

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2042355	(X3) Date Survey Completed 05/26/2021
Name of Provider or Supplier Dilip Elangbam	Street Address, City, State 10 Shady Lane, Suite 201, Muncy, 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 of review of the laboratory's procedure manuals and interview with laboratory director (LD), the laboratory failed to establish a procedure to assess the competency assessment of 1 of 1 testing personnel performing complete blood count (CBC) testing from 05/26/2019 to 05/26/2021. Findings include: 1. On the day of survey, 05/26 /2021, the LD could not provide a written policy and procedure to assess the competency assessment of 1 of 1 testing personnel performing complete blood count (CBC) testing from 05/26/2019 to 05/26/2021. 2. The LD confirmed the finding above on 05/26/2021 around 10:10 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation, lack of documentation and interview with the laboratory director (LD), the laboratory failed to document maintenance for 3 of 3 thermometers and 1 of 1 centrifuge from 05/26/2019 to 05/26/2021. Findings include: 1. On the day of survey, 05/26/2021, Observation of laboratory revealed: - A Thermo Scientific</p>

thermometer on a large refrigerator service sticker stated, Due 1/24/2014. - A Fisher scientific traceable thermometer's service sticker stated, Due 2/20/2019. - A K2 Mini refrigerators internal thermometer was in use, but a service sticker was not available. - A PSS 602 centrifuge used for endocrinology was in use, but a service sticker was not available. 2. The laboratory was unable to provide a maintenance policy or documentation of maintenance performed on the 3 of 3 thermometers and 1 of 1 centrifuge. 3. The refrigerators stored reagents for the Fast pack IP system and the Beckman coulter Ac T diff 2 analyzer. 4. The LD confirmed the findings above round 1:45 pm. *** REPEAT DEFICIENCY***

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on the review of patient test reports and interview with Laboratory Director (LD), the laboratory failed to include on patient endocrinology test reports either the patient's name and identification number, or a unique patient identifier and identification number from 05/26/2019 to the day of survey. Finding Include: 1. On the day of survey, 05/26/2021, a review of some test reports (3 of 3) revealed, the endocrinology test reports did not include a 2nd patient identifier or a unique patient identifier from 05/26/2019 to 05/26/2021. 2. The LD confirmed the finding above on 05/26/2021 around 1:30 pm.

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 observation of the laboratory, review of laboratory records, and interview with the laboratory director (LD), the LD failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory. Refer to 6018 and 6022.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that 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;

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the laboratory director (LD), the LD failed to ensure that all proficiency testing reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions in 2019, 2020 and 2021. Findings include: 1. On the day of survey, 05/26/2021, review of the AAB PT records revealed: - The following attestation statements were not signed in 2020 and 2021: 2020 Event #3 Hematology- not signed by LD or testing personnel. 2020 Event #3 Core Chemistry - not signed by LD. 2020 remedial event - not signed by LD. 2020 Event #2 Hematology - not signed by LD. 2020 Event #2 Core Chemistry - not signed by LD. 2020 Event #1 Hematology - not signed by LD or testing personnel. 2020 Event #1 Core Chemistry - not signed by LD. 2021 Event #1 Hematology - not signed by LD. - The following corrective actions were not documented in 2019 and 2020: 2019 Event #3: Free TY - 0% and Thyroid-Stimulating Hormone (TSH) - 0%. 2019 Event #3: Red Blood Cell Count (RBC) - 40% and Hematocrit (HCT) - 40%. 2020 Event #1: Red Blood Cell Count (RBC) - 80% and Hematocrit (HCT) - 80%. 2. The LD confirmed the finding above at the summation on 05/26/2021 around 2:45 pm.

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure that quality control (QC) and quality assessment (QA) programs were established and maintained to identify failures in quality as they occur from 05/26/2019 to 05/26/2021. Findings Include: 1. On the day of survey, 05/26/2021, review of records revealed, the following documents were not available from 05/26/2019 to 05/26/2021: A. Fast Pack IP System Analyzer - used to analyze TSH, FT4, PSA and Vitamin D. - I. The surveyor compared 5 of 5 patient test logs to the laboratory's QC records. Review of records revealed, QCs were not performed each day of patient testing on 7/24/2019, 7/06/2020, 07/13/2020, 03/21/2021 and 04/08/2021, when patient tests were performed. - II. Calibration verifications were not performed every six months for each analyte in 2019, 2020 and 2021. B. Beckman Coulter Ac T diff 2 - used to analyzed complete blood count. - I. Maintenance documents were not available from 05/26/2019 to 05/26/2021. - II. Calibrations were not documented from 05/26/2019 to 05/26/2021. - III. Corrective actions were not documented when background checks or QC failures occurred from 05/26/2019 to 05/26/2021. 2. The laboratory could not provide a Beckman Coulter Ac

T diff 2 policy that states the laboratory's procedures for dealing with background checks or QC failures. 3. The laboratory could not provide monthly QA activities performed from 05/2019 to 04/2021. 4. The LD confirmed the findings above during the summation on 05/26/2021 around 2:30 pm.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the laboratory director (LD), the Technical Consultant (Laboratory director) failed to evaluate and document the performance of 1 of 1 testing personnel (TP) responsible for the hematology and chemistry testing for their semi-annually competency during the first year in 2020. Findings include: 1. On the day of survey, 05/26/2021, the LD could not provide documentation of competency assessment performed on 1 of 1 TP for their semi-annually competency during their first year in 2020. 2. During the summation on 5/26/2021 around 2:30 pm, the LD confirmed TP#1 was hired June 1, 2021, but was not assessed for competency until March 20, 2021. *** REPEAT DEFICIENCY***