Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0461034	**(X3) Date Survey Completed** 05/09/2024
Name of Provider or Supplier Laboratory Corporation Of America	**Street Address, City, State** 217 La Rue France, Lafayette, LA	
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	A Validation survey was performed at Laboratory Corporation of America, CLIA ID 19D0461034, on May 6, 2024 through May 9, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the laboratory failed to ensure the competency assessments for the duties of the Technical Consultants, Technical Supervisors and General Supervisors matched the delegated responsibilities for five (5) of five (5) personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed four (4) Technical Consultants, four (4) Technical Supervisors, and three (3) General Supervisors. 2. Review of the laboratory's "Training and Competency Assessment Policy" revealed "Employees who fulfill the following roles as outlined by CLIA must have competency assessed upon their regulatory responsibilities, in addition to any testing responsibilities they may have such as: Clinical Consultant (CC), Technical Consultant (TC), Technical Supervisor (TS), General Supervisor (GS), and Testing personnel." 3. Review of personnel records, that included delegation documents and competency assessment worksheets, revealed the laboratory's "Supervisor Competency Assessment Worksheet" did not include, but not limited to, the delegated responsibility of performing testing personnel competency assessments. 4. In interview on May 7, 2024 at 8:50 am, Technical Supervisor 2 confirmed the laboratory's supervisor competency assessment forms did not include

	all duties delegated to each personnel serving as Technical Consultant, Technical Supervisor, and General Supervisor.
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: I. Based on review of the manufacturer's package inserts, the laboratory's online instructions for providers regarding specimen handling, policies, random selection of patient requisitions, and interview with personnel, the laboratory failed to reject samples for Cancer Antigen 125 (CA-125) and/or beta human chorionic gonadotropin (B-HCG) Chemistry testing that were not received per manufacturer's requirements for four (4) of six (6) patients reviewed. Findings: 1. Review of random selection of the manufacturer's package inserts and the laboratory's online instructions for providers revealed the specimen storage requirements differed for the following Chemistry analytes (not an inclusive list): a) CA-125: Manufacturer: "Stable for 5 days at 2-8 degrees C, 6 months at -20 degrees C" Laboratory's online instructions: "Storage instructions: Room temperature. Stability requirements: Room temperature: 14 days; Refrigerated: 14 days; Frozen: 14 days; Freeze/thaw cycles: Stable x 3" b) B-HCG: Manufacturer: "Stable for 3 days at 2-8 degrees C, 12 months at -20 degrees C (+/- 5 degrees C). Freeze once only." Laboratory's online instructions: "Storage instructions: Room temperature. Stability requirements: Room temperature: 14 days; Refrigerated: 14 days; Frozen: 14 days; Freeze/thaw cycles: Stable x 3" 2. Review of a random selection of patient requisitions revealed the following patient samples were not rejected: a) CA-125: Patient 12806871180: "transfer temperature: room temperature" Patient 12728406030: "2 RT (room temperature) SR (serum) Gel" b) B-HCG: Patient 12728406030: "2 RT (room temperature) SR (serum) Gel" Patient 12928402980: one (1) room temperature serum gel tube received via courier Patient 129928402200: one (1) room temperature serum gel tube received via courier 3. Review of the laboratory's "Specimen Rejection" policy revealed "follows manufacturer's recommendations regarding specimen acceptability and will not report results when the manufacturer's package insert prohibits the reporting of results because of type or condition of the specimen." 4. In interview on May 8, 2024 at 4:14 pm, Technical Consultant 4 confirmed B-HCG and CA-125 samples are received at room temperature. II. Based on observation by surveyors, review of policies, and interview with personnel, the laboratory failed to ensure specimen transport requirements were maintained. Findings: 1. Direct observation by surveyors on May 8, 2024 at 11:24 am revealed a courier delivered specimens in a large plastic cooler with a divider. The room temperature samples were on one side of the divider in biohazard bags inside of a larger bag and refrigerated samples on the other side of the divider in biohazard bags on top of ice packs. A small Styrofoam cooler with dry ice contained the frozen samples. The courier placed the bagged room temperature samples on a wire shelf in the laboratory, refrigerated samples in the laboratory's refrigerator, and frozen samples in a large cooler filled with dry ice. The courier scanned the bar code on each of the larger plastic bags to confirm delivery of picked

