Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	37D0475409	06/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pushmataha Hospital	510 E Main St, Antlers, OK	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 06/08,09,10,11/2021. The laboratory was found out of compliance with the following CLIA regulations: 493.801; D2000: Enrollment and Testing of Samples 493.1201; D5002: Bacteriology 493.1208; D5014: General Immunology 493.1405; D6000: Laboratory Director, Moderate Complexity Testing 493.1409; D6033: Technical Consultant 493.1441; D6076: Laboratory Director, High Complexity Testing The findings were reviewed with the hospital administrator, microbiology supervisor/testing person #1, and testing person #2 during an exit conference performed at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #2 and testing person #1, the laboratory failed to enroll in a proficiency testing program for quantitative serum pregnancy testing for seven of seven proficiency testing events. Findings include: (1) On 06/08/2021 at 10:00 am, testing person #2 stated to surveyor #2 the laboratory performed quantitative serum pregnancy testing using the Dimension EXL 200 analyzer; (2) Surveyor #2 reviewed proficiency testing records for 2019 (1st, 2nd, 3rd Chemistry events), 2020 (1st, 2nd, 3rd Chemistry events), and 2021(1st Chemistry events). There was no evidence the laboratory was enrolled in proficiency testing for

	quantitative serum pregnancy testing during the review period; (2) Surveyor #2 reviewed the records with testing person #1. Testing person #1 stated on 06/08/2021 at 03:40 pm the laboratory was not enrolled in proficiency testing for serum quantitative pregnancy.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for two of 33 events. Findings include: (1) On 06/08/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records, with the following identified: (a) Second 2019 Chemistry Core Event - The attestation statement had not been signed by the laboratory director or designee; (b) 2020 Hematology/Coagulation Event - The attestation statement had not been signed by the laboratory director or designee. (2) Surveyor #2 reviewed the records with testing person #2. Testing person #2 stated on 06/08/2021 at 04:00 pm the attestation statements had not been signed by the laboratory director as indicated above.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the microbiology supervisor, the laboratory failed to ensure the requirements were met for the subspecialty of Bacteriology. Findings include: (1) The laboratory failed to have written procedures that explained the current practices and procedures being performed in the microbiology department. Refer to D5401; (2) The laboratory failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (3) The laboratory failed to monitor the room temperature of the microbiology department for 18 of 18 months. Refer to D5413; (4) The laboratory failed to use materials that had not expired, had deteriorated, or were of substandard quality. Refer to D5417; (5) The laboratory failed to ensure the laboratory performed complete validations for 2 of 3 new microbiology culture test systems; and failed to ensure the

	validations for 2 of 3 microbiology culture test systems had been reviewed and evaluated by the laboratory. Refer to D5421; (6) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to ensure the requirements were met for the subspecialty of General Immunology. Findings include: (1) The laboratory failed to demonstrate the performance specifications for SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer. Refer to D5421.
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 a review of records, written policy, and interview with testing person #1, the laboratory failed to have a written technical consultant competency policy and general supervisor competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultant and one of one general supervisor. Findings include: (1) On 06/08/2021, surveyor #2 reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant and general supervisor; (2) Surveyor #2 reviewed personnel records for competency assessments performed during 2019, 2020, and 2021. There was no evidence of competencies performed for the technical consultant and general supervisor based on their job responsibilities; (3) Surveyor #2 asked testing person #1 if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. Testing person #1 stated on 06/08/2021 at 04:23 pm a policy had not been written and the above competencies had not been performed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1 and testing person #2, the laboratory failed to review and evaluate proficiency testing results for three of

