Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0666165	08/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Wv Office Of Laboratory Services	167 11th Avenue, South Charleston, WV	

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	Federal surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey at WV OFFICE OF LABORATORY SERVICES on August 26, 2024 to August 29, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and found to not be in compliance with the following condition-level CLIA requirements: 42 C.F.R. 493.1240 Condition: Preanalytic systems. 42 C.F.R. 493.1250 Condition: Analytic systems.
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 laboratory policies, competency assessments (2023 and 2024), and confirmed in an interview with Technical Supervisor (TS) -1, the laboratory failed to have a policy to address competency for 6 of 6 Technical Supervisors, 4 of 4 General Supervisors (GS) and 4 of 4 Testing Personnel (TP). Findings Include: 1. Review of laboratory documents revealed no documentation of a policy to address competency for the Technical Supervisors and General Supervisors in 2023 and 2024. 2. Review of laboratory competency assessments revealed no annual competency documentation in 2023 and 2024 for TS-1, TS-2, TS-3, TS-4, TS-5, GS-1, GS-2, GS-3, GS-4, and TP-1, TP-2, TP-3, TP-4. 3. In an interview on 8/27/2024 at 2:12pm, TS-1 corroborated that the laboratory did not have a policy to address competency for 6 of 6 TSs, 4 of 4 GSs and 4 of 4 TPs in 2023 and 2024.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Technical supervisor (TS) #1, the laboratory failed to follow their quality assessment (QA) procedure for 2 of 2 years (August 2022 to August 2024). The findings included: 1. The Quality assessment plan, 5.5 Quality assessment review: 5.5.1 "A random review of quality assessment for each unit is perform by either the section supervisor or a designated laboratory scientist from the section. 5.5.2 The section supervisor or designated laboratory scientist will choose one specimen from each unit and complete a QA quarterly review form". 2. The laboratory sections were unable to provide QA quarterly reviews performed for 2 of 2 years from August 2022 to August 2024. 3. Interview with TS#1 confirmed the findings above on August 29, 2024 at 1: 00 pm.
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 direct observation, review of manufacturer's instructions, laboratory's procedure manuals, and patient reports, the laboratory failed to meet the requirements for the preanalytical systems evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for the pre-analytical requirements of laboratory testing. Please see D5311, I. 2. The laboratory failed to follow manufacturer's instructions, written policies and procedures, for documenting pre-analytical specimen acceptability requirements of laboratory testing. Please see D5311, II.
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 direct observation, manufacturer's instructions for transport and processing,

and confirmed in interview, the laboratory failed to follow manufacturer's instructions for processing 5 of 5 Hologic Aptima Combo 2 Assay Tubes run on the Hologic Panther analyzer on August 27, 2024. Findings include: 1. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated the following on page 5: "Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen contains do not contact one another, and discard used materials without passing over open containers." 2. In direct observation, on 8/27/2024 at 10:21 AM, in the Laboratory Support Unit of the facility, 3 Hologic Aptima Combo 2 Assay Tubes for CT/GC were placed horizontally, physically touching one another by the specimen handler during intake, once removed from packaging, for counting and accessioning purposes. Additionally 2 CT/GC Hologic Aptima tubes for different patients were received together in one pack with 5 total specimens, touching one another. The patients observed are as follows: a. MRN 3536591, DOB 9/12/1983. b. MRN 3555722, DOB 7/10/1972. c. MRN 3558952, DOB 8/08/1991. d. MRN 3335016, DOB 5/01/1998. e. MRN 3347119, DOB 2/07/1974. 3. In an interview on 8/27/2024 at 10:25 AM, the supervisor of the Laboratory Support Unit corroborated these findings. Word Key: GC - Gonorrhea CT - Chlamydia Trachomatis 47272 II. Based on observation, manufacturer's instructions, laboratory written policy and procedure, patient submission forms, patient test reports, and interview with the supervisor of laboratory support, technical supervisor #1 (TS #1), and technical supervisor #3 (TS #3), the laboratory failed to document specimen acceptability for three of three Campylobacter specimens, one of one Salmonella specimens, one of one Escherichia coli specimens, two of two Rubella specimens, and eight of eight Syphilis specimens. Findings include: 1. On 08/27/2024 TS #1 confirmed the laboratory performed Campylobacter testing, Salmonella testing, and Escherichia coli testing submitted by outside clients using the Remel Cary Blair Transport Medium. 