	up samples. The laboratory did not monitor the temperature of the transported samples. 2. Further observation by surveyors on May 8, 2024 at 11:24 am revealed the following random selection of patients were received via courier: Patient 12928400650: 2 room temperature serum gel tube, 1 room temperature lavender top (EDTA) Patient 12928402200: 1 room temperature serum gel tube Patient 12928402980: 1 room temperature serum gel tube Patient 12928401810: 1 room temperature serum gel tube Patient 12928403710: 1 frozen stool, 1 room temperature Para Pak, 1 frozen Para Pak Patient 12928401550: 2 refrigerated serum gel tube, 1 room temperature lavender top (EDTA) Patient 12928401900: 1 room temperature lavender top (EDTA) Patient 12928401150: 1 room temperature serum gel tube Patient 12906850030: 1 refrigerated urine bottle, 1 room temperature urinalysis transport (red/yellow) 3. Review of the laboratory's "Logistics/Distribution-Route Procedures" policy revealed "Maintaining specimens at a specified temperature- A service representative must maintain all specimens picked up at the temperature in which they are presented by the client, unless special instructions are provided by the client (for example, freeze specimen). The documentation must be noted on the appropriate tracking manifest (frozen or LabCorp specimen tracking manifest). 4. In interview on May 8, 2024 at 11:24 am, the Accessioning supervisor confirmed the laboratory does not track the temperature during transport to ensure specimens are maintained at their required temperatures.
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 online specimen handling instructions, manufacturer's sample stability requirements, and interview with personnel, the laboratory failed to ensure written instructions for clients regarding specimen storage and stability matched the manufacturer's requirements. Findings: 1. In interview on May 6, 2024 at 1:43 pm , the Regional Operations Manager stated the laboratory's written instructions for specimens were located online. 2. In interview on May 7, 2024 at 10:38 am, the Regional Operations Manager stated the laboratory follows the manufacturer's specimen storage and stability requirements. 3. Review of the manufacturer's package inserts and the online written instructions for the following random selection of Chemistry analytes (not an inclusive list of the laboratory's test menu) revealed the laboratory's online specimen stability requirements differed from the manufacturers' : a) Ammonia: Manufacturer: "Place immediately on ice and centrifuge, preferably at 4 degrees C. Perform analysis within 20-30 minutes of venipuncture or freeze separated plasma immediately. Stability in plasma: 3 weeks at -38 degrees C" Laboratory's online instructions: "Specimen must be placed on ice immediately. Separate plasma from cells within 15 minutes of collection. Transfer specimen to a plastic transport tuber before freezing. Storage instructions: Freeze. Ammonia is stable for several days at -20 degrees C. Stability requirements: Refrigerated: 2 hours (stability provided by manufacturer or literature reference). Frozen : 3 days (stability provided by manufacturer or literature reference)." b) Folate: Manufacturer: "Serum: Stable for 2 hours at 15-25 degrees C, 2 days at 2-8 degrees C, 4 weeks at -20 degrees C (+/- 5 degrees C). Freeze only once. Protect from light. Store the samples at 2-8 degrees C if they cannot be measured immediately." Laboratory's

	online instructions:" Storage instructions: Refrigerate. Stability requirements: Room temperature : 1 day; Refrigerated: 7 days; Frozen: 14 days; Freeze/thaw cycles: Stable x 3" c) Cancer Antigen 125 (CA-125): Manufacturer: "Stable for 5 days at 2-8 degrees C, 6 months at -20 degrees C" Laboratory's online instructions: "Storage instructions: Room temperature. Stability requirements: Room temperature: 14 days; Refrigerated: 14 days; Frozen: 14 days; Freeze/thaw cycles: Stable x 3" d) Vitamin B12: Manufacturer: "Stable for 2 hours at 20-25 degrees C, 48 hours at 2-8 degrees C, 8 weeks at -20 degrees C (+/- 5 degrees C). Freeze once only." Laboratory's online instructions: "Storage instructions: Room temperature. Stability requirements: Room temperature: 7 days; Refrigerated: 7 days; Frozen: 14 days; Freeze/that cycles: Stable x 3" e) Beta human chorionic gonadotropin (B-HCG): Manufacturer: "Stable for 3 days at 2-8 degrees C, 12 months at -20 degrees C (+/- 5 degrees C). Freeze once only." Laboratory's online instructions: "Storage instructions: Room temperature. Stability requirements: Room temperature: 14 days; Refrigerated: 14 days; Frozen: 14 days; Freeze/thaw cycles: Stable x 3" 3. In further interview on May 7, 2024 at 10:38 am, the Regional Operations Manager confirmed the specimen stability requirements listed online did not match the manufacturer's requirements.