	33 events. Findings include: FAILURES (1) On 06/08/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records and identified the following failures: (a) First 2020 Chemistry Core Event (i) Direct Bilirubin - The laboratory failed the results for 1 of 5 samples (CH-03); (2) Surveyor #2 could not locate evidence in the records proving the failure had been addressed; (3) Surveyor #2 reviewed the records with testing person #1, and asked if corrective action had been taken and documented for the failure. Testing person #1 stated on 06/08/2021 at 04:07 pm corrective action had not been taken. BIASES (1) On 06/08/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2019 Chemistry Core Event (i) Phenytoin - 4 of 5 results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.6 (bb) Sample CH-08 - SDI of 2.7 (cc) Sample CH-09 - SDI of 2.3 (dd) Sample CH-10 - SDI of 2.5 (ii) Cholesterol HDL (High-Density Lipoprotein) - 3 of 5 results exhibited a negative bias (aa) Sample CH-07 - SDI of -2.1 (bb) Sample CH-08 - SDI of -2.5 (cc) Sample CH-10 - SDI of -2.2 (iii) CO2 - 4 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -2.7 (bb) Sample CH-07 - SDI of -3.3 (cc) Sample CH-09 - SDI of -3.4 (dd) Sample CH-10 - SDI of -3.3 (iv) Total Protein - 4 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -2.3 (bb) Sample CH-07 - SDI of -3.3 (cc) Sample CH-08 - SDI of -2.5 (dd) Sample CH-09 - SDI of -2.8 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with testing person #2. Testing person #2 stated on 06 /08/2021 at 03:53 pm the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of 33 events reviewed. Findings include: (1) On 06 /08/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records. The following was identified for one of 33 events: (a) First 2019 Hematology Event for Blood Cell Identification - One of five results had not been graded by the proficiency testing program: (i) For one of five results (ECI-15), the following was identified: (aa) ECI-15 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) Surveyor #2 reviewed the records with testing person #1 who stated on 06/08/2021 at 03:56 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program and corrective action had not been taken as indicated.
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 a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for test timing for Clostridium difficile testing for six of six test reports. Findings include: (1) On 06/09/2021 at 01:00 pm, testing person #2 stated to surveyor #2: (a) The laboratory performed C. Diff (Clostridium difficile) testing using the C. Diff Quik Chek Compete test kit. (2) On 06/09/2021, surveyor #2 reviewed the manufacturer's instructions: (a) Under the section titled, "TEST PROCEDURE" the following was identified: (i) "6. Add 2 drops of Substrate (white-capped bottle) to the Reaction Window. Read and record results visually after 10 minutes.". (b) Under the section titled, "INTERPRETATION OF RESULTS" the following was identified: (i) "1. Interpretation of the test is most reliable when the device is read immediately at the end of the 10 minute reaction period.". (3) Surveyor #2 then reviewed patient testing records on 06/15/2019, 07/20/2019, 02/28/2019, 08/08/2019, 01/09/2020 and 04/21 /2021 and identified the following for six of six patient test reports: (a) Patient #10045798 - The received date and time was on 02/28/2019 at 05:21 pm and the result date and time was on 02/28/2019 at 05:22 pm (1 minutes later); (b) Patient #10047248 - The received date and time was on 05/15/2019 at 05:27 pm and the result date and time was on 06/15/2010 at 07:05 pm (39 minutes later); (c) Patient #10047740 - The received date and time was on 07/20/2019 at 07:43 am and the result date and time was on 07/20/2019 at 08:23 am (40 minutes later); (d) Patient #10048077 - The received date and time was on 08/08/2019 at 10:58 pm and the result date and time was on 08/08/2019 at 10:58 pm. Since the received date and time and the result date and time was the same, the surveyor could not determine the sample was read visually after 10 minutes; (e) Patient #10050169 - The received date and time was on 01/09/2020 at 05:06 pm and the result date and time was on 01/09 /2020 at 06:44 pm (one hour 38 minutes later); (f) Patient #10056788 - The received date and time was on 04/21/2021 at 12:52 am and the result date and time was on 04 /21/2021 at 01:31 pm (39 minutes later). (4) The surveyor reviewed the findings with testing person #2. Testing person #2 stated on 06/09/2021 at 01:45 pm, the laboratory could not prove the specimen was collected, tested, and resulted as required by the manufacturer.
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 a review of written policies and procedures and interview with the microbiology supervisor, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the microbiology

department. Findings include: (1) On 06/09/2021 at 02:30 pm, the microbiology supervisor stated to surveyor #1 the laboratory began performing the following testing in the microbiology department on approximately 10/13/2019 (the exact start dates for each of the types of cultures could not be determined): (a) Throat Cultures for Group A Streptococcus using Hardy Diagnostics Group A Beta Strep Agar plates; (b) Urine Cultures including Identification and Susceptibility testing for isolates; (c) Blood Cultures (perform gram stain on positive cultures); (d) Gram Stain testing. (2) Surveyor #1 reviewed the microbiology procedure manuals titled, "Procedure Manual I Microbiology" and "Microbiology Procedure Manual II" and identified the manuals contained procedures that were not being performed in the laboratory as follows: (a) Procedure Manual I Microbiology (i) A procedure for CAMP test (ii) A procedure for 6.5% NaCl BHI Broth (iii) A procedure for Bile Solubility test (iv) A procedure using Bile Esculin Slant for Streptococcus Identification (v) A procedure for using the Remel Quality Control Slide for Gram Stain quality control (vi) A procedure for using the P Disc (vii) A procedure for Bacitracin Susceptibility testing (viii) A procedure for Remel Bactistaph kit (ix) A procedure for using the API Staph Trac Kit (x) A procedure for PYR test (xi) A procedure for Coagulase Plasma (xii) A procedure for Catarrhalis Test Disk (xiii) A procedure for BBL Dryslide Nitrocefin (b) Microbiology Procedure Manual II (i) A procedure for Modified Hodge test for the detection of Carbapenemase production (ii) A procedure for performing Sputum Cultures (iii) A procedure for the Two Disk Method for Screening for Pneumococci (iv) A procedure for performing Stool Cultures (v) A procedure for performing Spinal Fluid Cultures (vi) A procedure for Haemophilus Test Medium (3) Surveyor #1 reviewed the procedure manuals and the findings with the microbiology supervisor who stated on 06/09/2021 at 02:50 pm the above procedures were not performed in the laboratory and should not be included in the procedure manuals. 39088 Based on a review of the policy and procedure manual and interview with testing person #1 and testing person #2, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory for two of two procedures; failed to follow written procedures for one of two platelet poor plasma checks; failed to follow written procedures for 21 of 21 hematology quality control lot numbers; and failed to have a written procedure for manual differential testing. Findings include: BECKMAN ICON 25 hCG KIT (1) On 06/08/2021 at 04:00 pm, testing person #2 stated to the surveyor qualitative pregnancy testing using urine specimens was performed in the laboratory using the Beckman Icon 25 hCG test kit; (2) Surveyor #2 reviewed written policies and procedures manual titled, "Policy and Procedures". The procedure described the use of the "Beckman Icon 25 hCG Kit" which included both serum and urine patient samples; (3) Surveyor #2 reviewed the findings with testing person #1 who stated on 06/08/2021 at 04:39 pm, the laboratory did not use serum samples and the procedure in the manual did not reflect the laboratory's current method of performing qualitative pregnancy testing. TRANSFUSION SERVICES (1) On 06/08/2021 at 04:30 pm, testing person #1 stated to surveyor #2, the laboratory maintained O positive and O negative PRBC (Packed Red Blood Cells) for emergency release; (2) Surveyor #2, reviewed the written policies and procedures manual titled, "Policy and Procedures". The procedure titled, "General Laboratory" under the section, "BLOOD BANKING SERVICES" stated: (a) "19. In the case of an unexpected delivery the laboratory performs ABO and Rh (D) typing on the mother and informs the Physician of Rh (D) negative mothers. The laboratory does not stock Rhogham." (3) Surveyor #2 asked testing person #1 if the policy reflected the laboratory's current practice. On 06/08/2021 at 04:45 pm, testing person #1 stated the above policy did not reflect the laboratory's current practice. PLATELET POOR PLASMA CHECKS (1) On 06/08/2021, surveyor #2 reviewed the written policies and procedures manual titled, "Policy and Procedures". The