2. On 08/28/2024 TS #3 confirmed the laboratory performed the following testing from outside patient samples: a. Rubella testing using the Fisher Scientific Biokit Sure-Vue Rubella kit. b. Syphilis testing using the Becton Dickinson Macro-Vue RPR kit 3. Review on 08/27/2024 of manufacturer's instructions for specimen submitted using the Remel Cary Blair Transport Medium (Campylobacter testing, Salmonella testing, and Escherichia coli testing) and Rubella testing revealed the following instructions: a. Remel Cary Blair Transport Medium with an indicator (Campylobacter testing, Salmonella testing, and Escherichia coli testing) under section, "LIMITATIONS" stated, "4. Transport and storage of fecal specimens at 2-8C are very important for the recovery of certain enteric pathogens (e.g., Shigella, Campylobacter)." b. Fisher Scientific Biokit Sure-Vue Rubella kit (Rubella testing) under section "SPECIMEN COLLECTION AND STORAGE" stated, "2. If the test cannot be carried out on the same day, the serum must be stored between 2-8C for no longer than 8 days after collection. For longer periods the samples must be frozen (-20C)." 4. Observation on 08/28/2024 at 10:20 am of specimens arriving at the laboratory's specimen receiving department revealed the laboratory did not have a mechanism to ensure specimens were maintained according to manufacturer instructions for Campylobacter patient specimens: a. Patient E1791848 - Date of collection on 08/21/2024, received into the laboratory on 08/28/2024 for Campylobacter testing. 5. Review of laboratory specimen submission forms and patient reports on 08/28/2024 revealed the laboratory failed to document the specimen acceptability for the following: a. Campylobacter testing: i. Patient E24M0168990-01 - Specimen collected on 06/05/2024, received into the laboratory on 06/17/2024, and reported on 07/03/2024. ii. Patient E24M016888-01- Specimen collected on 06/13/2024, received into the laboratory on 06/14/2024, and reported on 06/21/2024. b. Salmonella testing: i. Patient E24M016996-01 - Specimen collected on 06/15/2024, received into the laboratory on 06/17/2024, and reported on 07/03/2024.

	c. Escherichia coli testing: i. Patient E24M016702-01 - Specimen collected on 06/07 /2024, received into the laboratory on 06/14/2024, and reported on 07/10/2024. d. Rubella testing: i. Patient E24016951-01 - Specimen collected on 06/14/2024, received into the laboratory on 06/17/2024, and reported on 06/18/2024. ii. Patient E24D021350-01 - Specimen collected on 08/01/2024, received into the laboratory on 08/02/2024, and reported on 08/06/2024. 6. Review on 08/27/2024 of the laboratory's written policy and procedure titled, "Rapid Plasma Reagin (RPR) 18 mm Circle Test for the Detection of Syphilis Qualitative and Quantitative Using DB Macro-Vue Reagents" under section, "6.0 SAMPLE REQUIREMENTS" stated, "6.4 Sample is stable for 7 days from collection at room, refrigerated, or frozen temperature." 7. Review of laboratory specimen submission forms and patient reports on 08/28/2024 revealed the laboratory failed to document the specimen acceptability for eight of eight Syphilis specimens: a. Patient E24D016941-01 - Specimen collected on 06/11 /2024, received into the laboratory on 06/17/2024, and reported on 06/18/2024. b. Patient E24D017074-01 - Specimen collected on 06/13/2024, received into the laboratory on 06/18/2024, and reported on 06/18/2024. c. Patient E24D017004-01 - Specimen collected on 06/13/2024, received into the laboratory on 06/18/2024, and reported on 06/18/2024. d. Patient E24D020745 - Specimen collected on 07/24/2024, received into the laboratory on 07/30/2024, and reported on 07/30/2024. e. Patient E24D020695-01 - Specimen collected on 07/24/2024, received into the laboratory on 07/30/2024, and reported on 07/30/2024. f. Patient E24D020698-01 - Specimen collected on 07/24/2024, received into the laboratory on 07/30/2024, and reported on 07/30/2024. g. Patient E24D020800-0 1- Specimen collected on 07/26/2024, received into the laboratory on 07/31/2024, and reported on 07/31/2024. h. Patient E24D021401-01 - Specimen collected on 07/30/2024, received into the laboratory on 08/05/2024, and reported on 08/06/2024. 8. Interview on 08/29/2024 at 09:30 am with TS #1 and TS #3 confirmed the laboratory failed to document specimen acceptability as indicated above.
