Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2023688	06/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood South Texas	2140 Babcock Road, Suite 201, San Antonio, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5300 - 42 C.F.R. 493.1240 Condition: Pre-Analytic Systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director; high complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. NOTE: THE FACILITY WAS ASKED TO CEASED TESTING FOR: - CHLAMYDIA AND GONORRHEA TESTING UTILZING ORAL PHARYNGEAL AND RECTAL SWABS, - CHLAMYDIA AND GONORRHEA TESTING OF URINE SAMPLES FOR PATIENTS UNDER THE AGE OF 14 YEARS - SYPHILLIS TESTING - HEMATOLOGY TESTING - SPERM COUNTS - CHEMISTRY AND ENDOCRINOLOGY TESTING. THE LABORATORY COMPLIED. PLEASE SEE THE ATTACHED LETTER. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists' hematology proficiency testing records from 2018 and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 1 of 2 attestation statements. The findings were: 1. A review of the laboratory's College of American Pathologists' hematology proficiency testing records from 2018 (FH1-A and FH1-B) revealed the laboratory failed to have documentation of the laboratory director signing 1 of 2 attestation statements. The event without documentation of the laboratory director signing the attestation was: FH1-B 2. The laboratory was asked to provide documentation of the laboratory director signing the attestation statement. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1455 hours in the lab - after his review of the records- confirmed the findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists' hematology proficiency testing results from 2018, and staff interview, it was revealed the laboratory failed to obtain an acceptable score for the analyte of platelets for Event FH1-B. The findings were: 1. A review of the laboratory's College of American Pathologists' hematology proficiency testing results from 2018 (FH1-A and FH1-B) revealed the laboratory failed to obtain an acceptable score for the analyte of platelets for Event FH1-B. The laboratory scored: 0%. 2. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1455 hours in the laboratory - after his review of the records- confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's MLE proficiency testing records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of the review of 1 of 3 proficiency testing events' results. The findings were: 1. A review of the laboratory's MLE proficiency testing records from 2017 (M1, M2, and M3) revealed the laboratory failed to have documentation of the review of the results for 1 of 3 events. The event missing documentation of review was: 2017 Event M2 2. The laboratory was asked to provide documentation of the review of 2017 Event M2. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1455 hours in the laboratory - after his review of the records- confirmed the findings. Key MLE - Medical Laboratory Evaluations
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 test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to provide overall quality in pre-analytic systems. The findings were: 1. The laboratory failed to have documentation of performing studies to support its samples stability/preservation, transportation, and storage requirements for its modified FDA-approved testing of oral and rectal swabs for Chlamydia and Gonorrhea (refer to D5311). 2. The laboratory failed to have documentation of providing instructions to clients for the stability/preservation and transportation of oral and rectal swabs for Chlamydia and Gonorrhea testing (refer to D5317). 3. The laboratory failed to have a quality assessment plan which could identify and correct issues in pre-analytic systems (refer to D5391).
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: Based on review of the laboratory's test menu, review of the laboratory's procedures the Aptima Combo 2 assay, review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory failed to have documentation of performing studies to support the conditions at which it received oral and rectal swabs testing utilizing the modified FDA-approved assay. The finding were: 1. A review of the laboratory's test menu revealed the laboratory started performing Chlamydia and Gonorrhea testing on oral and rectal swabs in 2017. This was a modification of the modification of the FDA-approved assay based on the sample types. The test was FDA-approved for endocervical swabs and male urethral swabs. The laboratory modified the assay by testing oralpharyngeal swabs and rectal swabs. 2. A review of the laboratory's procedure titled "Chlamydia & Gonorrhea (CT/GC) Screening" (revision 7/20/16) under the section titled "Specimen transport and storage before testing" revealed: "ALL Swab specimens: After collection , transport and store the swab in the swab specimen transport tube at 2C - 30C until tested. specimens must be assayed with the APTIMA Combo 2 Assay within 60 days of collection. If longer storage is needed, freeze at -20C to -70C for up to 90 days after collection. 3. The laboratory was asked to provide documentation of performing studies to support how it stated oral and rectal swabs were to be collected, transported and stored according to its policy. No documentation was provided. 4. The laboratory reported testing 41

	oralpharyngeal and rectal swabs from August 2017 to June 2018. 5. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1600 hours in the laboratory revealed the facility had not performed studies. He stated the facility decided to follow the instructions for endocervical and male urethral swabs provided by the manufacturer. This confirmed the findings.