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on observation, review of laboratory policies, lot rollover studies, and interview with personnel, the laboratory failed to follow their policy for verification of new prothrombin time (PT) reagent lots for one (one) of two (2) lot verifications reviewed. Findings: 1. Observation by surveyors during the laboratory tour on May 6, 2024 at 1:46 p.m. revealed the laboratory utilized a Sysmex CA-620 analyzer for prothrombin time testing. 2. Review of the laboratory's policy "Prothrombin Time /INR New Reagent Lot Verification & Installation Procedure" section "Specific Requirements" revealed the following requirements: - Verification of PT Reference Interval - Calculation of and Verification of New MNPT (Mean Normal Prothrombin Time) 3. Further review of the laboratory's policy revealed the new PT lot verification is accomplished utilizing twenty normal samples "...obtained locally from appropriately qualified normal volunteers." The policy further stated that volunteers "complete the Reference Individual Questionnaire...Only samples from individuals that meet the inclusion requirements can be included in the Normal Plasma set." 4. In interview on May 7, 2024 at 10:32 a.m., Technical Supervisor 1 stated she used both local donor samples and PrecisionBioLogic Cryocheck Normal Donor Set samples. 5. Review of the laboratory's PT new lot verification studies revealed the laboratory utilized five (5) local donor samples and fifteen (15) samples from the Cryocheck Normal Donor Set to verify the normal reference range and calculate the mean normal prothrombin time. 6. Further review of the laboratory's PT new lot verification studies revealed six (6) donor questionnaires, but the questionnaire for Donor Identification Number three (3) was incomplete. 7. In interview on May 7, 2024 at 10:32 a.m., Technical Supervisor 1 confirmed the questionnaire for Donor Three (3) was incomplete, and she was responsible for reviewing the questionnaires for acceptability. She confirmed the results for Donor Three (3) were utilized for the PT

	reference range verification and the calculation of the MNPT. II. Based on review of the laboratory's policies and patient test records as well as interview with personnel, the laboratory failed to follow their policy for Prothrombin Time testing for four (4) of five hundred forty-seven (547) samples reviewed. Findings: 1. Review of the laboratory's "Prothrombin Time and Activated Partial Thromboplastin Time" policy revealed "Prothrombin times and Activated Partial Thromboplastin times in unopened (whole blood) tubes are stable for at least 24 hours at room temperature 15 - 25 degrees Celsius." It further stated if testing is to be delayed, to centrifuge the tube, remove the plasma, and freeze. 2. Review of patient test records from July 2023 revealed the following whole blood samples were received at room temperature and tested for Prothrombin Time after twenty-four hours: - Specimen ID 194-068-7375-0: Collected 7/12/2023 at 1:42 p.m. and tested 7/13/2023 at 9:45 p.m. (Exceeded 24 hours by eight (8) hours and three (3) minutes) - Specimen ID 194-068-7374-0: Collected 7/12/2023 at 1:56 p.m. and tested 7/13/2023 at 6:38 p.m. (Exceeded 24 hours by four (4) hours and forty-two (42) minutes) - Specimen ID 195-068-7196-0: Collected 7/13/2023 at 1:29 p.m. and tested 7/14/2023 at 6:20 p.m. (Exceeded 24 hours by four (4) hours and fifty-one (51) minutes) - Specimen ID 195-068-7197-0: Collected 7/13/2023 at 2:40 p.m. and tested 7/14/2023 at 6:16 p.m. (Exceeded 24 hours by three (3) hours and thirty-six (36) minutes) 3. In interview on May 8, 2024 at 4:09 p.m., Technical Supervisor 2 confirmed the samples identified above were received as whole blood at room temperature and exceeded the twenty-four (24) hour sample stability when tested. In addition, both the Regional Operations Manager and Technical Supervisor 2 stated the testing personnel would be responsible for rejection of samples that exceeded stability requirements. III. Based on review of the laboratory's policies and patient test records as well as interview with personnel, the laboratory failed to complete testing for Fibrinogen within 24 hours for one (1) of thirty-four (34) samples reviewed. Findings: 1. Review of the laboratory's client services manual revealed fibrinogen samples "are stable at room temperature for 24 hours." It further stated if testing cannot be completed within 24 hours to centrifuge the tube and freeze the plasma. 