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 observations of the laboratory, interview with technical supervisor (TS) #1, and review of laboratory records, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 from August 2022 to August 2024. Refer to: 1. The laboratory failed to follow established procedures. Please see D5401. 2. The laboratory failed to establish complete procedures. Please see D5403. 3. The laboratory failed to signed all procedures. Please see D5407. 4. The laboratory failed to follow manufacturer's instructions. Please see D5411. 5. The laboratory failed to establish and document temperature and humidity conditions. Please see See D5413. 6. The laboratory failed to label reagents, solutions and chemical with expiration dates. Please see See D5415. 7. The laboratory failed to discard supplies that have exceeded their expiration. Please see D5417. 8. The laboratory failed to perform function checks. Please see D5435. 9. The laboratory failed to complete

	Individualized Quality Control Plan (IQCP) in use. Please see D5445. 10. The laboratory failed to complete the Individualized Quality Control Plans (IQCP) in use. Please see D5449.
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: Based on the laboratory's procedure, observation and interview with Testing Personnel (TP) -6, the laboratory failed to follow their own written policy in ensuring proper Panther Fusion Mag Wash intervals after testing 2,007 of 2,458 Chlamydia (CT)/Gonorrhea (GC) patient specimens from June 2024 to August 2024. Findings Include: 1. A review of the laboratory's procedure titled, "WV DHHR|BPH|OLS Diagnostic Immunology Section Standard Operating Procedure Revised 05/04/2023" revealed on page 17 of 23 the following: "14.6. Mag Wash Clean - The Mag Wash Clean maintenance task removes deposits that can build up inside the aspirators and associated tubing. This task can be run at any time the system is in the Setup or Ready state. The task takes 31 minutes to complete. It is required that this task be performed daily after testing ..." 2. A review of the laboratory's test volume records (Panther Fusion Serial Number 03373) between June 1, 2024 and August 29, 2024 showed daily Mag Wash Clean maintenance was not performed after testing 623 of 645 CT /GC specimens in June, 703 of 986 CT/GC specimens in July, and 681 of 827 CT/GC specimens in August. 3. In an interview on 8/27/24 at 2:30pm, TP-6 confirmed the Panther Fusion Mag Wash settings were not set as per the laboratory section's policy, corroborating the findings. Word Key: GC - Gonorrhea CT - Chlamydia Trachomatis
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 a review of the laboratory's written policies and procedures and interview with technical supervisor #1 (TS #1) and technical supervisor #3 (TS #3), the laboratory failed to have complete written procedures for three of three written procedures reviewed. Findings included: 1. On 08/28/2024 TS #3 confirmed the following tests were performed in the Diagnostic Immunology department: a. Rubella testing using the Fisher Scientific Biokit Sure-Vue Rubella kit. b. Syphilis testing using the Becton Dickinson Macro-Vue RPR kit c. Hepatitis B testing using the Bio-Rad Monolisa Anti-HBs EIA test. 2. Review of laboratory written procedures on 08/28/2024 for the testing above revealed the laboratory failed to have complete procedures that included the description of the course of action to take if a test system becomes inoperable for three of three procedures. 3. Interview with TS #1 on 08/28/2024 at 1:15 pm confirmed the findings above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the microbiology laboratory procedure and interview with the laboratory supervisor (TS) #2, the laboratory failed to ensure the two of five microbiology laboratory procedures were approved, signed, and dated by the current laboratory director. Findings Included: 1. On the day of survey, August 27, 2024 at 2:00 pm, review of the laboratory procedure revealed the Meridian Bioscience Alethia analyzer Procedure and the Biofire Torch respiratory panel (RP) 2.1 procedure (two out of five reviewed) were not signed, and dated by the current laboratory director. 2. Interview with TS#2 confirmed the above procedures that were signed on August 27, 2024 at 2:45 pm.