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 records and staff interview, it was revealed the laboratory failed to have documentation of providing clients with instructions for the collection and transport of oralpharyngeal and rectal swabs for Chlamydia and Gonorrhea testing. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started performing Chlamydia and Gonorrhea testing on oralpharyngeal and rectal swabs in 2017. This was a modification of the modification of the FDA-approved assay based on the sample types. The test was FDA-approved for endocervical swabs and male urethral swabs. The laboratory modified the assay by testing oralpharyngeal swabs and rectal swabs. 2. The laboratory was asked to provide documentation providing instructions to clients for the collection and transport of oralpharyngeal and rectal swabs. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1610 hours in the laboratory revealed the facility did not provide instructions for oralpharyngeal and rectal swab collection and transport. This confirmed the findings.
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: I. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have a quality assessment plan which could identify and correct issues in pre-analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to identify and correct that the laboratory failed to have studies for the stability/preservation, transport, and storage of oral and rectal swabs for Chlamydia and Gonorrhea testing (refer to D5311). 2. The laboratory's quality assessment plan failed to identify and correct that the laboratory failed to provide instructions to clients on the stability/preservation and transport of oral and rectal swabs for Chlamydia and Gonorrhea testing (refer to D5317). 39812 II. Based on review laboratory policy titled "PPST High Complexity Laboratory-Blood Specimen Collection & Transport" and the Sysmex XP-300 operator's manual, the laboratory's quality assurance plan did not identify specimen acceptability and rejection requirements. Findings included: 1. Laboratory policy titled "PPST High Complexity Laboratory-Blood Specimen Collection & Transport" stated that a specimen for CBC

	(Complete Blood Count) "must be rcvd by Day 2" and "Rcvd on Day 3=Rejection." 2. The operator's manual for Sysmex XP-300 under "Conditions of Collection" stated "Venipuncture specimens should be collected into EDTA (Ethylenediaminetetraacetic acid) anticoagulant and processed within 4 hours of collection. If specimens cannot be processed within 4 hours, they should be refrigerated at 2-8C." Under "Sample Stability and Storage Performance Characteristics", the manual further revealed that the stability of a specimen stored at 2-8C is 24 hours. The laboratory failed to follow manufacturer instructions for acceptability and rejection.
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 records, and staff interview, it was revealed the laboratory failed to provide overall quality in analytic systems. The findings were: 1. The laboratory failed to include panic values, normal ranges, and instructions for the notification of panic values in its procedure (refer to D5403). 2. The laboratory failed to follow the manufacturer's instructions for sysphilis testing (refer to D5411). 3. The laboratory failed to ensure verification studies were complete (refer toD5421). 4. The laboratory failed to ensure establishment studies were complete (refer to D5423). 5. The laboratory failed to have documentation of performing required maintenance (refer to D5429). 6. The laboratory failed to tested titered controls each day of patient testing (refer to D5451). 7. The laboratory failed to have documentation of verifying control values prior to use (refer to D5469). 8. The laboratory failed to have a quality assessment plan which could identify and correct issues in analytic systems (refer to D5791).
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: Based on review laboratory procedures and confirmed in interview with laboratory staff, the laboratory failed to define panic values, failed to establish normal ranges, and failed to provide instructions for the reporting of panic values for complete blood count testing performed on the Sysmex XP-300 as part of its procedure. Findings included: 1. Review of the laboratory procedure manual revealed the laboratory failed to include in its procedure: a. A procedure to define panic values for analytes included in a complete blood count (CBC). When laboratory was asked for a procedure, none was provided. b. Established normal ranges for those analytes included in a complete blood count (CBC). When laboratory was asked for documentation, none was provided. c. Instructions for the reporting panic values for those analytes included in a complete blood count (CBC). When laboratory was asked for a policy, none was provided. 2. According to records, the laboratory's annual volume was 1 CBC test. 3. The laboratory staff confirmed the above findings in an interview on 06/15/2018 at 09: 17 AM in the laboratory.