2. Review of patient test records from July 2023 revealed the following sample was received for fibrinogen testing as whole blood at room temperature and tested after twenty-four hours: - Specimen ID 205-284-0351-0: Collected 7/24/2023 at 11:05 a.m. and analyzed 7/25/2023 at 6:06 p.m. (Exceeded 24 hours by seven (7) hours and one (1) minute) 3. In interview on May 8, 2024 at 4:09 p.m., Technical Supervisor 2 confirmed the sample identified above was received as whole blood at room temperature and exceeded the twenty-four (24) hour sample stability when tested. In addition, both the Regional Operations Manager and Technical Supervisor 2 stated the testing personnel would be responsible for rejection of samples that exceeded stability requirements.
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 observation, review of the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for one (1) of three (3) storage areas in the laboratory. Findings: 1. Observation by surveyors during the laboratory tour on May 6, 2024 at 1:46 p.m. revealed the laboratory stored the following supplies in the "Storage Supplies 2" room: a) BD Vacutainer C&S Preservative Urine Tube - storage requirements 4 - 25 degrees Celsius b) BD Vacutainer K2 EDTA Blood Collection Tubes - storage requirements 4 - 25 degrees Celsius c) BD Vacutainer SST Blood Collection Tubes - storage requirements 4 - 25 degrees Celsius 2. Review of the laboratory's 2024 temperature and humidity log for the room identified above revealed the laboratory defined the acceptable room temperature limits as 15 - 30 degrees Celsius. 3. In interview on May 6, 2024 at 3:17 p.m., the Regional Operations Manager stated he was unaware the laboratory was storing the supplies identified above in the room. He confirmed the laboratory's acceptable room temperature limits exceeded the manufacturer's acceptable room temperature limits for supplies stored there. 36645 II. Based on observation by surveyors during the laboratory tour, manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the accessioning room and three (3) draw station rooms where specimen collection devices were stored. Findings: 1. Observation by surveyors during the tour of the entire laboratory at 2:12 pm revealed the draw station 1, 2, and 3 and the accessioning rooms had the following specimen collection devices stored without monitoring of the room temperature: a) Draw Station 3 room: BD Vacutainer K2EDTA blood collection tubes BD Vacutainer SST 8.5 ml blood collection tubes BD Vacutainer PPT Plasma collection tubes BD Vacutainer Trace Element K2EDTA blood collection tubes BD Vacutainer SST 3.5 mL blood collection tubes BD Vacutainer Buffered Na Citrate blood collection tubes BD Vacutainer Sodium Fluoride blood collection tubes b) Accessioning room: BD Vacutainer Urine C and S collection tubes Aptima Urine Specimen Collection kit BD Vacutainer UA Preservative collection tubes c) Draw Station 1 room: BD Vacutainer ACD-A blood collection tubes BD Vacutainer K2EDTA blood collection tubes BD Vacutainer SST 8.5 ml blood collection tubes BD Vacutainer SST 3.5 mL blood collection tubes BD Vacutainer Buffered Na Citrate blood collection tubes d) Draw Station 2 room: BD Vacutainer ACD-A blood collection tubes BD Vacutainer K2EDTA blood collection tubes BD Vacutainer SST 8.5 ml blood collection tubes BD Vacutainer SST 3.5 mL blood collection tubes BD Vacutainer Buffered Na Citrate blood collection tubes 2. Review of the manufacturers' storage requirements revealed the following: BD Vacutainer collection tubes storage temperature: 4-25 degrees Celsius Aptima Urine Collection kits storage temperature: 15-30 degrees Celsius 3. In interview on May 6, 2024 at 2:38 pm, the Regional Operations Manager confirmed the temperature was not monitored in the accessioning and draw station 3 room. 4. In further interview on May 6, 2024 at 3:30 pm, the Regional Operations Manager confirmed the room temperature was not monitored in the draw station rooms 1 and 2.