	procedure titled, "General Laboratory" under the section, "Semi-annual validation of platelet poor plasma" which stated, "Twice annually the lab will validate the platelet poor plasma is be being achieved."; (2) Surveyor #2 reviewed 2019 and 2020 Semi-annual validation of platelet poor plasma check log and identified the following: (a) The laboratory had performed the platelet poor plasma check once in 2019 (06/05/2019). (3) Surveyor #2 asked testing person #2 if the laboratory had performed the platelet poor plasma check twice in 2019. Testing person #2 stated on 06/08/2021 at 10:30 am, the laboratory had did not perform the platelet poor plasma checks twice in 2019 as indicated above. SYSMEX XP-300 (1) On 06/09/2021, surveyor #2 reviewed the written policies and procedures manual titled, "Policy and Procedures". The procedure titled, "Sysmex XP-300 Automated Hematology Instrument" under the section, "Starting a New Lot of Controls" which stated, "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot."; (2) Surveyor #2 reviewed 21 lot numbers of hematology quality control material that had been used between 05/03/2020 through the second day of the survey (06/09/20201) and identified the following: (a) Eightcheck-3WP X-Tra lot# 00850710 (low), lot# 008507011 (normal), and lot# 00850712 was tested three days (03/30/2020, 03/31/2020, and 04/01/2020) before put into use on 05/03/2020; (b) Eightcheck-3WP X-Tra lot# 01690710 (low), lot# 01690711 (normal), and lot# 01690712 was tested two days (06/28/2020, 06/29/2020, and 06/30/2020) before put into use on 07/28/2020; (c) Eightcheck-3WP X-Tra lot# 02530710 (low), lot# 02530711 (normal), and lot# 02530712 was tested three days (09/21/2020 and 09/22/2020) before put into use on 09/26/2020; (d) Eightcheck-3WP X-Tra lot# 02370710 (low), lot# 02370711 (normal), and lot# 02370712 was not tested before put into use on 11/17/2020; (e) Eightcheck-3WP X-Tra lot# 02370710 (low), lot# 02370711 (normal), and lot# 02370712 was not tested before put into use on 11/17/2020; (f) Eightcheck-3WP X-Tra lot# 03370710 (low), lot# 03370711 (normal), and lot# 03370712 was not tested before put into use on 01/25/2021; (g) Eightcheck-3WP X-Tra lot# 10550710 (low), lot# 10550711 (normal), and lot# 10550712 was not tested before put into use on 03/31/2021; (3) Surveyor #2 reviewed the findings with testing person #2. Testing person #2 stated on 06/09/2021 at 03:25 pm, the laboratory had not followed the laboratory's written procedure when starting a new lots of hematology quality control materials. MANUAL DIFFERENTIAL POLICY (1) On 06/09/2021 at 02:45 pm, testing person #2 stated to surveyor #2 Manual Differential testing was performed in the laboratory; (2) On 06/09/2021, surveyor #2 reviewed the written policies and procedures manual titled, "Policy and Procedures". The procedure titled, "Sysmex XP-300 Automated Hematology Instrument" but was not able to locate a written procedure for manual differential testing; (3) Surveyor #2 reviewed the procedure manual with testing person #2, testing person #2 stated on 06/09/2021 at 03:55 pm, the procedure had not been written.
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 a review of the microbiology procedure manuals and interview with the microbiology supervisor, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On 06/09/2021 at 02:30 pm, the microbiology supervisor stated to