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, review of patient records, and confirmed in interview with TS-1, the laboratory failed to follow manufacturer's instructions in ensuring CT/GC specimens are not run on patients under the age of 14 for 296 of 20,262 CT/GC specimens run on the Hologic Panther analyzer from January 2023 to August 2024. Findings Include: 1. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated the following on page 20: "Limitations: P. The performance of the Aptima Combo 2 Assay has not been evaluated in adolescents less than 14 years of age." 2. A review of the laboratory's Laboratory Information Management System (STARLIMS) patient report generated from January 2023 to August 2024 shows 296 patient specimens

	whose age demographics fell under the age of 14 at the time of testing. 3. In an interview on 8/28/2024 at 1:05pm, the TS-1 explained that 296 out of the 20,262 CT /GC patient specimens tested since January 2023, according to the STARLIMS report, were of patients under the age of 14, and confirmed the findings.
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 manufacturer's instructions, temperature records, and interview with technical supervisor #3 (TS #3), the laboratory failed to ensure the refrigerator temperatures were maintained as required by the manufacturer for Rubella testing, Syphilis testing, and Hepatitis B testing for four of four months. Findings included: 1. On 08/28/2024 TS #3 confirmed the following tests were performed in the Diagnostic Immunology department: a. Rubella testing using the Fisher Scientific Biokit Sure-Vue Rubella kit. b. Syphilis testing using the Becton Dickinson Macro-Vue RPR kit. c. Hepatitis B testing using the Bio-Rad Monolisa Anti-HBs EIA test. 2. Review of manufacturer's instructions on 08/28/24 stated the following: a. Rubella testing - Fisher Scientific Biokit Sure-Vue Rubella kit under section, "Storage and handling of reagents" stated, "Reagents and controls will remain stable through the expiration date shown on the label when stored between 2 and 8C." b. Syphilis testing - Becton Dickinson Macro-Vue RPR kit under section, "Storage of Antigen" stated, "Refrigerate at 2 to 8C." c. Hepatitis B testing - Bio-Rad Monolisa Anti-HBs EIA test under section, "Reagents" stated, "Store the kit at 2-8C". 3. Review of refrigerator temperature records from January 2024 through April 2024 and May 2024 through August 2024 revealed temperatures were documented colder than 2C for four of four months: a. "VWR Fridge" (Rubella and Syphilis testing) located in the "RPR Station" documented temperatures colder than 2C for four of four months. 1. May (Specific Days 24,30). 2. June (Specific Days 3,7,11,12,21,24). 3. July (Specific Days 1,10,12,15,22,23,24,29,31). 4. August (Days 1,2,5,6,13, 15,19,27). b. "Centinental Dual" (Hepatitis B testing) located in the "HIV/Hep Lab Evolis Lab" documented temperatures colder than 2C for four of four months. 1. January (Specific Days 17,28,30). 2. February (Specific Days 2,9,12,15,16,21,23). 3. March (Specific Days 5,7,14,). 4. April (Specific Days 3,12). 4. Interview on 08/29/2024 with TS #3 confirmed the findings above. II. Based on manufacturer's instructions, temperature records, and interview with the technical supervisor (TS #1), the laboratory failed to ensure blood collection tubes were stored according to manufacturer's instructions for four of four months. Findings included: 1. Observation on 08/27/2024 at 09:35 am of the testing supplies in the container room revealed six boxes (100 tubes each box - Lot# 4109429) of BD Vacutainer SST Blood Collection Tubes with a storage requirement of 4 - 25 degrees Centigrade (C). 2. Review of temperature records on 08 /27/2024 from January 2024 through April 2024 revealed no evidence the laboratory monitored the room temperature of the container room for four or four months. 3. Interview with TS#1 on 08/27/2024 at 09:40 am confirmed the findings above. III.

