

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0183623	(X3) Date Survey Completed 09/15/2022
Name of Provider or Supplier Titusville Area Hospital	Street Address, City, State 406 West Oak St, Titusville, PA	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the histopathology department and interview with the Histotechnologist, the laboratory failed to establish and follow safety procedures to keep 3 of 3 containers of Xylene in the correct storage area on the date of survey. Findings: 1. Epredia Xylene Safety Data Sheets (SDS) states for storage of xylene reagent, " Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. Keep out of the reach of children. Store away from other materials." 2. The surveyor observed on 9/14/2022 at 09:25, 3 of 3 bottles of Xylene were in a cabinet with other laboratory reagents in the Histopathology area, the cabinet was not appropriate for storage of flammable reagents. 3. Interview with the HT, on 09/14/2022 at 09:30 am, confirmed the above findings.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory's competency policy, competency assessment records and interview with the Laboratory Manager (LM), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 2 Technical Consultants (TC), 1 of 2 Technical Supervisors (TS), and 1 of 12 General Supervisors (GS) for their supervisory roles from 06/17/2020 to the date of survey. Findings include: 1. On the day of survey, 09/14/2022 at 09:33 am, the LM could not provide a competency assessment policy to assess the competency of the following personnel for their supervisory skills from 06/17/2020 to 09/14/2022: - 1 of 2 TC (on CMS 209, personnel #2) - 1 of 2 TS (on CMS 209, personnel #2) - 1 of 12 GS (on CMS 209, personnel #2) 2. The LM could not provide documentation for delegation of duties for the TS,TC,GS (CMS 209, personnel #2). 3. The LM confirmed the findings above on 09/15/2022 around 02:15 pm. B. Based on review of the laboratory's Employee Competency procedure, annual competency records, and interview with Laboratory Manager (LM), the laboratory failed to establish a complete procedure that includes all six components required for competency assessment for 13 of 13 Testing Personnel who performed Hematology, Routine Chemistry, Urinalysis, Microbiology and Immunochemistry examinations from 06/17/2020 to the date of survey. Findings include: 1. On the day of survey, 09/14/2022 at 10:40 am, the competency assessment policy reviewed at the time of survey did not include the six points of CLIA required for competency assessment. 2. The LM confirmed the findings above on 09/15/2020 around 02:15 p.m. *This is a repeat deficiency.

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 review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory manager (LM), the laboratory failed to verify the accuracy for PT testing performed in 2020, 2021, and 2022. Findings Include: 1. On the day of survey, 09/14/2022 at 10:30 am, review of the laboratory's API proficiency testing records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the proficiency testing agency: a.) 2022 Microbiology 2nd Event: -12 of 12 Blood Culture MIC/Zone Diameter Value -12 of 12 Blood Culture Susceptibility Interpretation -12 of 12 Urine Culture MIC/Zone Diameter Value b.) 2022 Immunology/Immunochemistry 1st Event: -1 of 5 Antigen Identification (Blood Bank Compatibility) -1 of 5 Ortho ID-MTS Anti-IgG Gel Test c.) 2022 Microbiology 1st Event: -9 of 9 CSF Culture MIC /Zone Diameter Value -9 of 9 CSF Culture Susceptibility Interpretation -1 of 5 Gram Stain -8 of 8 Urine Culture MIC/Zone Diameter Value d.) 2021 Hematology /Coagulation 2nd Event: -1 of 5 Blood Cell Identification -1 of 2 Sperm Count (Hemocytometer) e.) 2021 Immunology/Immunochemistry 3rd Event -1 of 5 Antigen Identification (Blood Bank Compatibility) f.) 2021 Chemistry Event #2: -1 of 2 Folate g.) 2021 Chemistry-Miscellaneous 1st Event -1 of 3 Body Fluid Creatinine