	surveyor #1 the laboratory began performing the following testing in the microbiology department on approximately 10/13/2019 (the exact start dates for each of the types of cultures could not be determined): (a) Throat Cultures for Group A Streptococcus using Hardy Diagnostics Group A Beta Strep Agar plates; (b) Urine Cultures including Identification and Susceptibility testing for isolates; (c) Blood Cultures (perform gram stain on positive cultures); (d) Gram Stain testing. (2) Surveyor #1 reviewed the microbiology procedure manuals titled, "Procedure Manual I Microbiology" and "Microbiology Procedure Manual II" and identified the manuals had not been approved, signed and dated by the laboratory director until 03/04/2020; (3) Surveyor #1 reviewed the findings with the microbiology supervisor who stated on 06/09/2021 at 04:05 pm, the two microbiology procedure manuals had not been approved by the laboratory director prior to beginning patient testing. 39088 Based on a review of the procedure manual and interview with testing person #2, the laboratory failed to ensure written policies and procedures had been approved, signed, and dated by the laboratory director. Findings include: (1) On 06/09/2021 at 12:45 pm, testing person #2 stated to surveyor #2 the laboratory began patient testing on 02/22/2020 for the following: (a) Hemoglobin A1C (b) Pro BNP (B-type Natriuretic Peptide) (2) The survey reviewed the manual titled, "Policy and Procedures", which contained written policies and procedures. There was no indication the Hemoglobin A1C and BNP testing had had been approved, signed, and dated by the laboratory director; (3) Surveyor #2 showed the manual to testing person #2. Testing person #2 stated on 06 /09/2021 at 01:25 pm, the Hemoglobin A1C and Pro BNP policies and procedures and had not been signed and dated by the laboratory director.
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: Based on a review of records, observation, manufacturer's instructions, and interview with the microbiology supervisor and testing person #2, the laboratory failed to monitor the room temperature of the microbiology department for 18 of 18 months; failed to ensure control materials were stored as required for 6 of 6 months; and failed to ensure the Sysmex XP-300 analyzer was stored as required by the manufacturer for 6 of 6 months. Findings include: MICROBIOLOGY DEPARTMENT ROOM TEMPERATURE (1) On 06/09/2021 at 03:45 pm, the microbiology supervisor stated to surveyor #1 the laboratory began performing gram stain, throat cultures; and blood and urine culture identification and susceptibility testing on approximately 10/13/2019 (the exact start date for each type of culture could not be determined); (2) On 06/09 /2021 at 04:20 pm surveyor #1 observed the microbiology department, which was located in a separate room connected to the laboratory. The following were examples of materials used for assisting in the identification of bacterial isolates, stored at room temperature, with the manufacturer's storage requirements: (a) BD BBL Gram Crystal Violet, lot #0204251; storage requirement of 15-30 degrees (C) Centigrade; (b) BD BBL Gram Iodine, lot #0204378; storage requirement of 15-30 degrees C; (c) BD