	Based on observations of the laboratory, lack of room temperature records and interview with the technical supervisor (TS) #1, the laboratory failed to document room temperatures and humidity conditions in the microbiology department laboratories and media room from August 2022 to August 2024. Findings Included: 1. On the days of survey, August 27, 2024 to August 29, 2024, observation of the media room and microbiology department laboratories revealed, daily room temperatures and humidity conditions were not monitored / documented from August 2022 to August 2024. 2. The following are a sample of instrument and reagent/chemicals temperatures and humidity requirements: A. Media Room: a. 1 of 1 bottle of Oxoid Heart Infusion Broth - 10-30 degrees Celsius (C). b. 1 of 1 bottle of Oxoid Urea Agar Base: 10C-30C. c. 1 of 1 bottle of Oxoid Alkaline Peptone water: 10C-30C. d. 1 of 1 bottle of Sigma Acridine Orange - store a room temperature. e. 1 of 1 bottle of Milliporo Microbiology Meat Extract: 15C-25C. f. 1 of 1 bottle of BD Difco GN Broth: 2C-25C. g. 1 of 1 bottle of BD Difco Gelatin: 2C-25C. h. 1 of 1 bottle of BD Difco Oxford Medium Base: 2C-25C. i. 1 of 1 bottle of BD Difco XLD Agar: 2C-25C. B. Microbiology Department: a. 4 of 4 bottle of Remel Gram Stains: 20C - 25C. b. 3 of 3 boxes of Gene Xpert Carba-R Cartridges: 2C - 28C. c. 1 of 1 Nikon Eclipse E400 microscope instructions specifications and rating, operating environment, " temperature 20C-40C and humidity max 85%". d. 1 of 1 Zeiss Primo Star microscope operating manual, 5 Appendix, Ambient conditions operation, "Permissible ambient temperature 5-40 C and Permissible humidity max. 75% at 35 C. e. 1 of 1 Gene Xpert DX System Operator Manuel 4.3, "operating temperatures: 15C-30C" and Humidity: 0% - 95%". f. 1 of 1 Maldi Bruker Biotyper System User manual 2.5, "Environmental requirements, 16C-33C. g. 1 of 1 Biofire Torch operators manual, Chapter 4 Performance specifications, operating specifications, "15C-30C at 20 to 80% humidity (non-condensing)". 3. The Microbiology department was unable to provide documentation of daily room temperatures and humidity conditions monitored in the Enterics, ARLN and bacteriology laboratories. 4. The laboratory was unable to provide documentation of daily room temperatures and humidity conditions monitored in the media room. 5. Interview with TS#1 confirmed the findings on August 29, 2024 at 1:00 pm. 47107 IV. Based on direct observation, manufacturer's instructions, and interview with TS-3, the laboratory failed to monitor and document relative humidity in the room for 1 of 1 Bio-Rad Evolis analyzers validated for testing. Findings Include: 1. Upon a laboratory tour on 8/27/2024 at 9:23am, 1 of 1 Bio-Rad Evolis analyzers was observed in operation in the Immunology section, with no relative humidity monitoring or documentation. 2. A review of the operator's manual titled "Bio-Rad Laboratories System Installation Manual: Evolis System Effective Date 01JAN16", stated the following under "Pre-Installation Instructions": "Environmental/Climate Requirements: Relative Humidity 10 to 90%, non-condensing". 3. In an interview on 8/28/2024 at 3:00pm, TP-6 explained that there was not a system in place to monitor and record relative humidity in the testing area where the Bio-Rad Evolis was located, corroborating the findings. V. Based on direct observation, manufacturer's instructions, and interview with TS-1, the laboratory failed to monitor and document the room temperature for 2 or 2 storage rooms in which temperature dependent supplies were stored. Findings Include: 1. During a tour of the laboratory on 8/27/2024 at 9:23am, the following laboratory supplies were observed in the storage rooms without temperature monitoring: a. 20 boxes of Aptima Multitest Swab Specimen Collection Kits, Lot 89648U, expiration date 2025-07-31; manufacturer storage temperature requirements 15-30 degrees Celsius. b. 10 packages of Copan eSwabs, Lot N30403100, expiration date 2024-11-18, manufacturer storage temperature requirements 5-25 degrees Celsius. 2. During an interview on 8/28/2024 at 9:31am, the TS-1 corroborated the findings that room temperature was not being monitored and recorded in the storage rooms.

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: Based on observations of the media room and interview with the technical supervisor (TS) #2, the laboratory failed to establish and document expiration dates for 17 out to 17 reagents and chemicals in use. Findings Included: 1. On the day of survey, August 27, 2024, a sampling of the following reagents and chemicals were observed in the media laboratory without expiration dates: a. 1 of 1 bottle of Sigma Acridine Orange - Lot#65H3575. b. 1 of 1 bottle of Oxoid Heart Infusion Broth - Lot#2836743. c. 1 of 1 bottle of D-(+)-Cellobiose - Lot22150. d. 5 of 5 bottles of Sigma Bromothymol Blue - 26996KH. e. 5 of 5 bottles of Sigma Cresol Red, Indicator - 01025ME. f. 2 of 2 bottle of Sigma -Aldrich Sodium phosphate dibasic - Lot#BCBX5924. g. 1 of 1 bottle of Sigma -Aldrich Sodium hydroxide - Lot#MKCG2622. h. 1 of 1 bottle of Fisher Chemical 500 ml 10 pH buffer Solution - Lot#233928. 2. The laboratory was unable to provide a procedure on establishing expirations dates for reagents and chemicals received without one stated. 3. Interview with TS#2 confirmed the findings on August 27, 2024 at 11:00 am.