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 observation by surveyors, review of manufacturer's package insert, and interview with laboratory personnel, the laboratory failed to label the Gram Iodine reagent currently in use for patient testing with the open expiration date after reconstitution. Findings: 1. Observation by surveyors during the laboratory tour on May 6, 2024 at 1:46 p.m. revealed the following bottle of Gram stain reagent in use for patient testing: - Remel Iodine: Lot 134156, manufacturer's expiration date 3/26 /2025, open date 4/29/2024 2. Further observation revealed the bottle identified above did not have an open expiration date documented. 3. Review of the manufacturer's package insert for Remel Iodine revealed "Use Gram Iodine within 3 months after reconstitution." 4. In interview on May 7, 2024 at 10:11 a.m., Technical Supervisor 2 stated she was unaware the Remel Iodine had a new expiration date once reconstituted.
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 observation by surveyors during the laboratory tour and interview with personnel, the laboratory failed to ensure specimen collection tubes did not exceed their expiration dates at one (1) of three (3) draw stations and one (1) of six (6) accessioning stations. Findings: 1. Observation by surveyor during the tour of the entire laboratory on May 5, 2024 at 2:12 pm revealed the following expired items: a) Draw Station 3 room: BD Vacutainer ACD-B collection tube, lot 3016607, expiration date: 2024-03-31, quantity: one (1) tube b) Accessioning area one (1) station: BD Vacutainer Urine C and S collection tubes: lot 2096378, expiration date: 2023-10-31, quantity: two (2) tubes BD Vacutainer Urine C and S collection tubes: lot 253779, expiration date: 2022-03-31, quantity: four (4) tubes 2. In interview on May 6, 2024 at 2:36 pm, the Regional Operations Manager confirmed the identified items were expired.
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 observation by surveyors, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Findings: 1. Observation by surveyors during the

	laboratory tour on May 6, 2024 at 1:46 p.m. revealed the laboratory utilized a BacT /Alert 3D analyzer for microbial detection in blood cultures. 2. Review of the BacT /Alert 3D November 2023 validation records revealed the laboratory did not include precision studies. 3. In interview on May 7, 2024 at 8:45 a.m., Technical Supervisor 2 confirmed the laboratory did not perform precision studies when validating the BacT /Alert 3D analyzer.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, quality control (QC) records, manufacturer's instructions, random selection of patient final reports, and interview with personnel, the laboratory failed to establish complete quality control procedures that included monitoring the accuracy and precision of reporting titers for Rapid Plasma Reagin (RPR) testing. Findings: 1. Observation by surveyors during the laboratory tour on May 6, 2024 revealed the laboratory utilized the AIX 1000 instrument for RPR testing. 2. Review of the manufacturer's instructions for use revealed the following: a) "9.1 Assay Controls: Quality control requirement must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and each laboratory's Quality Control Procedure. At a minimum. the controls provided with the assay should be included in each day of testing." b) "9.2 Results Interpretation: Titer (e.g. 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256) 3. Review of the laboratory's "Rapid Plasma Reagin (RPR), GSD AIX1000" policy under the "Quality Control" section revealed "The Reactive and Nonreactive controls provided with the assays are to be tested at least once for each shift that the assay is performed to confirm reactivity of the antigen. Additionally, the positive control must be run using the low titer action once for each shift titers are performed." 4. Review of the laboratory's "Quality Control Program" policy revealed "For syphilis serology, a negative control and positive controls of known titers or graded reactions must be run concurrently with patient samples." 5. Review of the laboratory's July 2023 and March 2024 RPR QC logs revealed the laboratory performed nonreactive, reactive, and reactive low titer (1:2, 1:4, or 1:8) controls each day of patient testing. 6. Review of a random selection of patient test reports from July 2023 and March 2024 revealed the following patients had high titer results reported: July 7, 2023: Patient 187068724409 Reactive 1:128 March 19, 2024: Patient 078068722609 Reactive 1:32 7. In interview on May 8, 2024 at 4:14 pm, Technical Consultant 4 stated the laboratory performs a low titer control, which is +/- 1 of the expected titer of the reactive control. Technical Consultant 4 stated the laboratory follows their procedures and does not perform high titer controls.

