

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0183623	(X3) Date Survey Completed 06/18/2020
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
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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manuals and interview with technical supervisor (TS), the laboratory failed to follow their competency assessment policy to evaluate the competency of 11 of 12 testing personnel (TP) and to establish a policy to access the competency of 9 of 10 regulatory personnel in 2019 and 2020. Findings include: 1. The Laboratory Employee Competency policy states "Competency assessment, which includes six procedures must be performed for testing personnel for each test that the individual is approved by the laboratory director to performed. Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patients specimen. Thereafter, competency assessment must be performed at least annually". 2. On the day of survey, 06/17/2020, the laboratory did not assess the competency of 11 of 12 TP for each test they were approved by the laboratory director to performed in 2019 and 2020 and did not evaluate the competency of 2 of 2 new TP for semiannual competency in 2020. 3. The laboratory employee competency policy did not include measures to assess the competency of 9 out of 10 regulatory personnel in 2019 and 2020. 4. The TS confirmed the findings above on 06/17/2020 around 10:00 am.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without</p>

analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on laboratory record review, and interview with the technical supervisor (TS), the laboratory director failed perform and verify the accuracy of Lactophenol cotton blue smear examinations performed from 06/20/2018 to the day of survey. Findings include: 1. On the day of survey, 06/17/2020, The TS could not provided documentation of proficiency testing performed or documentation of accuracy performed for Lactophenol cotton blue smear examinations performed in 2018, 2019 and 2020. 2. The TS confirmed the finding above on 06/17/2020 around 2:15 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 technical supervisor (TS), the laboratory failed to include, step-by-step performance procedures and quality control procedures for bacteriology and hematology microscopic examination policies and immunology test kit policies from 2018 to the day of survey. Findings Include: 1. On the day of survey, 06/17/2020, review of the laboratory's policies revealed, the following areas were not included in the test procedures: Step-by-step performance procedures: - Manual differential body fluid policy Quality control procedures: - Manual diff body fluid policy - Crystal analysis for body fluid - Body fluid analysis - Synovial fluid cell count - Cerebral spinal fluid analysis - C-chip Hemocytometer - Qualitative Infections Mononucleosis - Qualitative serum Hcg Test - Fungal Lactophenol cotton blue smear 2. The laboratory could not provide Quality control records for: - BBL Rapid Urea Broth - Fungal Lactophenol cotton blue smear - Crystal analysis for body fluid - Body fluid analysis - Synovial fluid cell count - Cerebral spinal fluid analysis - C-chip Hemocytometer 3. The laboratory could not provide an Individual quality control plan (IQCP) for the following tests: - Qualitative Infections Mononucleosis performed on the Sure Vue Signature Mono Kit. - Qualitative serum Hcg Test performed on the Cardinal Health Hcg Kit. - BBL Bactec

	<p>Blood culture bottles. 4. The TS confirmed the findings above on 06/18/2020 around 12:00 pm</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the histopathology laboratory and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to ensure expired reagents were not used beyond the expiration dates. Findings Include: 1. On the day of survey, 06/17/2020, while on tour on the histopathology laboratory, the examiner observed the following reagents were expired: - 1 of 1 bottle of American Masters Tech Scientific Inc. Squeezies, Red Tissue Marking Dye, Lot#: 45280 Expired: 1/12/2019 - 1 of 1 bottle of American Masters Tech Scientific Inc. Squeezies, Black Tissue Marking Dye, Lot#: 47218 Expired: 09/26/2019 - 1 of 1 bottle of American Masters Tech Scientific Inc. Squeezies, Orange Tissue Marking Dye, Lot#: 47218 Expired: 09/26/2019 - 1 of 1 bottle of American Masters Tech Scientific Inc. Squeezies, Blue Tissue Marking Dye, Lot#: 47218 Expired: 09/26/2019 2. The TS and LD confirmed the findings above on 06/17/2020 around 12:20 pm.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) proficiency testing (PT) scores and interview with technical supervisor (TS), the laboratory director failed to review and evaluate the laboratory's performance that required corrective action for Hematology 2020 event 1 PT scores. Findings Include: 1. The PT Guideline Policy states, "1. Scores less than 100 must be addressed. 2. Scores less than 80% are considered unsuccessful participation (PADOH requires a score of 100%, a score less than 100% requires correction action). 2. On the day of survey, 06/17/2020, review of API PT documents revealed, the laboratory did not document a corrective action for API 2020 event 1, WBC score of 80%. 3. The TS confirmed the findings above at 06/17/2020 around 10:30 am. ****WBC = White Blood Cell</p>
<p>D6125</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency assessment records, review of American proficiency Institute (API) proficiency testing (PT) records and interview with the technical supervisor (TS), the TS failed to assess the competency of all TP through external proficiency testing samples or internal blind testing samples for tests performed in the Chemistry, Hematology, Immunology, Microbiology,

Immunochemistry and Urinalysis departments in 2018 and 2019. Findings Include:

1. On the day of survey, 06/17/2020, review of TP competency assessment records and API PT records revealed, annual competency performed in 2018 and 2019 did not include the assessment of external proficiency testing samples or internal blind testing samples for all TP who performed testing in Chemistry, Hematology, Immunology, Microbiology, Immunochemistry and Urinalysis departments. 2. The TS confirmed the finding above on 06/18/2020 around 12:00 pm.