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: Based on review of the manufacturer's instructions for the ASI RPR Card Test for Syphilis, review of the laboratory's test records for syphilis testing, review of the manufacturer's instructions for Qwik Check Beads, review of the laboratory's test records for semen analysis, review of patient test records, and staff interview, it was revealed the laboratory failed to : A) follow the manufacturer's instructions of only performing RPR testing when the room temperature was 20 - 30C, and B) follow the manufacturer's instructions for testing quality controls in duplicate for sperm counts. The findings were: A) RPR Testing 1. A review of the manufacturer's instructions for the ASI RPR Card for Syphilis (CPT code: 86592) under the section titled "Preparation for the Assay" revealed: "Allow all reagent and samples to war to room temperature (20 - 30C) before use." 2. A review of syphilis test records from October 2017 to December 2017 identified the following days where patient testing was performed when the documented room temperature was outside the manufacturer's defined range: Date Temp 10/16/17 19.6C 12/27/17 19.8C 3. A review of patient test records from the identified days revealed the following patients: Date ID 10/16/17 192919 193010 153765 183774 12/27/17 197124 115091 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1440 hours in the laboratory - after his review of the records- confirmed the findings. B) Semen Counts 1. A review of the manufacturer's instructions for the QwikCheck Beads quality control material for sperm counts under the section titled "
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 verification studies, and staff interview, it was revealed the laboratory failed to ensure the studies were complete prior to performing patient testing. The findings were: 1. Based on review of the laboratory's verification studies performed in 2017 and 2018 it was revealed the laboratory failed to have documentation of the following studies: a) Sperm counts - accuracy - precision b) ASI Syphilis - no positive sample tested as part of accuracy - no precision c) Siemens XPand analyzer - no precision - no verification of patient normal ranges The following analytes were tested: Sodium Thyroid Stimulating Hormone Total Bilirubin Total Protein Triglycerides Blood Urea Nitrogen LDL Cholesterol Calcium Chloride Cholesterol Creatinine CO2 Glucose Potassium Albumin Alkaline Phosphatase Alanine Transaminase Aspartate Transminase HDL Cholesterol Direct Bilirubin 2. The laboratory was asked to provide documentation of the missing studies. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on June 15, 2018 at 1145 hours in the laboratory confirmed the findings. 39812 II. A. Based on review laboratory records, patient records and confirmed in interview with laboratory staff, the laboratory failed to verify reference intervals for analytes included in a complete blood count for the appropriate patient population. Findings included: 1. Review of the laboratory records revealed the laboratory did not establish reference intervals for the appropriate patient population. When the laboratory was asked to provide reference range studies, none was provided. 2. Review of 1 of 1 CBC patient report, revealed the following normal ranges: WBC 4.0-11.0 RBC 4.00-6.20 HGB 12.0-17.0 HCT 36.0-50.0 MCV 80-99 MCH 27.0-33.0 MCHC 32.0-36.0 RDW 10.0-14.5 PLT 150-400 MPV 7-11.5 NEU % 45.0-80.0 NEU # 2.80-8.00 LEU % 21.0-47.0 LEU # 1.00-4.00 Mixed % 2.0-10.0 Mixed # 0.0-1.6 3. During an interview on 06/15/18 at 09:17AM in the laboratory, the testing personnel stated "Have not had enough specimens to establish normal ranges. The testing personnel confirmed the above findings. II. B. Based on review laboratory records and confirmed in interview with laboratory staff, the laboratory failed to follow Sysmex XP-300 operator's manual instructions to verify that the method for CBC testing produced correct results. Findings included: 1. The Sysmex XP-300 operator's manual instructions titled "Correlation Studies and Reference Range Verification" stated, "Samples for Correlation should be kept at room temperature during the analysis. a. CBC samples should be analyzed within 4 hours of collection and on both analyzers within 2 hours of each other." b. The instructions further stated, "The CLSI Method Comparison and Bias Estimation Using Patient Samples, suggests at least 40 specimens, 20 normal and 20 abnormal." 2. Review of the laboratory's verification studies, revealed the laboratory used 16 samples for the verification studies performed on 07/20/2017. a. The laboratory did not document the collection time and test time for 16 of 16 samples used for the verification study. b. The laboratory tested 16 samples for the verification study. The laboratory failed to follow the instrument manufacturer's instructions to test at least 40 specimens, 20 normal and 20 abnormal. 3. During an interview on 06/15/18 at 10:52AM in the laboratory, the testing

