7, TP-8, TP-9, TP-10, TP-11, TP-16) performing moderate complexity testing. Refer to D6030. 4. The laboratory director failed to ensure all approved procedures were available to all testing personnel. Refer to D6031. 5. The Laboratory Director failed to specify in writing the responsibilities and duties 3 of 8 Testing Persons (TP-7, TP-8, TP-12) performing moderate complexity testing. Refer to D6032.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, and patient test records, the laboratory director failed to ensure requirements for moderate complexity preanalytic systems were met, as evidenced by: 1. The laboratory failed to ensure patient test requisitions solicited the time of collection for wet mount specimens collected in the clinic and analyzed in the stat laboratory for 8 of 8 patients on 01/24 /2019 (random sampling). Refer to D5305. 2. The laboratory failed to define in their written policy the stability of wet mount specimens to ensure integrity of specimens when received and analyzed in the stat laboratory. Refer to D5311, IV.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of personnel files and confirmed in interview the Laboratory Director failed to ensure that 1 of 8 Testing Persons (TP-6) received the appropriate training in moderate complexity testing prior to patient testing. Findings: 1. Review of personnel files for TP-6 revealed a hire date of 04/2017. There were no documented training records for the Evolis analyzer. Semiannual competency records revealed competency was evaluated on 12/2017 and 04/2018. The Laboratory Director failed to ensure TP-6 received the appropriate training in moderate complexity testing prior to patient testing. 2. During an interview on 01/23/2019 at 10:30 am, the Laboratory Director stated that he was aware that he failed to evaluate and document the annual performances of personnel involved in performing moderate complexity testing. He stated that he did not always have time to perform the annual assessments. This confirmed the above findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory's policy, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 8 of 8 Testing Persons (TP-5, TP-6, TP-7, TP-8, TP-9, TP-10, TP-11, TP-16) performing moderate complexity testing. Findings: 1. Review of the laboratory's policy manual revealed there was no policy for personnel performing moderate complexity testing. 2. Review of the CMS 209 form revealed 8 Testing Persons (TP-5, TP-6, TP-7, TP-8, TP-9, TP-10, TP-11, TP-16) performing moderate complexity testing. 3.During an interview on 01/22/19 at 2:36 pm, General Supervisor-2 (GS-2) stated that there was a policy manual for personnel, however, he could not find it. No policy manual was provided. 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure/policy manual, and quality control records, the laboratory director failed to ensure all approved procedures were available to all testing personnel, as evidenced by: 1. The laboratory failed to implement written policies and procedures for preparing their own potassium hydroxide (KOH) and saline for wet mount tests. Refer to D5403, II. 2. The laboratory failed to implement QC procedures for reagin plasma reagin (RPR) card test and Biorad BioPlex 2200 analyzer. Refer to D5403, III.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties 3 of 8 Testing Persons (TP-7, TP-8, TP-12) performing moderate complexity testing. Findings: 1. Review of the CMS 209 form listed TP-7 as a testing person performing moderate complexity procedures in the area of: diagnostic immunology. A copy of a job description for "Medical Laboratory Technician, Grade A, Serology Section" was in the personnel file, however, it was not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures TP-7 was authorized to perform. Review of the CMS 209 form listed TP-12 as a testing person performing moderate complexity procedures in the area of: diagnostic immunology, mycology, and parasitology. A copy of job duties for "Medical Laboratory Technician, STAT Laboratory" was in the personnel file, however, it was not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures TP-12 was authorized to perform with/without supervision. 2. During an interview on 01/23/2018 at 10:30 am, the Laboratory Director stated that some employees had transitioned into other departments and, therefore, their personnel files may not have been updated. This confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, quality control records, patient records, and personnel files, the technical consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant failed to ensure manufacturer's instructions were followed. Refer to D6036. 2. The technical consultant failed to establish a quality control program appropriate for testing performed and establishing the parameters for acceptable levels of analytic performance ensuring that these levels are maintained throughout the entire testing process. Refer to D6042. 