BBL Gram Decolorizer, lot #0204280; storage requirement of 15-30 degrees C; (d) BD BBL Gram Safranin, lot #0224567; storage requirement of 15-30 degrees C; (e) BD DMCA Indol Reagent, lot #B0D004M; storage requirement of 15-30 degrees; (f) BD Oxidase Reagent droppers, lot #B03C098M; storage requirement of 15-30 degrees C; (g) BD Catalase Reagent droppers, lot #B02D083M; storage requirement of 15-30 degrees C. (3) Surveyor #1 reviewed microbiology temperature records from January 2020 to date and could not locate records to show the room temperature was being monitored. Surveyor #1 then asked the microbiology supervisor if the temperature of the microbiology department was being monitored. The microbiology supervisor stated to surveyor #1 on 06/09/2021 at 04:30 pm, the laboratory was not monitoring the room temperature of the microbiology department. CONTROL MATERIALS STORAGE (1) On 06/10/2021 at 02:45 pm, surveyor #1 observed the contents of the Kenmore freezer, which was a frost-free freezer. The following control materials were being stored in the freezer, along with the manufacturer's storage requirements: (a) Bio-Rad Liquid Assayed Multiqual controls - 12 bottles of level 3 lot #45833; the storage requirement was -20 to -70 degrees (C) Centigrade. In addition, the3 instructions contained in the package insert stated, "Avoid storing this product in a frost-free freezer"; (b) Bio-Rad Liquichek Cardiac Markers Plus controls - 5 bottles of level 1 1 lot #87811 and 3 boxes containing 6 bottles each of level 3 lot #87813; the storage requirement was -20 to -70 degrees C. In addition, the instructions contained in the package insert stated, "For optimum performance, avoid storing this product in a frost-free freezer"; (c) Bio-Rad Immunoassay Plus controls - 12 bottles of level 3 lot #85221; the storage requirement was -20 to -70 degrees (C) Centigrade. (2) On 06/10/2021 at 02:50 pm, the microbiology supervisor and testing person #2 stated the following to surveyor #1: (a) The Bio-Rad Liquid Assayed Multiqual controls were used to perform quality control procedures for Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, CK (Creatine Kinase), Chloride, Sodium, Creatinine, Glucose, Lipase, Magnesium, Total Protein, HDL (High Density Lipoprotein), Total Cholesterol, and Triglyceride testing performed on the Siemens Dimension EXL-200 analyzer; (b) The Bio-Rad Liquichek Cardiac Markers Plus controls were used to perform quality control procedures for CKMB, Pro-BNP and Troponin I testing performed on the Siemens Dimension EXL-200 analyzer; (c) The Bio-Rad Immunoassay Plus controls were used to perform quality control procedures for Free T4 (Thyroxine), HCG (Human Chorionic Gonatropin), and TSH (Thyroid Stimulating Hormone) testing performed on the Siemens Dimension EXL-200 analyzer. (3) Surveyor #1 reviewed temperature records for 8 months (January 2021 to date). In addition to the freezers being frost-free, the documented temperatures were warmer than -20 C (the warmest temperature allowed for the materials) during 6 of 6 months as follows: (a) January - 31 of 31 documented temperatures were warmer than -20 degrees C (b) Februay - 28 of 28 documented temperatures were warmer than -20 degrees C (c) March - 31 of 31 documented temperatures were warmer than -20 degrees C (d) April - 30 of 30 documented temperatures were warmer than -20 degrees C (e) May - 31 of 31 documented temperatures were warmer than -20 degrees C (f) June - 10 of 10 documented temperatures were warmer than -20 degrees C (4) Surveyor #1 reviewed the records with the microbiology supervisor and testing person #2. Both stated on 06/10/2021 at 03:00 pm, am, they were not aware the manufacturer did not allow storage of the materials in a frost-free freezer, and the freezer temperatures were unacceptable as shown above. SYSMEX XP-300 ANALYZER STORAGE (1) On 06/08/2021 at 10:22 am, the microbiology supervisor stated to surveyor #1 CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) On 06/10/2021, surveyor #1 reviewed the manufacturer's

	environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) Surveyor #1 reviewed laboratory humidity records from January 2021 to date and identified documented humidity readings were less than 30% for 6 of 6 months as follows: (a) January 2021 - 31 of 31 humidity readings were documented as less than 30%; (b) March 2021 - 28 of 28 humidity readings were documented as less than 30% ; (c) April 2021 - 12 of 30 humidity readings were documented as less than 30% (days 01,02,03,04,08,13,18,19,20,21,22,23); (d) May 2021 - 11 of 31 humidity readings were documented as less than 30% (days 18,19,20,24,25,26,27,28,29,30,31); (e) June 2021 - 9 of 10 humidity readings were documented as less than 30% (days 01,02,03,04,05,07,08,09,10). (4) Surveyor #1 reviewed the records with the microbiology supervisor and testing person #2. Both stated on 06/10/2021 at 02:50 pm, the humidity of the laboratory had been maintained below 30% as indicated above.
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 and interview with the microbiology supervisor, the laboratory failed to label containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 06/08/2021 at 10:22 am, the microbiology supervisor stated to surveyor #1 the laboratory performed manual differential testing; (2) Surveyor #1 observed the laboratory on 06/08/2021 at 10:25 am and identified 3 unlabeled Copeland jars, appearing to contain materials used to stain peripheral blood smears; (3) The microbiology supervisor stated to surveyor #1 on 06/08/2021 at 10:28 am, the containers contained materials that were used to stain peripheral blood smears for performing manual differential testing: (4) Surveyor #1 explained to the laboratory manager the containers must be labeled with the identity, expiration date, and lot numbers of the staining materials.
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 a review of records and interview with the microbiology supervisor, the laboratory failed to use materials that had not expired, had deteriorated, or were of substandard quality. Findings include: (1) On 06/08/2021 at 09:52, the microbiology supervisor stated to surveyor #1 the laboratory performed gram stain testing from culture isolates and positive blood cultures; (2) On 06/10/2021 surveyor #1 reviewed the QC (quality control) and patient log for urine cultures performed from 02/01/2021