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: Based on direct observation, and manufacturer's instructions, the laboratory failed to ensure 4 of 4 supplies were not expired and available for patient testing. Findings include: 1. In direct observation, on 8/27/2024 at 9:23am, the following were expired in the storage rooms and in the diagnostic immunology section: a. 1 box of 1,000 Biohit Optifit Tips, Lot PR144116, manufacturer expiration date 2023-04 b. 3 boxes of Qiagen QIAamp Viral RNA Mini Kit (250), Lot 56904383, manufacturer expiration date 2023-02-19
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must

	be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the laboratory's written quality assessment plan, manufacturer's instructions, and interview with technical supervisor #3 (TS #3), the laboratory failed to follow the laboratory's written protocol for ensuring the Diagnostic Immunology centrifuge was functioning properly for 17 of 17 months. Findings included: 1. On 08/28/2024 TS #3 confirmed the laboratory performed Syphilis testing using the Fujirebio Serodia TP-PA kit. 2. Review of manufacturer's instructions on 08/27/28 under section, "10. ABSORPTION PROCEDURE" stated, "3) Centrifuge for 5 minutes at 2000 rpm." 3. Review of the laboratory's written "Quality Assessment Plan" on 08/28/2024 under section, "4.7.4 CENTRIFUGES" stated, "Centrifuges are calibrated annually using a certified tachometer. Readings are recorded onto the log sheet accompanying the centrifuge." 4. Review of laboratory records on 08/28/2024 revealed no documentation of the annual centrifuge calibration from January 2023 through July 2024. 5. Interview on 08/29/2024 at 09:30 am confirmed the findings above.
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 microbiology laboratory quality control records and interview with the technical supervisor (TS) #2, the laboratory failed to evaluate the ongoing effectiveness for three of three Individualized Quality Control Plans (IQCP). Findings Included: 1. On the day of survey, August 28, 2024, review of the microbiology laboratory IQCPs revealed, the following IQCP were established and signed by the laboratory director on the below date: a. Biofire Respiratory Panel (RP) 2.1 - November 15, 2015. b. Biofire Gastrointestinal (GI) panel - November 15, 2015. c. Biomerieux ETEST Minimum Inhibitory Concentration (MIC) - March 16, 2024. 2. The laboratory could not provide ongoing monitoring of the effectiveness three of three IQCP after the above established dates. 3. Interview with TS#2 confirmed the above findings on August 28, 2024 at 10:10 am.
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: Based on review of the microbiology laboratory quality control records and interview with the technical supervisor (TS) #2, the laboratory failed to update and establish Individualized Quality Control Plans (IQCP) for two of two Biofire Torch panels in use from 2022 to 2024. Findings Included: 1. On the day of survey, August 28, 2024, review of the microbiology laboratory IQCPs revealed, two of two IQCP in use were for the below panels run on the Biofire Film Array system: a. Biofire Respiratory Panel (RP) 2.1 - Signed on November 15, 2015. b. Biofire Gastrointestinal (GI) panel - Signed on November 15, 2015. 2. The laboratory could not provide IQCPs established for the Biofire RP2.1 and GI Panels used on the Biofire Torch system. 3. From August 2022 to August 2024, the laboratory analyzed 688 RP2.1 panels and 75 GI panels. 4. Interview with TS#2 confirmed the above findings on August 28, 2024 at 10:10 am.
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: I. Based on review of the testing personnel's hire date, laboratory's competency records, and interview with TS-3, the technical supervisor failed to evaluate and document the semiannual competency of 1 of 1 newly hired testing personnel (TP). Findings Include: 1. A review of the laboratory's personnel records identified TP-7 was hired in November 2023. 2. A review of the laboratory's competency records on 8 /27/2024 identified no documentation of semiannual competency for TP-7, since TP-7's date of hire in November 2023. 3. In an interview on 8/27/2024 at 1:50pm, TS-3 explained she did an initial training checklist, but not a formal semiannual evaluation of new hires in the TP role. Additionally, she explained she did not have any raw data to substantiate semiannual competency for TP-7, corroborating the findings.