3. The technical consultant (who is also the laboratory director) failed to evaluate and document the performance 2 of 8 Testing Persons (TP-12, TP-16) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Refer to D6053. 4. The technical consultant (who is also the laboratory director) failed to evaluate and document the annual performances 2 of 8 Testing Persons (TP-9, TP-10) responsible for moderate complexity testing. Refer to D6054.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and manufacturer's instructions, the technical consultant failed to ensure manufacturer's instructions were followed, as evidenced by: 1. The stat laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 166 days of 166 of QC and 69 of 69 patients from 05/2018 through 12/2018. Refer to D5411, III. 2. The main laboratory failed to follow manufacturer's instructions for using the correct saline in quantitative rapid plasma reagin (RPR) card test procedure for 102 of 102 days of QC from 06/2018 through 10/2018 and 01/2019 and 22 of 22 patients from 01/2019 (random sampling of patients and QC). Refer to D5411, IV. 3. The laboratory failed follow manufacturer's instructions to document the preparation date and revised expiration date for 3 of 3 prepared Bio Rad GS HIV Combo Ag/Ab EIA (Enzyme Immunosorbant Assay) reagents. Refer to D5415, IV. 4. The laboratory failed to ensure alcohol reagent was not used past its expiration date. Refer to D5417, I.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, quality control

	records, and patient records, the technical consultant failed to establish a quality control program appropriate for testing performed and establishing the parameters for acceptable levels of analytic performance ensuring that these levels are maintained throughout the entire testing process, as evidenced by: 1. The stat laboratory failed to implement an IQCP for syphilis health check when QC was tested less frequent than required. Refer to D5445. 2. The stat laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 166 of 166 days from 05/2018 through 12/2018. Refer to D5449, I. 3. The stat laboratory failed to include negative and positive control material every day of patient testing for syphilis health check for 7 of 7 days from 07/2018 through 12/2018 (random sampling). Refer to D5449, II. 4. The main laboratory failed to document negative and positive control material for qualitative rapid plasma reagin (RPR) card test for 102 of 102 days in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01 /2019). Refer to D5449, III. 5. The stat laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 3 of 3 lot numbers in 2018 (random sampling 05/2018 through 12/2018). Refer to D5469, I. 6. The main laboratory failed to establish criteria for acceptability of control material for quantitative rapid plasma reagin (RPR) card test for 2 of 2 lot numbers in 2018 and 2019 (random sampling from 06/2018 through 10/2018 and 01/2019). Refer to D5469, II. 7. The laboratory failed to establish the criteria for acceptability and that statistical parameters (standard deviation, mean) for each lot number were defined and available for BioPlex 2200 Syphilis Total control material current lot (effective 10/22 /2018). Refer to D5469, III.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files and confirmed in interview the technical consultant (who is also the laboratory director) failed to evaluate and document the performance 2 of 8 Testing Persons (TP-12, TP-16) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings 1. Review of personnel files for TP-12 revealed an initial training assessment was performed on 4/2016 for wet preps, RPR, and rapid HIV. There was no documentation of a semiannual performance for wet preps, RPR, and rapid HIV (due 10/2016). 2. Review of personnel files for TP-16 revealed an initial training assessment was performed on 09/20/2016 for slide preparation and evaluation; microscopy. There was no documentation of a semiannual performance for slide preparation and evaluation; microscopy (due 03/2017). 3. During an interview on 01 /23/2019 at 10:30 am, the technical consultant stated that he was aware that he failed to evaluate and document the semiannual performances of personnel involved in performing moderate complexity testing. He stated that he did not always have time to perform the semiannual assessments. This confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the

	performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed in interview, the technical consultant (who is also the laboratory director) failed to evaluate and document the annual performances 2 of 8 Testing Persons (TP-9, TP-10) responsible for moderate complexity testing. Findings: 1. Review of personnel records for TP-9 revealed there was no annual competency assessment performed in 2018. Review of personnel records for TP-10 revealed there were no annual competency assessments performed in 2016 and 2017. 2. During an interview on 01/23/2019 at 10:30 am, the technical consultant stated that he was aware that he failed to evaluate and document the annual performances of personnel involved in performing moderate complexity testing. He stated that he did not always have time to perform the annual assessments. This confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, manufacturer's instructions, patient test records, laboratory's client service manual, temperature logs, personnel files, and CMS 209 form, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure requirements were met for preanalytic and analytic systems. Refer to D6082. 2. the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failure in quality as the occur. Refer to D6094. 3. The laboratory director failed to ensure all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's defined performance characteristics were defined. Refer to D6096. 4. The Laboratory Director failed to ensure that 1 of 4 General Supervisors (GS-3) received the appropriate training in high complexity training. Refer to D6102. 5. The Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 4 of 4 General Supervisors for high complexity testing and 14 of 14 Testing Persons performing high complexity testing. Refer to D6103. 6. The laboratory director failed to ensure an approved procedure was available to all testing personnel. Refer to D6106. 7. The Laboratory Director failed to specify in writing the responsibilities and duties of 3 of 4 General Supervisors (GS-2, GS-3, GS-4) and 7 of 14 Testing Persons (TP-8, TP-9, TP-12, TP-14, TP-15, TP-16, TP-17) performing high complexity testing. Refer to D6107.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all

	aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, patient test requisitions, manufacturer's instructions, patient test records, and laboratory's client service manual, the laboratory director failed to ensure requirements were met for preanalytic and analytic systems, as evidenced by: 1. The laboratory failed to ensure urine Aptima gonorrhea (GC) and chlamydia (Chl) samples were within temperature specifications 2-30 degrees C for transport and receiving in the laboratory. Refer to D5311, I. 2. The laboratory failed to implement in their procedure a patient gram stain slide labeling policy. Refer to D5311, II. 3. The laboratory failed to ensure patient gram stain slides received into the stat laboratory for analysis were labeled with patient name or unique patient identifier for 7 of 7 patients on 01/23/2019 (random sampling). Refer to D5311, III. 4. The laboratory failed to define in their written policy the stability of wet mount specimens to ensure integrity of specimens when received and analyzed in the stat laboratory. Refer to D5311, IV. 5. The laboratory failed to have their staff follow their procedures with the HIV-1 NAAT testing. Refer to D5401, I. 6. The laboratory failed to ensure written policies were consistent with one another and with the laboratory's practice for changing gram stain reagents. Refer to D5401, II. 7. The laboratory failed to follow its own written policy to use a calibrated nephelometer to confirm the required McFarland standard for MGIT drug susceptibility testing. Refer to D5401, III. 8. The laboratory failed to follow its own written procedure and manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the GenProbe Accuprobe Neisseria Gonorrhea Culture Identification Test. Refer to D5401, IV. 9. The laboratory failed to follow their own written policy to ensure that the specified ATCC organism was utilized for quality control testing. Refer to D5401, V.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's procedure manual, manufacturer's instructions, patient test records, and maintenance/environmental records, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failure in quality as the occur, as evidenced by: 1. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Refer to D5391. 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and

	documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of temperature logs and manufacturer's instructions, the laboratory director failed to ensure all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's defined performance characteristics were defined. The laboratory failed to document corrective action when the temperature range exceeded manufacturer's requirements for the storage of BD blood collection tubes for 2 of 40 days in 2018 (July 2018, September 2018). Refer to D5785.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel files and confirmed in interview the Laboratory Director failed to ensure that 1 of 4 General Supervisors (GS-3) received the appropriate training in high complexity training. Findings: 1. Review of personnel files revealed GS-3 a hire date of 09/5/2017. The only initial training in the personnel file was for Influenza dated 01/23/2018. No other training was available. The file contained checklists for the following: Bacillus, Brucella, Tularensis, Pestis, Pseudomallei, and Zika, however, they were not completed. 2. During an interview on 01/23/2019 at 10:30 am, the laboratory director stated that he was aware that he failed to evaluate and document the annual performances of personnel involved in performing high complexity testing. He stated that he did not always have time to perform the annual assessments. This confirmed the above findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory's policy, and confirmed in interview, the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 4 of 4 General Supervisors for high complexity testing and 14 of 14 Testing Persons performing high complexity testing. Findings: 1. Review of the CMS 209 form revealed 4 General