h.) 2020 Microbiology 3rd Event: -1 of 2 Wound Culture (non consensus) i.) 2020 SARS-CoV2 3rd Event: -1 of 2 SARS-CoV2 Liquid (Molecular) 2. The LM confirmed the findings above on 09/15/2022 around 02:15 pm.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's procedures and interview with the laboratory manager (LM), the laboratory failed to include, step-by-step performance procedures for immunohematology, new method and test validations, and quality control procedures for hematology testing performed in 2020 to the day of survey. Findings Include: 1. On the day of survey, 09/15/2022 at 12:00 pm , review of the laboratory's policies revealed, the following areas were not included in the test procedures: Step-by-step performance procedures: - Quarantine of blood products - New Method and test validation Quality control procedures: - Nasal eosinophils - Fecal leukocytes - Sedimentation Rate 2. The LM confirmed the findings above on 09/15/2022 around 02:15 pm

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:

A. Based on review of the Beckman Coulter AcT Diff 5 analyzer validation records and interview with the General Supervisor (GS) #9, the laboratory failed to establish

criteria for acceptable performance specifications for 13 of 13 analytes performed on the Beckman Coulter AcT Diff 5 analyzer from 12/02/2021 to the date of survey. Findings Include: 1. On the day of survey, 09/15/2022 around 09:45 am, review of the Beckman Coulter AcT Diff 5 analyzer validation records revealed, the validation performed on 12/02/2021 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy and reportable ranges for the following analytes: - White Blood Count (WBC) - Red Blood Count (RBC) - Hemoglobin (HGB) - Hematocrit (HCT) - Mean Corpuscular Volume (MCV) - Mean Corpuscular Hemoglobin (MCH) - Mean Corpuscular Hemoglobin Concentration (MCHC) - Platelet (PLT) - Neutrophils (NEU) - Lymphocytes (LYM) - Monocytes (MON) - Eosinophyls (EOS) - Basophyls (BAS) 2. The GS confirmed the findings above on 09/15/2022 around 02:15 pm. B. Based on review of the Ortho Gel ID-MTS validation records and interview with the General Supervisor (GS) #3, the laboratory failed to establish criteria for acceptable performance specifications for 4 of 4 analytes performed on the Ortho Gel ID-MTS from 02/28/2022 to the date of survey. Findings Include: 1. On the day of survey, 09/15/2022 around 11:42 am, review of the Ortho Gel ID-MTS validation records revealed, the validation performed on 02/08/2022 did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy and Reportable ranges for the following analytes: - ABO Blood Group Testing (ABO) - Rhesus factor (Rh) - Anitbody Screening (ABS) - Compatibility Testing (XM) 2. The laboratory director did not review and approve the validation studies for the Ortho Gel ID-MTS testing. 3. The GS confirmed the findings above on 09/15/2022 around 02:15 pm.

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:
A.) Based on review of the laboratory's Individualized Quality Control Plans (IQCP) and interview with the Laboratory Manager (LM), the laboratory failed to produce a complete IQCP for the Cepheid Gene Expert System, Sure-Vue Mono Screen Kit, Cardinal Health hCG Combo Kit, BD Bactec FX 40, and Meridian Immunocard when implementing an IQCP from 06/17/2020 to 09/14/2022. Findings include: 1. On the days of survey, 09/14/2022 at 12:45 pm, the laboratory failed to provide a complete IQCP for the following: - 2 of 3 parts of an IQCP for Mononucleosis Rapid Testing (Sure-Vue Mono Screen Kit): no documentation provided for risk assessment (RA) and quality assessment (QA). -2 of 3 parts of an IQCP for HCG Combo Rapid Testing (Cardinal Health hCG Combo): no documentation provided for RA and QA. -1 of 3 parts of an IQCP for Blood Cultures (BD Bactec FX 40): no documentation provided for QA. 2. The laboratory failed to provide a separate Risk Assessment for each the following tests: -Cepheid Gene Expert System -Clostridium Dificile (C Diff)

Cartridge -4 Plex Cartridge: Flu A, Flu B, RSV, SARS-CoV-2 -Meridian Immunocard
-Campylobacter Antigen (Campy Ag) -Shigatoxin 3. The LM confirmed the findings
above on 9/15/2022 around 02:15 pm.