	to 02/17/2021. It was identified that expired Decolorizer, (lot 9177406, expiration date 01/31/2021) and Iodine (lot #9177386, expiration date 01/31/2021) had been used 5 of 5 days of patient testing to perform gram stain testing on isolates from 6 patients: (a) Patient #10055669 - Gram stain performed on 02/02/2021 (b) Patient 10055738 - Gram stain performed on 02/05/2021 (c) Patient #10055763 - Gram stain performed on 02/08/2021 (d) Patient #10055768 - Gram stain performed on 02/09/2021 (e) Patient #10055846 - Gram stain performed on 02/17/2021 (f) Patient #10055852 - Gram stain performed on 02/17/2021 (3) Surveyor #1 reviewed the records with the microbiology supervisor who stated on 06/10/2021 at 12:27 pm, the documentation showed expired stain had been used as stated above.
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 a review of records and interview with the microbiology supervisor, the laboratory failed to ensure the laboratory performed complete validations for 2 of 3 new microbiology culture test systems; and failed to ensure the validations for 2 of 3 microbiology culture test systems had been reviewed and evaluated by the laboratory. Findings include: THROAT CULTURE TESTING (1) On 06/09/2021 at 02:30 pm, the microbiology supervisor stated to surveyor #1 the laboratory began performing Throat Cultures for Group A Streptococcus using Hardy Diagnostics Group A Beta Strep Agar plates in the microbiology department (the exact start date could not be determined): (2) Surveyor #1 reviewed the validation data for test system. The records showed the following: (a) The validation for throat cultures, which consisted of testing in the laboratory and sending to the reference laboratory, had been performed from 12/29/2019 through 01/31/2020; (b) Patient throat cultures had been reported out prior to validating the testing as follows: (i) Patient #10049769 - Reported on 12/12/2019 (ii) Patient #10049826 - Reported on 12/16/2019 (iii) Patient #10050191 - Reported on 01/13/2020 (c) There was no documentation the laboratory had reviewed and evaluated the validation data. (3) Surveyor #1 reviewed the records with the microbiology supervisor who stated the following on 06/09/2021 at 03:00 pm: (a) Patient throat cultures had been reported prior to the completion of the validation; (b) The laboratory had not documented that the validation data had been reviewed and evaluated by the laboratory. BLOOD CULTURE TESTING (1) On 06/09/2021 at 02:30 pm, the microbiology supervisor stated to surveyor #1 the laboratory began performing Blood Culture testing in the microbiology department (the exact start date could not be determined); (2) Surveyor #1 reviewed the validation data for test system. The records showed the following: (a) The validation for Blood Culture testing had been performed from 12/20/2019 through 01/12/2020 using 19 patients. 18 of the patient cultures were negative and 1 was postive; (b) The laboratory had sent the 18 negatives to a reference laboratory to confirm and compare the results, however, the 1 positive had not been sent to the reference laboratory to confirm and compare the result and there was no documentation to prove the laboratory had

	attempted to verify additional positive blood cultures, therefore, surveyor #1 determined the laboratory did not definitively ensure they would be able to obtain positive blood culture results. (c) Patient blood cultures had been reported out prior to validating the testing as follows: (i) Patient #10049672 - Reported on 12/09/2019 (ii) Patient #10049689 - Reported on 12/10/2019 (iii) Patient #10049702 - Reported on 12 /12/2019 (iv) Patient #10049795 - Reported on 12/19/2019 (e) There was no documentation the laboratory had reviewed and evaluated the validation data. (3) Surveyor #1 reviewed the records with the microbiology supervisor who stated the following on 06/09/2021 at 03:35 pm: (a) The laboratory had not included positive cultures in the study; (b) Patient blood cultures had been reported prior to the completion of the validation; (c) The laboratory had not documented that the validation data had been reviewed and evaluated by the laboratory. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.") 39088 Based on a review of records and interview with testing person #2, the laboratory failed to demonstrate the performance specifications for SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer. Findings include: (1) On 06/09/2021 at 03:15 pm, testing person #2 stated to surveyor #2 the laboratory began SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer on 12/17/2020; (2) Surveyor #2 reviewed the performance specification records for the new test system and could not locate any performance specification records; (3) Surveyor #2 reviewed the findings with testing person #2, who stated on 06/09/2021 at 04:25 pm, the laboratory had not demonstrated the performance specifications as stated above. (4) Examples of patient testing: (a) Patient #10055024 - Tested on 12/21/2020 (b) Patient #10055292 - Tested on 01/04/2021 (c) Patient #10055187 - Tested on 01/04/2021 (d) Patient #10055272 - Tested on 01/04/2021 (e) Patient #10055435 - Tested on 01/18/2021 (f) Patient #10055555 - Tested on 01/25/2021 (g) Patient #10055641 - Tested on 02/01/2021 (h) Patient #10055774 - Tested on 02/08/2021 (i) Patient #10055775 - Tested on 02/08 /2021 (j) Patient #10055882 - Tested on 02/10/2021 (k) Patient #10056083 - Tested on 03/08/2021 (l) Patient #10056116 - Tested on 03/08/2021 (m) Patient #10056956 - Tested on 05/03/2021
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 a review of records and interview with testing person #1, the laboratory failed to follow their function check protocol for ensuring the urinalysis centrifuge was functioning properly for four of four function checks. Findings include: (1) On 06 /08/2021 at 03:50 pm, testing person #1 stated the following to surveyor #2: (a) The