	Supervisors supervising high complexity testing and 14 Testing Persons performing high complexity testing. 2. Review of the laboratory's policy manual revealed there was no policy for personnel performing high complexity testing. 3. During an interview on 01/22/19 at 2:36 pm, General Supervisor-2 (GS-2) stated that there was a policy manual for personnel, however, he could not find it. No policy manual was provided. 4. During the exit interview on 01/25/2019 at 4:05 pm, the Laboratory Director confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory's procedure manual and HIV-1 records, the laboratory director failed to ensure an approved procedure was available to all testing personnel. The laboratory did not have procedures for the HIV-1 quantitative testing that started in December 2018. Refer to 5403, I.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties of 3 of 4 General Supervisors (GS-2, GS-3, GS-4) and 7 of 14 Testing Persons (TP-8, TP-9, TP-12, TP-14, TP-15, TP-16, TP-17) performing high complexity testing. Findings: 1. Review of the CMS 209 form listed GS-2 as a supervisor of high complexity procedures in the areas of: bacteriology, mycobacteriology, parasitology, virology, and diagnostic immunology. The laboratory director did not specify, in writing, the duties and delegations of the supervisor, as applicable. Review of the CMS 209 form listed GS-3 as a supervisor of high complexity procedures in the areas of: virology and diagnostic immunology. The laboratory director did not specify, in writing, the duties and delegations of the supervisor, as applicable. Review of the CMS 209 form listed GS-4/TP-2 as a supervisor of high complexity procedures in the areas of: bacteriology, virology, and diagnostic immunology. The laboratory director did not specify, in writing, the duties and delegations of the supervisor, as applicable. Review of the CMS 209 form listed TP-8 as a testing person performing high complexity procedures in the area of: mycobacteriology. A copy of a job description for "Microbiologist C, Microbiology Section" was in the personnel file, however, it was not signed by the laboratory

	director. The laboratory director did not specify, in writing, which procedures TP-8 was authorized to perform with/without supervision. Review of the CMS 209 form listed TP-9 as a testing person performing high complexity procedures in the area of: mycobacteriology. A signed job description for "Medical Laboratory Technician, Grade A, Serology Section" was in the personnel file, however, there was not one for mycobacteriology. The laboratory director did not specify, in writing, which procedures TP-9 was authorized to perform with/without supervision. Review of the CMS 209 form listed TP-12 as a testing person performing high complexity procedures in the area of: diagnostic immunology and bacteriology. A copy of job duties for "Medical Laboratory Technician, STAT Laboratory" was in the personnel file, however, it was not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures TP-12 was authorized to perform with /without supervision. Review of the CMS 209 form listed TP-14 as a testing person performing high complexity procedures in the area of: diagnostic immunology. A copy of a job description for "Arbovirus testing at DCHHS, Microbiologist I" and another one for "Microbiologist I" were in the personnel file, however, they were not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures TP-14 was authorized to perform with/without supervision. Review of the CMS 209 form listed TP-15 and TP-17 as a testing persons performing high complexity procedures in the areas of: bacteriology, virology, and diagnostic immunology. A copy of a job description for "Arbovirus testing at DCHHS, Microbiologist I" and another one for "LRN, Laboratory Response Network" were in the personnel file, however, they were not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures each testing person was authorized to perform with/without supervision. Review of the CMS 209 form listed TP-16 as a testing person performing high complexity procedures in the area of: mycobacteriology. The laboratory director did not specify, in writing, which procedures TP-16 was authorized to perform with/without supervision. 