	personnel was asked for the correlation study raw data. The testing personnel stated "All we have is what's in the binder." The testing personnel was asked if the laboratory was aware of the Sysmex requirement of 40 specimens. The testing personnel stated, "Didn't have that many". The testing personnel confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's establishment studies performed on the laboratory's modified FDA-approved assay for Chlamydia and Gonorrhea testing on the Panther system, and staff interview, it was revealed the laboratory failed to have documentation of performing complete studies. The findings were: 1. Based on review of test menu revealed the laboratory modified the FDA-approved methodology on the Panther analyzer for Chlamydia and Gonorrhea testing by modifying the sample types tested. The laboratory modified the methodology by performing testing on oral pharyngeal and rectal swabs. The laboratory also modified the testing by performing testing on urine samples from patients under the age of 14 years which the manufacturer had not evaluated. 2. A review of the laboratory's establishment studies revealed the laboratory failed to have documentation of the following: a) oral pharyngeal and rectal swabs - pre-analytic studies (refer to D5311) - precision - sensitivity - specificity, including interfering substances b) patients under the age of 14 - precision - sensitivity - specificity, including interfering substances 3. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14 /2018 at 1650 hours in the laboratory revealed the laboratory has only performed comparison studies (accuracy) with samples from other labs for its studies. This confirmed the 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 review of the manufacturer's instructions for the ASI RPR Test for Syphilis,

review of the laboratory's maintenance records, and staff interview, it was revealed the laboratory failed to have documentation of performing the maintenance procedure of washing the needle each day of use. The findings were: 1. A review of the manufacturer's instructions for the ASI RPR Test for Syphilis (CPT code: 86592) under the section titled "Assay Protocol - Qualitative" revealed: "7. Remove and wash the needle at the end of each shift." 2. A review of the laboratory's syphilis maintenance records from January 2018 to April 2018 revealed the laboratory failed to have documentation of washing the needle after each shift for 79 of 79 days. 3. The laboratory was asked to provide documentation of washing the needle as required. No documentation was provided. 4. The laboratory reported performing 5234 qualitative syphilis tests annually. 5. In an interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1225 hours in the laboratory, he stated the laboratory washed the needle each day, however did not document the maintenance. This confirmed the findings. 39812 A. Based on review laboratory policy manual and laboratory maintenance records, the laboratory failed to document instrument maintenance with the frequency specified by the manufacturer for the Gen-Probe Panther instrument (Serial Number 2090001454, Model 902615) for Chlamydia/ Gonorrhea (CT/GC) monthly environmental maintenance. Findings included: 1. Review of the laboratory policy titled "Procedural Controls for Environmental Testing (Gen-Probe) stated "Environmental Testing will be performed on a monthly basis." 2. A review of the laboratory's maintenance logs revealed the laboratory failed to have documentation of monthly maintenance for 7 out of 17 months from 01/2017 through 05/2018. Review of the laboratory maintenance record for CT (Chlamydia) and GC (Gonorrhea) for 01/12/2017 through 05/31/2018 titled "Monthly Environmental Testing Log" revealed the months without documentation were: April 2017 May 2017 August 2017 September 2017 October 2017 January 2018 March 2018 B. Based on review laboratory policy manual and laboratory maintenance records, the laboratory failed to document instrument maintenance with the frequency specified by the manufacturer for the Gen-Probe Panther instrument (Serial Number 2090001454, Model 902615) for Human papillomavirus (HPV) monthly environmental maintenance. Findings included: 1. Review of the laboratory policy titled "Procedural Controls for Environmental Testing (Gen-Probe) stated "Environmental Testing will be performed on a monthly basis." 2. A review of the laboratory's maintenance logs revealed the laboratory failed to have documentation of monthly maintenance for 7 out of 17 months from 01/2017 through 05/2018. Review of the laboratory maintenance record for Human papillomavirus (HPV) for 01/12/2017 through 05/31 /2018 titled "HPV Monthly Environmental Testing Log" revealed the months without documentation were: April 2017 May 2017 August 2017 September 2017 October 2017 Jan 2018 March 2018 C. Based on review of the Sysmex XP-300 operator's manual, maintenance records, and confirmed in interview with laboratory staff, the laboratory failed to provide documentation for the performance of maintenance on the Sysmex XP-300 at the frequency it required for 19 of 21 months from September 2016 to May 2018. Findings included: 1. Review of the Sysmex XP-300 operator's manual policy titled "Cleaning and Maintenance" (Revision 2, June 2014) stated: a. Daily Clean TD chambers and diluted sample lines Check trap chamber level and discard b. Weekly Clean SRV tray c. Every Month (or every 1500 samples) Clean TD Clean waste chamber d. Every 3 Months (or every 4500 samples) Clean SRV 2. Review of the laboratory's Sysmex XP-300 maintenance records from September 2016 through May 2018 revealed no maintenance documented for 19 of 21 months. The months without documentation of monthly maintenance were: October 2016 November 2016 January 2017 February 2017 March 2017 April 2017 May 2017 June 2017 July 2017 August 2017 September 2017 October 2017 November 2017 December 2017 January 2018 February 2018 March 2018 April 2018 May 2018 3.