	laboratory performed urine sediment testing; (i) The specimens were processed in the McKesson Variable Speed Centrifuge (serial number LT1706468) centrifuge at a speed of 1500 rpm (Revolutions Per Minute) and a time of 5 minutes; (ii) Centrifuges were checked (speed and timer checks) every six months. (2) Surveyor #2 reviewed the centrifuge function check records that had been performed in 2019, 2020, and 2021. The centrifuge speed had been checked as follows: (a) McKesson Variable Speed Centrifuge (i) 10/29/2019 for 2238 rpm (ii) 04/29/2020 for 2342 rpm (iii) 10/20/2020 for 2416 rpm (iv) 04/21/2021 for 2434 rpm (4) Surveyor #2 reviewed the records with testing person #1 and asked if the speed had been checked at a rate of 1500 rpms according to the laboratory's policy for performing urine sediment testing. Testing person #1 stated on 06/08/2021 at 04:41 pm, the checks had not be checked at 1500 rpm as indicated 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 a review of records and interview with testing person #2, the laboratory failed to ensure an IQCP included the required components. Findings include: (1) On 06/08/2021 at 09:40 am, testing person #2 stated to the following to surveyor #1: (a) The laboratory performed D-dimer testing using the Alere Biosite Triage analyzer; (b) An IQCP (Individualized Quality Control Program) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP for the test systems and identified a formal QCP (Quality Control Plan) and QA (Quality Assessment) plan had not been included in the IQCP (it consisted of a Risk Assessment only); (3) Surveyor #1 reviewed the records with testing person #2 who stated on 06/08/2021 at 11:30 am, a QCP and QA plan had not been included in the IQCP.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to follow the manufacturer's specifications for quality control materials for two of two lot numbers. Findings include: (1) On 06/10/2021 at 11:30 am, testing person #2 stated to surveyor #2: (a) Lactic Acid and Chloride testing was performed on the Dimension ExL 200 analyzer; (b) Two levels of Bio-Rad

	Liquid Assay Multiqual control materials were tested each day of patient lactic acid and chloride testing. (3) Surveyor #2 reviewed the manufacturer's instructions (package insert) for the control materials, which stated: (a) Bio-Rad Liquid Assay Multiqual qualilty control- "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (4) Surveyor #2 reviewed quality control records for two lot numbers of control materials used from 01/17/2020 through the third day of the survey (06/10/2021). It was identified that the laboratory had not used the laboratory's established range as follows: (a) Bio-Rad Liquid Assay Multiqual (i) Level 1 lot #45831 and level 3 lot #45833 - put into use on - 01/17/2020 was currently being used. (b) Chloride (i) Level 1 - Established a mean of 75.2 and standard deviation of 0.71 (aa) The laboratory entered into the analyzer a mean of 76.3 and a standard deviation of 2.60 (c) Lactic Acid (i) Level 1 - Established a standard deviation of 0.06 (aa) The laboratory entered into the analyzer a standard deviation of 0.12 (ii) Level 2 - Established a mean of 5.61 and standard deviation of 0.12 (aa) The laboratory entered into the analyzer a mean of 5.91 and a standard deviation of 0.18 (5) Surveyor #2 reviewed the above findings with testing person #2, who stated on 06/10/2021 at 02:00 pm, the laboratory did not implement the established mean and/or standard deviation for chloride and lactic acid as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the microbiology supervisor/testing person #1 and testing person #2, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have written procedures that explained the current practices and procedures being performed in the microbiology department and the laboratory; failed to follow written procedures; and failed to have a written procedure for manual differential testing. Refer to D5401; (b) The laboratory failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (c) The laboratory failed to monitor the room temperature of the microbiology department for 18 of 18 months; failed to ensure control materials were stored as required for 6 of 6 months; and failed to ensure the Sysmex XP-300 analyzer was stored as required by the manufacturer for 6 of 6 months. Refer to D5413; (d) The laboratory failed to label containers with the identity, expiration date, and lot number of the contents. Refer to D5415; (e) The laboratory failed to use materials that had not expired, had deteriorated, or were of

	substandard quality. Refer to D5417; (f) The laboratory failed to ensure the laboratory performed complete validations for 2 of 3 new microbiology culture test systems; failed to ensure the validations for 2 of 3 microbiology culture test systems had been reviewed and evaluated by the laboratory; and failed to demonstrated the performance specifications for SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer. Refer to D5421; (g) The laboratory failed to ensure an IQCP included the required components. Refer to D5445; (h) The laboratory failed to follow the manufacturer's specifications for quality control materials for two of two lot numbers. Refer to D5479.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer. Refer to D6013; (2) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for two of 33 events. Refer to D6016.
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 a review of records and interview with testing person #1, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for SARS-CoV-2 antibody testing on the Dimension ExL 200 analyzer. Refer to D5421.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for two of 33 events. Findings include: (1) On 06/08/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing events. For two of 33 events, the attestation statements had been signed approximately two to eight months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2019 Immunology Event - The sample testing had been completed on 04/04/2019, and the attestation statement had not been signed by the laboratory director/designee until 06 /05/2019; (b) First 2019 Chemistry Miscellaneous Event - The sample testing had been completed on 05/07/2019, and the attestation statement had not been signed by the laboratory director/designee until 01/08/2020. (2) Surveyor #2 reviewed the findings with testing person #1 who stated on 06/08/2021 at 04:05 pm the attestations had been signed approximately two to eight months after the proficiency samples had been tested. Surveyor #2 explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #1, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035. (2) The technical consultant failed to ensure evaluations included all moderate complexity testing; and failed to ensure personnel performing moderate complexity testing had been evaluated at least annually. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such

certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with testing person #1, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for seven of 13 competency evaluations performed. Findings include: (1) On 06/08/2021, surveyor #2 reviewed records for 13 persons performing moderate complexity testing in 2019, 2020, and 2021. The records showed the evaluation for seven of 13 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 05/30/2019, 03/10/2020 and 03/10/2021 evaluations had been performed by testing person #1(this person had a HEW certification and met the general supervisor qualifications at 493.1461(c)(3)(ii)); (b) Testing Person #3 - The 05 /30/2019, 03/10/2020 and 05/17/2021 evaluations had been performed by testing person #1; (c) Testing Person #4 - The 03/10/2020 and 03/15/2021 evaluations had been performed by testing person #1; (d) Testing Person #5 - The 03/10/2020 and 03 /10/2021 evaluations had been performed by testing person #1; (e) Testing Person #7 - The 03/19/2019, 03/10/2020 and 03/10/2021 evaluations had been performed by testing person #1; (f) Testing Person #9 - The 03/19/2019, 03/10/2020 and 03/10/2021 evaluations had been performed by testing person #1; (g) Testing Person #10 - The 03 /19/2020 and 03/20/2021 evaluations had been performed by testing person #1. (2) Surveyor #2 explained to testing person #1 and testing person #2 that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a masters degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 1 year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). Testing person #1 stated to surveyor #2 on 06/08/2021 at 04:49 pm, the evaluations had been performed by an individual who did not meet the years of experience of a technical consultant.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the technical consultant failed to ensure evaluations included all moderate complexity for 10 of 13 testing persons; and failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of 13 persons. Findings include: C. DIFF QUIK CHEK COMPLETE TEST KIT (1) On 06/08/2021 at 02:30 pm, testing person #2 stated to surveyor #2 the laboratory performed Clostridium difficile using the C.Diff Quik Chek Complete test kit; (2) Surveyor #2cthen reviewed 2019, 2020, and 2021 personnel records. The following was identified: (a) Testing Person #1 - Although evaluations had been performed on 01/16/2019, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (b) Testing Person #2 - Although evaluations had been performed on 05/30/2019, 03/10/2020, and 03/10/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (c) Testing Person #3 - Although evaluations had been performed on 05/30/2019, 03/10/2020, and 05/17/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (d) Testing Person #4 - Although evaluations had been performed on 05/30/2019, 03/10/2020, and 03/15/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (e) Testing Person #5 - Although evaluations had been performed on 01/30/2019, 03/10/2020, and 03/10/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (f) Testing Person #6 - Although evaluations had been performed on 01/30/2019 and 05/17/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (g) Testing Person #7 - Although evaluations had been performed on 03/19/2019, 03/10/2020, and 03/10/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (h) Testing Person #9 - Although evaluations had been performed on 03/19/2019, 03/10/2020, and 03/10 /2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (i) Testing Person #10 - Although evaluations had been performed on 05/30/2019, 03/10/2020, and 03/10/2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing; (j) Testing Person #11 - Although evaluations had been performed on 03/19/2020, and 03/20 /2021, there was no evidence the person had been evaluated for performing Clostridium difficile testing. (2) Surveyor #2 reviewed the findings with testing person #1. Testing person #1 stated on 06/08/2021 at 04:18 pm that evaluations did not include Clostridium difficile testing. ANNUAL COMPETENCY (1) Surveyor #2 reviewed personnel records for 13 persons who performed moderate complexity testing during 2019, 2020, and to date in 2021. For one of the 13 persons (testing person #11), there was no evidence an annual evaluation had been performed as follows: (a) Testing Person #3 - Between 06/15/2018 and 03/19/2020. (3) Surveyor #2 reviewed the findings with testing person #1 and testing person #2 who both stated on 06/08/2021 at 04:36 pm, the annual evaluation had not been performed as indicated above.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the microbiology supervisor, the laboratory director failed to provide overall management and direction for high complexity culture testing performed in the microbiology department of the laboratory. Findings include: (1) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer to D6086; (2) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6094; (4) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 a review of records and interview with the microbiology supervisor, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the laboratory performed complete validations for 2 of 3 new microbiology culture test systems; and failed to ensure the validations for 2 of 3 microbiology culture test systems had been reviewed and evaluated by the laboratory. Refer to D5421.
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 a review of records, manufacturer's instructions, observation, and interview with the microbiology supervisor, the laboratory director failed to ensure that quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory monitored the room temperature of

	the microbiology department for 18 of 18 months. Refer to D5413; (2) The laboratory director failed to ensure the laboratory did not use materials that had not expired, had deteriorated, or were of substandard quality. Refer to D5417.
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 a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the microbiology supervisor, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5421.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the microbiology supervisor, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings include: (1) The laboratory director failed to ensure the laboratory had written procedures that explained the current practices and procedures being performed in the microbiology department. Refer to D5401; (2) The laboratory director failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Refer to D5407.