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 laboratory policies and interview with personnel, the laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Findings: 1. Review of the laboratory's policy "Individual Quality Control Plan IQCP" section "Monitor the QCP for effectiveness" revealed "Reapproval of the quality control plan by the laboratory director or designee at least annually." 2. Review of the following IQCPs revealed the plans were not reapproved annually: a) Staphaurex - Reapproved in June 2022 and May 2024 (missing 2023) b) Microbiology media - Reapproved in January 2023 (missing 2024) c) Rapid Ana II - Reapproved in June 2022 and May 2024 (missing 2023) d) Rotavirus - Reapproved in June 2022 and May 2024 (missing 2023) 3. In interview on May 7, 2024 at 10:32 a.m., Technical Supervisor 2 stated the laboratory changed their reapproval requirement to every two (2) years but did not change the policy.
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 laboratory's test menu, manufacturer's package insert, quality control (QC) records, and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for manual cerebrospinal fluid (CSF) cell counts per manufacturer's requirements. Findings: 1. Review of the laboratory's test menu revealed the Quantimetrix Spinalscopics Spinal Fluid Cell Count Controls are utilized for manual CSF cell counts. 2. Review of the Quantimetrix Spinalscopics's package insert under "Expected Ranges" section revealed for each laboratory to "establish its own precision parameters." 3. Review of

	the laboratory's QC records revealed the laboratory did not establish their own means and ranges for the current lot number (level 1: lot 200031, level 2: lot 200032) of Spinalscopics control. 4. In interview on May 8, 2024 at 2:00 pm, Technical Supervisor 1 confirmed the Spinalscopics manufacturer's QC means and ranges are verified, not established. 5. Review of the laboratory's test menu revealed the laboratory performs three (3) manual body fluid cell counts annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based review of laboratory temperature logs and policies as well as interview with personnel, the laboratory failed to take corrective actions when the room temperature in microbiology was not maintained between 20 to 25 degrees Celsius as required by the laboratory for thirteen (13) of three hundred sixty-five (365) days reviewed. Findings: 1. Review of the laboratory's 2023 temperature logs revealed two rooms in microbiology with acceptable room temperature limits defined as 20 to 25 degrees Celsius. 2. Further review of the temperature logs revealed the laboratory failed to maintain the room temperature between 20 to 25 degrees Celsius per the laboratory's requirements for the following rooms and dates: a) Micro 1 - December 7, 2023: 19 degrees Celsius - December 11, 2023: 19 degrees Celsius - December 12, 2023: 19 degrees Celsius - December 13, 2023: 19 degrees Celsius - December 19, 2023: 19 degrees Celsius - December 21, 2023: 19 degrees Celsius - December 24, 2023: 19 degrees Celsius - December 27, 2023: 19 degrees Celsius - December 28, 2023: 19 degrees Celsius - December 29, 2023: 19 degrees Celsius - December 30, 2023: 19 degrees Celsius - December 31, 2023: 19 degrees Celsius b) Micro 2 - December 29, 2023: 19 degrees Celsius 3. Review of the laboratory's "Temperature Monitoring" policy revealed "Inform the appropriate supervisor or designee of the malfunction and document the action taken in the 'Comments' section on the temperature log," but no corrective actions were documented for the dates and temperatures identified above. 4. In interview on May 7, 2024 at 4:30 p.m., Technical Supervisor 2 confirmed the laboratory did not document corrective actions for the dates and temperatures identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

	laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's test menu, policies, random selection of quality control records, manufacturer's instrument manual, and interview with personnel, the laboratory failed to perform corrective actions for calibration failures for one (1) of thirty six (36) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on May 6, 2024 at 2:12 pm and review of the laboratory's test menu revealed the laboratory utilized the Roche C6000 instrument for direct and total bilirubin testing. 