2. During an interview on 01/23/2018 at 10:30 am, the Laboratory Director stated that some employees had transitioned into other departments and, therefore, their personnel files may not have been updated. This confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, environmental records, verification studies, quality control records, and personnel records, the technical supervisor failed to provide technical supervision, as evidenced by: 1. The technical supervisor failed to provide technical and scientific oversight. Refer to D6112. 2. The technical supervisor failed to ensure verification of all test procedures performed and establishment of the laboratory's test performance characteristics. Refer to D6115. 3. The technical supervisor failed to establish a quality control program appropriate for the testing performed. Refer to D6117. 4. The technical supervisor (who is also the laboratory director) failed to evaluate and document the performance of and 5 of 14 Testing Persons (TP-4, TP-12, TP-14, TP-16, TP-17) responsible for high complexity testing at least semiannually during the first year the individual tests patient

	specimens. Refer to D6127. 5. The technical supervisor (who is also the laboratory director) failed to evaluate and document the annual performances for 10 of 14 Testing Persons (TP-1, TP-2, TP-3, TP-8, TP-9, TP-10, TP-12, TP-14, TP-15, TP-16) responsible for high complexity testing. Refer to D6128.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, environmental records, manufacturer's instructions, and maintenance records, the technical supervisor failed to provide technical and scientific oversight, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for the Aptima combo urine gonorrhea and chlamydia testing. Refer to D5411, I. 2. The laboratory failed to follow gram stain manufacturer's instructions for staining patient slides for 8 of 8 patients 01/23/2019 (random sampling). Refer to D5411, II. 3. The laboratory failed to follow manufacturer's instructions for utilizing the correct ATCC organisms for quality control testing for the BD DrySlide Oxidase test. Refer to D5411, V. 4. The laboratory failed to monitor room temperature where aptima reagents are stored in the hallway. Refer to D5413, I. 5. The laboratory failed to monitor and document temperature of the stat laboratory in which reagents were stored. Refer to D5413, II. 6. The laboratory failed to monitor specimen collection tube storage and specimen blood collection temperature requirements for the Quantiferon TB Gold specimen collection tubes. Refer to D5413, III. 7. The laboratory failed to monitor room temperature as required for the Quantiferon TB Gold ELISA (Enzyme-linked immunosorbent assay) test. Refer to D5413, IV. 8. The laboratory failed to monitor the humidity for the BacTec MGIT 960 mycobacterial detection system. Refer to D5413, V. 9. The laboratory failed to define a temperature range for the phlebotomy room, in which collection supplies were stored, to ensure temperature did not exceed manufacturer instructions for 12 of 12 months in 2018. Refer to D5413, VI. 10. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes according to manufacturer's requirements for storage. Refer to D5413, VII. 11. The laboratory failed to monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Refer to D5413, VIII. 12. The laboratory failed monitor and document temperature for the storage of BD blood collection tubes and swab sets according to manufacturer's requirements for storage. Refer to D5413, IX. 13. The laboratory failed to label gram stain reagent secondary containers with identity (including lot number) and poured/expiration dates. Refer to D5415, I. 14. The laboratory failed to ensure vials of mycobacteriology ATCC organisms were labeled with a preparation date and an expiration date specified by the manufacturer. Refer to D5415, II. 15. The laboratory failed to have documentation of the open date 6 of 6 bottles of Kinyoun and Auramine Rhodamine staining reagents. Refer to D5415, III. 16. The laboratory failed to ensure prepared reagents of saline stored in secondary containers were labeled with identification, concentration, poured dates, preparation dates, and expiration dates. Refer to D5415, V. 17. The laboratory failed to ensure that Quantiferon TB Gold blood collection tubes were not expired prior to testing. Refer to

