Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2042355	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dilip Elangbam	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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel #1 (TP), the laboratory failed to perform calibration verification at least once every six months for 1 of 1 Fast Pack IP chemistry analyzer from 05/27/2021 to the date of survey. Findings include: 1. On the date of survey, 06/14/2023 at 02:00 pm, the laboratory

	could not provide calibration verification records for the required analytes tested on 1 of 1 Fast Pack IP chemistry analyzer from 05/27/2021 to 06/14/2023. 2. TP #1 confirmed the findings above on 06/14/2023 around 03:00 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, 6022, 6054, and 5439.
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 Proficiency Institue (API) proficiency testing (PT) records, lack of documentation, and interview with testing personnel #1 (TP), the LD failed to ensure that 5 of 12 API PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective actions in 2021, 2022 and 2023. Findings include: 1. On the day of survey, 05/26/2021 at 11:35 am, review of the API PT records for 2021, 2022, and 2023 revealed the following: - Corrective action was not documented for the following API PT reports: - 2021 API Event # 3 Hematology/Coagulation: Red Blood Cell (80%), Hematocfrrit (80%), Hemoglobin (40%), White Blood Cell (80%). - The following API PT records were not availaible at the time of inspection: - 2021 API Event # 1 Core Chemistry (testing report) - 2023 API Event #1 Hemtology/Coagulation (signed attestation) - 2022 API Event #3 Hematology/Coagulation (signed attestation) - 2022 API Event # 3 Core Chemistry (signed attestation) 2. TP #1 confirmed the finding above on 06/14/2023 around 3:00 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 record review 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 05/27 /2021 to 06/14/2023. Findings Include: 1. On the day of survey, 06/14/2023 at 01:49 pm, the laboratory could not provide documentation of QC performed each day of patient testing for the following 4 of 4 chemistry analytes tested on the Fast Pack IP System analyzer from 05/27/2021 to 06/14/2023: - Thyroid Stimulating Hormone (TSH) - Thyroxine (FT4) - Prostate Specific Antigen (PSA) - Vitamin D (Vit D) 2. The laboratory could not provide documentation of QC and background checks performed each day of patient testing for complete blood cell counts (CBC) performed on 1 of 1 Beckman Coulter AcTdiff2 analyzer for the following months: - September 2022 - December 2021 - November 2021 - October 2021 - June 2021 3. Further review of the laboratory's QC records revealed that corrective actions were not documented for 3 of 31 days in October 2022 when QC failures occurred on the Beckman Coulter AcTdiff 2 hematology analyzer. - 10/11/22: CBC testing was performed on 6 patients - 10/10/22: CBC testing was performed on 6 patients - 10/06 /2022: CBC testing was performed on 6 patients 4. The laboratory could not provide documentation of monthly QA activities performed in 2021, 2022, and 2023. 5. The LD confirmed the findings above on 06/14/2023 around 03:00 pm.
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 lack of competency assessment (CA) records and interview with testing personnel #1 (TP), the technical consultant (TC) failed to assess the competency of 2 of 3 testing personnel (TP) for routine chemistry and hematology examinations in 2021 and 2022. Finding Include: 1. On the day of the survey, 02/03/2023 at 09:30 am, the laboratory could not provide CA records for 2 of 3 TP (CMS 209 personnel #3, and #4) who performed routine chemistry examinations on the Fast Pack IP analyzer and complete blood cell counts on the Beckman Coulter AcTdiff 2 analyzer in 2021 and 2022. 2. TP #1 confirmed the findings above on 06/14/2023 around 03:00 pm.