2. Review of the bilirubin quality control records for March 25, 2024 through May 4, 2024 revealed a calibration flag on the following date without documentation of corrective actions: April 22, 2024: Level 1 and Level 2: Direct Bilirubin Alarm: "Cal. E" 3. Review of the manufacturer's instrument manual revealed the following: "Cal. E (Sample flag): Alarm: Calibration result abnormal (Sample flag). Description: No calibration data or previous calibration data used. Cal. E appears on each QC and patient sample for the affected test until the problem is resolved. Cause: No valid calibration stored in the system of the last calibration has failed. Remedy: 1. Correct the condition causing the alarm that occurred during the last calibration attempt. 2. Recalibrate." 4. In interview on May 8, 2024 at 10:26 am, Testing Personnel 1 stated the calibration failed on April 22, 2024 and should have repeated. Testing Personnel 1 further stated the calibration failure was not caught and thirty six (36) patients were tested on April 22, 2024. Testing Personnel 1 confirmed the laboratory did not have documentation of correction actions.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to follow their policy for verification of new prothrombin time (PT) reagent lots for one (one) of two (2) reagent lots reviewed. Refer to D5401 I. 2. The laboratory failed to follow their policy for Prothrombin Time testing for four (4) of five hundred forty-seven (547) samples reviewed. Refer to D5401 II. 3. The laboratory failed to follow their policy for Fibrinogen testing for one (1) of thirty-four (34) samples reviewed. Refer to D5401 III. 4. The laboratory failed to label the Gram Iodine reagent currently in use for patient testing with the open expiration date after reconstitution. Refer to D5415. 5. The laboratory failed to ensure specimen collection tubes did not exceed their expiration dates at one (1) of three (3) draw stations and one (1) of six (6) accessioning stations. Refer to D5417. 6. The laboratory failed to have complete performance verification studies for the BacT/Alert 3D analyzer. Refer to D5421. 7. The laboratory failed to establish complete quality control procedures that included

	monitoring the accuracy and precision of reporting titers for Rapid Plasma Reagin (RPR) testing. Refer to D5441. 8. The laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Refer to D5445. 9. The laboratory failed to establish their own means and ranges for QC material utilized for manual cerebrospinal fluid (CSF) cell counts per manufacturer's requirements. Refer to D5469. 10. The laboratory failed to take corrective actions when the room temperature in microbiology was not maintained between 20 to 25 degrees Celsius as required by the laboratory for thirteen (13) of three hundred sixty-five (365) days reviewed. Refer to D5781. 11. The laboratory failed to perform corrective actions for calibration failures for one (1) of thirty six (36) days reviewed. Refer to D5783.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to reject samples for Cancer Antigen 125 (CA-125) and/or beta human chorionic gonadotropin (B-HCG) Chemistry testing that were not received per manufacturer's requirements for four (4) of six (6) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure specimen transport requirements were maintained. Refer to D5311 II. 3. The laboratory failed to ensure written instructions for clients regarding specimen storage and stability matched the manufacturer's requirements. Refer to D5317. 4. The laboratory failed to follow their policy for verification of new prothrombin time (PT) reagent lots for one (one) of two (2) lot verifications reviewed. Refer to D5401 I. 5. The laboratory failed to follow their policy for Prothrombin Time testing for four (4)

	of five hundred forty-seven (547) samples reviewed. Refer to D5401 II. 6. The laboratory failed to follow their policy for Fibrinogen testing for one (1) of thirty-four (34) samples reviewed. Refer to D5401 III. 7. The laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for one (1) of three (3) storage areas in the laboratory. Refer to D5413 I. 8. The laboratory failed to monitor the room temperature of the accessioning and draw station rooms where specimen collection devices were stored. Refer to D5413 II. 9. The laboratory failed to ensure specimen collection tubes did not exceed their expiration dates at one (1) of three (3) draw stations and one (1) of six (6) accessioning stations. Refer to D5417.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish complete quality control procedures that included monitoring the accuracy and precision of reporting titers for Rapid Plasma Reagin (RPR) testing. Refer to D5441. 2. The laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Refer to D5445.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5783.