	D5417, II. 18. The laboratory failed to ensure blood collection containers did not exceed their expiration date. Refer to D5417, III. 19. The laboratory failed to ensure reagents, quality control (QC), calibration materials, and blood collection containers did not exceed their expiration date. Refer to D5417, IV. 20. The laboratory failed to have documentation of performing all required daily (26 of 158 testing days), weekly (12 of 72 weeks), and monthly (5 of 18 months) maintenance. Refer to D5429.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and verification studies, the technical supervisor failed to ensure verification of all test procedures performed and establishment of the laboratory's test performance characteristics, as evidenced by: 1. The laboratory failed to have documentation of performing verification studies on the Evolis (Serial Number 9163701015) before testing for GS HIV Combo Ag/Ab EIA testing. Refer to D5421. 2. The laboratory failed to have a system in place that twice a year defines the relationship between using two different panther instruments while testing anal/nasophargnal swabs and urine specimens for gonorrhea and chlamydia. Refer to D5775.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and quality control records, the technical supervisor failed to establish a quality control program appropriate for the testing performed, as evidenced by: 1. The laboratory failed to follow their quality assessment plan for Cepheid Gene xpert MTB/RIF test. Refer to D5447. 2. The laboratory failed to check each batch of media for its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response. Refer to D5477.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of personnel files and confirmed in interview the technical supervisor (who is also the laboratory director) failed to evaluate and document the performance of and 5 of 14 Testing Persons (TP-4, TP-12, TP-14, TP-16, TP-17) responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of personnel files for TP-4 revealed an initial training assessment was performed on 2/8/2017 for GISP culture confirmation, 05/24/17 for QuantiFERON TB-Gold Assay, and 02/19/2017 for Panther TMA Testing/Operation. There was no documentation of a semiannual performance for GISP culture confirmation (due 8/2017), QuantiFERON TB-Gold Assay (due 11/2017), and Panther TMA Testing/Operation (due 8/2017). 2. Review of personnel files for TP-12 revealed an initial training assessment was performed on 4 /2016 for dark field microscopy. There was no documentation of a semiannual performance for dark field microscopy (due 10/2016). 3. Review of personnel files for TP-14 revealed an initial training assessment was performed on 03/07/2016 for Aptima HIV-1 Assay. There was no documentation of a semiannual performance for Aptima HIV-1 Assay (due 9/2016). 4. Review of personnel files for TP-16 revealed an initial training assessment was performed on 09/12/2016 for Biosafety Level 2 and 3, 10/27/16 for GeneXpert, 09/01/2016 for GeneProbe Accuprobe, 11/04/2016 for MGIT Drug Susceptibility, 12/09/16 for Culture Analysis (liquid and solid media), and 08/30/2016 for QuantiFERON. There was no documentation of a semiannual performance for Biosafety Level 2 and 3 (due 03/2017), GeneXpert (due 04/2017), GeneProbe Accuprobe (due 03/2017), MGIT Drug Susceptibility (due 05/2017) Culture Analysis (liquid and solid media) (due 06/2017), and QuantiFERON (due 02 /2017). 5. Review of personnel files for TP-17 revealed an initial training assessment was performed 04/17/2017 for select agents (Bacillus, Brucella, Tularesnis, Pestis, Psuedomallei, Zika). There was no documentation of a semiannual performance for select agents (due 10/2017). 6.During an interview on 01/23/2019 at 10:30 am, the technical supervisor stated that he was aware that he failed to evaluate and document the semiannual performances of personnel involved in performing high complexity testing and knew that it is a repeat deficiency from the previous survey performed in 2016. He stated that he did not always have time to perform the semiannual assessments. This confirmed the above findings. This was a repeat deficiency from 07 /18/2016.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed in interview, the technical supervisor (who is also the laboratory director) failed to evaluate and document the annual performances for 10 of 14 Testing Persons (TP-1, TP-2, TP-3, TP-8, TP-9, TP-10, TP-12, TP-14, TP-15, TP-16) responsible for high complexity testing. Findings: 1. Review of personnel records for TP-1 revealed the last documented annual competency assessment was performed on 01/15/2015. Review of personnel records for TP-2 revealed there were no documented annual competency assessments since

	the employee was hired in April 2009. Review of personnel records for TP-3, TP-14 and TP-16 revealed there was no annual competency assessments performed in 2017. Review of personnel records for TP-8, TP-10, and TP-15 revealed there were no annual competency assessments performed in 2016 and 2017. Review of personnel records for TP-9 revealed there was no annual competency assessment performed in 2018. Review of personnel records for TP-12 revealed there was no annual competency assessment performed in 2016. 2. During an interview on 01/23/2019 at 10:30 am, the technical supervisor stated that he was aware that he failed to evaluate and document the annual performances of personnel involved in performing high complexity testing. He stated that he did not always have time to perform the annual assessments. This confirmed the above findings.