	During an interview on 06/15/18 at 09:17 AM in the laboratory the testing personnel stated, "The instrument has not been turned on in 3 months." The testing person did not provide any explanation about the other 16 months of missing maintenance documentation.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's syphilis procedure, review of the laboratory's syphilis quality control records, review of patient test records from January 2018 to May 2018, and staff interview, it was revealed the laboratory failed to have documentation of testing titered controls each day of patient testing. The findings were: 1. A review of the laboratory's procedure titled "ASI RPR CARD TEST FOR SYPHILIS" (effective date: 03/17) revealed the laboratory was to test a negative, weak reactive and nonreactive control each day of testing for qualitative testing. If the qualitative test was reactive, the laboratory was to then perform a semiquantitative test, or titer to determine the strength of the reaction. 2. Further review of the procedure revealed the testing of titered controls was not part of the laboratory's procedure for semiquantitative testing. 3. A review of patient test records from January 2018 to May 2018 identified the following patients for which semiquantitative results were reported, however the laboratory failed to have documentation of testing titered controls. (See patient alias listed for identification) Date ID Titer 01/18 patient 1 1:64 02/02 patient 2 1:128 02/14 patient 3 1:2 02/16 patient 4 1:12 03/06 patient 5 1:32 03/26 patient 6 1:64 04/03 patient 7 1:128 04/18 patient 8 1:32 05/15 patient 9 1:64 4. The laboratory was asked to provide documentation of testing titered controls each day of patient testing for the identified days. No documentation was provided. 5. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1223 hours in the laboratory revealed the facility did not test titered controls and was not aware they were required to do so. This confirmed the findings.
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: Based on review of the manufacturer's instructions for the BioRad Lyphochek Assayed Chemistry Control Levels 1 and 2, the BioRad Lyphochek Diabetes Control Levels 1 and 2, the BioRad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3, review of the laboratory and staff interview, it was revealed the laboratory failed to have documentation of established its own acceptable ranges. The findings were: 1. A review of the manufacturer's instructions for the BioRad Lyphochek Assayed Chemistry Control Levels 1 and 2 (04030-00, 2016-09) under the section titled "Assignment of Values" revealed:"It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 2. A review of the manufacturer's instructions for the BioRad Lyphochek Diabetes Control Levels 1 and 2 (4037, 2016-05) under the section titled "Assignment of Values" revealed: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 3. A review of the manufacturer's instructions for the BioRad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3 (1536-00, 2016-06) under the section titled "Assignment of Values" revealed: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 4. A review of the laboratory's quality control records from 2017 and 2018 revealed the laboratory utilized the following lots on control material: a) Lyphochek Assayed Chemistry Controls Lot: 26430 Lot: 14490 b) Lyphochek Diabetes Controls Lot: 33940 Lot: 33930 c) Lyphochek Immunoassay Plus Control Lot: 40340 Lot: 40330 5. The laboratory was asked to provide documentation of establishing its own acceptability ranges for each lot as stated by the manufacturer. No documentation was provided. 6. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/15/2018 at 1245 hours in the laboratory revealed the facility used the ranges provided by the manufacturer to assess the quality control acceptability. This confirmed the findings. 39812 Based on review Sysmex XP-300 quality control data, direct observation and confirmed in interview with laboratory staff, the laboratory failed to provide documentation of verifying new lots of Quality Control material prior to patient testing for the Sysmex XP-300 analyzer. Findings included: 1. Review of the one CBC (complete blood count) patient report from 11/01/2017, revealed the following quality control material tested: Lot Number 72560710; expiration 2017/12 /20 Lot Number 72560711; expiration 2017/12/20 Lot Number 72560712; expiration 2017/12/20 No documentation for verification of acceptable ranges was provided. 2. A tour of the laboratory on 06/15/2018 at 09:30AM revealed two packages of the following Sysmex control material: Lot Number 81430710; expiration 2018/08/29 Lot Number 81430711; expiration 2018/08/29 Lot Number 81430712; expiration 2018/08 /29 No documentation for verification of acceptable ranges was provided. 3. According to records, the laboratory's annual volume was 1 CBC test. 4. During an interview on 06/15/18 at 09:51 AM in the laboratory, the testing personnel was asked for the Sysmex XP-300 QC range verification documentation. No documentation was provided. The testing personnel confirmed the above findings.