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to reject samples for Cancer Antigen 125 (CA-125) and/or beta human chorionic gonadotropin (B-HCG) Chemistry testing that were not received per manufacturer's requirements for four (4) of six (6) patients reviewed. Refer to D5311 I. 2. The laboratory failed to ensure specimen transport requirements were maintained. Refer to D5311 II. 3. The laboratory failed to ensure written instructions for clients regarding specimen storage and stability matched the manufacturer's requirements. Refer to D5317. 4. The laboratory failed to follow their policy for verification of new prothrombin time (PT) reagent lots for one (one) of two (2) lot verifications reviewed. Refer to D5401 I. 5. The laboratory failed to follow their policy for Prothrombin Time testing for four (4) of five hundred forty-seven (547) samples reviewed. Refer to D5401 II. 6. The laboratory failed to follow their policy for Fibrinogen testing for one (1) of thirty-four (34) samples reviewed. Refer to D5401 III. 7. The laboratory failed to define acceptable room temperature limits within the manufacturer's required ranges for one (1) of three (3) storage areas in the laboratory. Refer to D5413 I. 8. The laboratory failed to monitor the room temperature of the accessioning and draw station rooms where specimen collection devices were stored. Refer to D5413 II. 9. The laboratory failed to ensure specimen collection tubes did not exceed their expiration dates at one (1) of three (3) draw stations and one (1) of six (6) accessioning stations. Refer to D5417.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to ensure that a quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to establish complete quality control procedures that included monitoring the accuracy and precision of reporting titers for Rapid Plasma Reagin (RPR) testing. Refer to D5441. 2. The laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Refer to D5445.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure specimen transport requirements were maintained. Refer to D5311 II. 2. The laboratory failed to label the Gram Iodine reagent currently in use for patient testing with the open expiration date after reconstitution. Refer to D5415.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Refer to D5445. 2. The laboratory failed to establish their own means and ranges for QC material utilized for manual cerebrospinal fluid (CSF) cell counts per manufacturer's requirements. Refer to D5469.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5793.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure the competency assessments for the duties of the Technical Consultants, Technical Supervisors and General Supervisors matched the delegated responsibilities for five (5) of five (5) personnel reviewed. Refer to D5209. 2. The Technical Supervisors failed to ensure annual competency assessments for three (3) of four (4) microbiology testing personnel included review of quality control records in 2023. Refer to D6123.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure specimen transport requirements were maintained. Refer to D5311 II. 2. The laboratory failed to label the Gram Iodine reagent currently in use for patient testing with the open expiration date after reconstitution. Refer to D5415.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure that a quality control program was established and maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to follow their Individual Quality Control Plan (IQCP) for annual reapproval for four (4) of four (4) IQCPs reviewed. Refer to D5445. 2. The laboratory failed to establish their own means and ranges for QC material utilized for manual cerebrospinal fluid (CSF) cell counts per manufacturer's requirements. Refer D5469.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the Technical Supervisors failed to ensure annual competency assessments for three (3) of four (4) microbiology testing personnel included review of quality control records in 2023. Findings: 1. Review of personnel records for the following personnel revealed the laboratory did not include data to support documentation of review of quality control records: a) Testing Personnel 2 - Microscan - Vitek - Rapid NH/Rapid ANA - Gram stain - Trichrome stain - Pathodx - Staphaurex b) Testing Personnel 3 - Microscan - Vitek - Rapid NH/Rapid ANA - Gram stain - Trichrome stain - Pathodx - Staphaurex c) Testing Personnel 10 - Microscan - Rapid NH/Rapid ANA - Gram stain - Trichrome stain - Pathodx - Staphaurex 2. In interview on May 7, 2023 at 10:15 a. m., Technical Consultant 2 confirmed the laboratory did not have documentation as identified above.