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 review laboratory temperature logs and confirmed in interview with laboratory staff, the laboratory failed to have documentation of corrective actions when documenting temperatures outside of the laboratory's established ranges. Findings included: 1. Review of the laboratory temperature logs from 11/30/2016 to 12/31/2016 titled "Daily Freezer Temperature Check Documentation Log" stated "Acceptable Range= 2 to 8 Celsius." According to the acceptable range specified on the temperature log, 37 out of 37 temperature readings were out of range. The following are the dates and temperatures recorded on the temperature log: Date/2016 AM PM 11/30 -14.6C -17.7C 12/1 -13.5C -12.6C 12/2 -18.8C -14.6C 12/5 -17.4C -11.3C 12/6 -18.4C -13.7C 12/7 -14.3C -13.5C 12/8 -17.2C -19.2C 12/9 -15.9C -15.2 C 12/12 -16.9C -11.6C 12/14 -20.9C -10.8C 12/15 -13.1C -17.3C 12/16 -13.1C -19.9 C 12/19 -16.9C -11.9C 12/20 -16.0C -17.2C 12/22 -21.2C No temperature recorded 12/27 -14.9C -18.1C 12/28 -12.4C -10.0C 12/29 -12.0C -12.2C 12/30 -17.3C -13.5C 2. Review of the laboratory temperature log for 12/05/2016, 12/12/2016, 12/19/2016 and 12/27/2016 titled "Minimum and Maximum Freezer Temperature Log" stated "Acceptable Range= 2 to 8 Celsius". According to the acceptable range specified on the temperature log, 8 out of 8 temperature readings were out of range. The following are the dates and temperatures recorded on the temperature log: Date/2016 Minimum Refrig Temp Maximum Refrig Temp 12/5 -18.9C 4.9C 12/12 -18.5C 1.8C 12/19 -19.9 C 3.9C 12/27 -19.9C 4.9C 3. Review of the laboratory temperature logs for 02/01/2018 and 05/18/2018 titled "2x Daily Freezer Temperature Check Log", stated "Acceptable Range: 2C to 8C. ' According to the acceptable range specified on the temperature log, 64 out of 64 temperature readings were out of range. The following are the dates and temperatures recorded on the temperature log: Date/2018 AM PM 2/1 -13.9C -14.2C 2/2 -15.0C -15.2C 2/5 -13.4C -12.9C 2/6 -14.6C -13.4C 2/7 -15.1C -14.8C 2/8 -14.6C -13.1C 2/9 -14.9C -13.0C 2/12 -12.1C -13.3C 2/13 -14.2C -13.8C 2/14 -11.9C -12.6C 2/15 -13.9C -14.2C 2/16 -13.7C -13.3C 2/20 -15.6C -15.1C 2/21 -13.5C -12.7C 2/22 -12.4C -13.2C 2-23 -14.5C -14.8C 2/26 -14.1C -17.1C 2/27 -12.2 C -13.3C 2/28 -17.0C -15.8C 5/1 -15.9C -16.4C 5/2 -14.9C No temperature recorded 5/3 -15.9C -15.1C 5/4 -16.1C -14.2C 5/7 -17.5C -16.8C 5/8 -14.9C -15.6C 5/9 -16.7C -17.0C 5/10 -14.7C -17.8C 5/11 -15.6C No temperature recorded 5/14 -15.8C -14.9C 5/15 -14.3C -13.4C 5/16 -14.8C -16.1C 5/17 -16.1C -16.2C 5/18 -14.5C -12.5C 4. Review of the laboratory temperature logs from 01/03/2017 to 05/21/2018 titled "Weekly Minimum and Maximum Freezer Temperature Log", stated "Acceptable Range: -10 to -20C." According to the acceptable range specified on the temperature log, 57 out of 144 recorded temperatures were out of range. No temperatures were documented for 05/15/2017. The following are the dates and out of range temperatures recorded on the temperature log: Date/2017 Minimum Freezer Maximum Freezer Temperature Temperature 1/3 5.7C 1/9 1.9C 1/18 5.6C 1/23 2.9C 1/30 6.6C 2/7 5.2C 2/13 -8.5C 4.3C 2/20 0.9C 2/27 3.1C 3/06 3.1C 3/13 1.1C 3/20 2.4 C 3-27 0.9C 4/03 2.0C 4/11 2.8C 4/17 0.3C 4/24 1.9C 5/1 0.7C 5/8 3.0C 5/23 0.1C 9/18 -6.7C 9/25 -5.8C 10/2 -6.7C 10/9 -6.3C 10/16 -7.0C 10/23 -5.3C 10/30 -4.5C 11/6 -5.1C 11/13 -5.1C 11/20 -5.1C 11/27 -4.3C 12/4 -4.6C 12/13 -5.2C 12/18 -5.2C 12/26 -4.9C Date/2018 Minimum Freezer Temperature 1/2 -4.4C 1/8 -4.4C 1/17 -3.6C 1/22 -4.0C 1/29 -4.9C 2/5 -4.5C 2/12 -4.3C 2/20 -3.7C 2/26 -5.3C 3/05 -5.9C 3/12 -6.2C 3/19 -4.7C 3/26 -5.0C 4/02 -7.9C 4/09 -6.2C 4/16 -7.0C 4/23 -6.3C 4/30 -6.3C 5/7 -6.5 C 5/14 -9.1C 5/27 -4.3C 5. Review of the laboratory temperature log from 09/01/2017 to 09/30/2017 titled "Minimum and Maximum Refrigerator Temperature Log" stated "Acceptable Range: 2C to 8C." The laboratory failed to monitor and document room temperature and humidity on the correct temperature log. Numbers recorded on this

	log are as follows: Date Minimum Maximum Refrig. Refrig. Temp Temp 9/1 21.7C 43C 9/5 21.7C 50C 9/6 21.5C 40C 9/7 20.0C 32C 9/11 20.7C 35C 9/12 20.2C 35C 9 /13 20.7C 34C 9/14 21.7C 46C 9/15 21.9C 46C 9/18 21.7C 50C 9/19 21.7C 53C 9/20 21.9C 52C 9/21 21.5C 54C 9/22 21.7C 52C 9/25 21.7C 51C 9/26 21.7C 50C 9/27 21.5 C 50C 9/28 20.3C 50C 9/29 21.5C 47C There were no recorded values for: 9/2, 9/3, 9 /4, 9/8, 9/9, 9/10, 9/16, 9/17, 9/23, 9/24, 9/30. 6. Review of the laboratory temperature log from 01/01/2017 to 01/31/2017 titled "Daily Room Temperature and Humidity Check Documentation Log" stated "Acceptable Range: 15 to 25C for Room Temperature." The laboratory failed to monitor the acceptable room temperature ranges for the following days. Date Room Temp 1/10 25.1oC 1/11 25.5oC 1/12 26.2 oC 7. During an interview on 06/14/2018 at 04:00PM in the laboratory, the Testing Person stated "We could not get the freezer temperature to -20C and we do not use the freezer anymore." The Testing person confirmed the above findings. Word Key: WBC-White Blood Count RBC-Red Blood Count HGB-Hemoglobin (HGB) HCT-Hemtocrit (HCT) MCV-Mean Corpuscular Volume MCH-Mean Corpuscular Hemoglobin MCHC-Mean Corpuscular Hemoglobin Concentration RDW-Red Cell Distribution Width PLT-Platelet MPV-Mean Platelet Volume NEU%-Neutrophil Percent NEU#-Absolute Neutrophils LEU%-Lymphocyte Percent LEU#-Absolute Lymphocytes Mixed%-Mixed Percent Mixed#-Absolute Mixed Refrig- Refrigerator Temp-Temperature Rcvd-Received
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 records, and staff interview, it was revealed the laboratory failed to have a quality assessment plan which could identify and correct issues in analytic systems. The findings were: 1. The laboratory's quality assessment plan failed identify and correct that the laboratory did not include panic values, normal ranges, and instructions for the notification of panic values in its procedures (refer to D5403). 2. The laboratory's quality assessment plan failed to identify and correct that the laboratory did not follow the manufacturer's instructions for sysphilis testing (refer to D5411). 3. The laboratory's quality assessment plan failed to identify and correct that the laboratory did not ensure verification studies were complete (refer toD5421). 4. The laboratory's quality assessment plan failed to identify and correct that the laboratory did not ensure establishment studies were complete (refer to D5423). 5. The laboratory's quality assessment plan failed to identify and correct that the laboratory did not have documentation of performing required maintenance (refer to D5429). 6. The laboratory's quality assessment plan failed to identify and correct that the laboratory did not test titered controls each day of patient testing (refer to D5451). 7. The laboratory's quality assessment failed to identify and correct that the laboratory did not have documentation of verifying control values prior to use (refer to D5469).
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient results, and staff interview, it was revealed the laboratory failed provide the disclaimer stating the performance characteristics for an assay were performed by the laboratory on patient results. The findings were: 1. A review of patient test reports from August 2017 to June 2018 for patient samples tested by the laboratory's modified FDA-approved assay for Chlamydia and Gonorrhea testing revealed the laboratory failed to provide the necessary disclaimer stating performance characteristics were performed the laboratory on 41 of 41 patient results. The patient identification numbers were: 194261 182146 92088 196727 196029 197489 186109 187440 188679 (o) 188679 (r) 188368 188904 (o) 188904 (r) 190208 190425 3889 190920 192129 (o) 192129 (r) 191586 177120 17007 181513 181418 161779 183145 822 184561 6266 198576 153954 150356 (o) 150356 (r) 152670 186077 (o) 186077 (r) 177503 200443 196458 209881 2. The laboratory was asked to provide documentation of including the disclaimer as part of its patient reports. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 06/14/2018 at 1650 hours in the laboratory revealed the facility was unaware of the necessity to document the disclaimer of patient reports. This confirmed the findings. Key (o) - oral swab (r) - rectal swab
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 records, and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings were: 1. The laboratory director failed to ensure verification studies were complete (refer to D6013). 2. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). 3. The laboratory director failed to ensure a quality control plan was developed and followed (refer to D6020). 4. The laboratory director failed to ensure a quality assesment plan was developed and followed (refer to D6021). 5.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies and staff interview, it was revealed the laboratory director failed to ensure the studies were complete (refer to D5421).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, it was revealed the laboratory director failed to ensure corrective actions were performed when proficiency testing results were unacceptable (refer to D2121).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's syphilis quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was defined to ensure controls of titered reactivity were tested (refer to D5451).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment Plan and staff interview, it was revealed the laboratory director failed to ensure a quality assessment program was developed. The findings were: 1. The laboratory director failed to ensure a quality assessment plan was developed to identify and correct issues in analytic systems (refer to D5791).
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 laboratory's submitted form CMS-209, the laboratory's personnel records and staff interview, it was revealed the Technical Consultant failed to have documentation of performing annual competency assessments for existing CT/GC testing on the Panther System in 2017 for 2 of 2 persons. Findings included: 1. Review of the laboratory's CMS-209 form listed 2 testing persons. 2. Review of personnel records revealed no documentation of 2017 competency assessments for 2 of 2 testing persons. 3. During an interview on 06/14/18 at 10:00 AM in the conference room, the testing personnel was asked to provide 2017 competency for all testing person. No documentation was provided. The testing personnel confirmed the above findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to

	reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted form CMS-209, the laboratory's personnel records and staff interview, the laboratory failed to provide documentation of competency assessment for testing personnel prior to performing patient testing when new test methodologies were introduced. 1. Review of the laboratory's CMS-209 form listed 2 testing persons. 2. Review of personnel records revealed the implementation of the following new test methodologies: a. Semen Analysis 12/14 /2017 b. Rapid Plasma Reagin test (RPR) 08/01/2017 c. Dimension EXL 09/09/2016 d. Sysmex XP 300 06/14/2016 3. Review of personnel records revealed no documentation of competency assessment prior to performing patient testing for 2 of 2 testing persons. 4. During an interview on 06/14/18 at 10:00 AM in the conference room, the laboratory staff was asked to provide competency for new platforms for all testing persons. No documentation was provided. The laboratory staff 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 records, and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings were: 1. The laboratory director failed to ensure establishment studies were complete (refer to D6082). 2. The laboratory director failed to ensure a quality assessment plan was developed and followed (refer to D6094).
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 establishment studies for its modified FDA-approved assays and staff interview, it was revealed the laboratory director failed to ensure test systems developed had complete studies (refer to D5423).
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 the laboratory's quality assessment records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment plan identified failures in quality. The findings were: 1. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected issues in pre-analytic systems (refer to D5391). 2. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected issues in analytic systems (refer to D5791).