Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2042355	06/05/2025
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
D0000	A recertification survey was conducted by the Pennsylvania State Agency for Dilip Elangbam on 06/05/2025. The laboratory was found out of compliance with the following conditions: 493.1250 Condition: Analytic systems.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with the laboratory director (LD), the laboratory failed to provide 3 of 3 API PT Chemistry Core and 3 of 3 API PT Hematology /Coagulation attestation statements signed by the analyst for 2024. Findings include: 1. On the day of survey, 6/5/2025, the laboratory failed to provide attestation statements signed by the testing personnel (TP) for 3 of 3 API PT Chemistry Core and 3 of 3 API Hematology/Coagulation events performed in 2024. 2. The LD confirmed the finding above on 6/5/2025 at 1:30 pm.
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 lack of documentation and interview with Testing Personnel (TP) #1 and the laboratory director (LD), the laboratory failed to establish and follow a written policy or procedure to assess employee competency for 1 of 1 TP that performed chemistry and hematology testing from 06/14/2023 to 6/5/2025. Findings include: 1. On the day of survey, 6/5/2025 at 11:00 am, the laboratory failed to provide a written policy to assess the six required procedures of a competency assessment for 1 of 1 TP (CMS 209 TP#1) that performed moderate complexity hematology and chemistry testing from 06/14/2023 to 06/05/2025. 2. The laboratory performed 250 endocrinology examinations and 100 hematology examinations in 2024 (CMS 116, estimated annual volume). 3. The LD confirmed the above findings on 6/5/2025 at 1:00 pm.
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 laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 3 API Hematology /Coagulation events in 2025 and 1 of 3 API Chemistry Core events in 2024. Findings: 1. On the day of survey, 6/5/2025 at 10:50 am., review of the laboratory's API PT results revealed the laboratory failed to verify the accuracy of PT results not graded by the PT agency for the following events: a. API Hematology/Coagulation: 2025 Event #1 b. API:Core Chemistry: 2024 Even t # 3 2. The LD confirmed the finding above on 6/5/2025 at 1:45 pm.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, observation of the laboratory, and interview with testing personnel (TP) #1, the laboratory failed to follow policies to ensure specimen integrity was maintained (collection, storage, and transport conditions) for specimens stored in 1 of 1 feezer to be used for endocrinology testing peformed at a later date from 06/14 /2023 to the date of the survey . Findings include: 1. The FastPack Systems Operating

	manual states the following for Handling and Storing of Specimens: Remove serum or plasma from the cells prior to storage at 2-8 degrees Celcius. If not tested within 24 hours, samples should be frozen at -20 degrees Celcius or colder for up to 2 months. 2. On 6/5/2025, during observation in the laboratory, specimens stored for endocrinology testing did not have the serum or plasma removed from the cells prior to storage. 3. Interview with TP#1 on 6/5/2025 at 11:30 am revealed that endocrinology testing is performed every other week. 4. TP #1 confirmed the above findings on 6/5/2025 at 12:15 pm.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 from 6/14/2023 to 6/5 /2025. Refer to 5413, 5421, 5437, 5439, 5477, and 5783.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: A. Based on observation in the laboratory, review of laboratory temperature records, and interview with Testing Personnel (TP) #1, the laboratory failed to monitor and document temperatures to ensure proper storage of reagents for 490 of 722 days from 6/14/2023 to 6/5/2025 when testing personnel are not present in the laboratory. Findings include: 1. On the day of survey, 6/5/2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the following refrigerators currently in use in the laboratory: Reagent Refrigerator - 1 Beckman Coulter DxH 500 Series Calibrator. Storage requirements 2C to 8C. - 1 Beckman Coulter DxH 500 Series Quality Control. Storage requirements 2C to 8C. - 2 FastPack System TSH Calibrators. Storage requirements 2C to 8C. - 3 FastPack System FT4 Calibrators. Storage requirements 2C to 8C. - 2 FastPack System TSH Reagent Kits. Storage requirements 2C to 8C. - 2 FastPack System FT4 Reagent Kits. Storage requirements 2C to 8C. - 1 FastPack System PSA Reagent Kit. Storage requirements

	2C to 8C. Med Refrigerator - 1 FastPack System PSA Reagent Kit. Storage requirements 2C to 8C. - 1 FastPack System Vitamin D Reagent Kit. Storage requirements 2C to 8C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document refrigerator/freezer temperatures for 490 of 722 days from 6/14/2023 to 6/5/2025. 3. TP #1 confirmed the findings above on 6/5 /2025 at 1:00 pm. B. Based on record review, lack of documentation, and interview with Testing Personnel (TP) #1, the laboratory failed to monitor and document daily humidity readings to ensure proper operating conditions were met for 1 of 1 FastPack System chemistry analyzer used for endocrinology examinations from 6/14/2023 to 6 /5/2025. Findings include: 1. On the day of survey, 6/5/2025 at 12:30 am, review of laboratory temperature records revealed the laboratory failed to monitor and document daily humidity readings to ensure operating conditions were met for 1 of 1 FastPack System analyzer used for endocrinology examinations from 6/14/2023 to 6/5/2025. 2. The manufacturer's acceptable temperature and humidity ranges for the FastPack System is as follows: - Temperature 15C to 32C - Humidity 10% to 90% Relative Humidity 3. TP#1 confirmed the findings above on 6/5/2025 at 1:00 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Laboratory Director (LD) and testing personnel (TP) #1, the laboratory failed to establish criteria for acceptable performance specifications for Complete Blood Count (CBC) testing performed on 1 of 1 Beckman Coulter DxH 520 hematology analyzer before reporting patient results from March 2024 to the date of survey. Findings Include: 1. On the day of the survey, 06/05/2025 at 11:00 am, review of the Beckman Coulter DxH 520 performance specification records revealed the validation performed in March 2024 for CBC testing did not include the laboratory's acceptable criteria for performance specifications for precision, accuracy, and reportable ranges. 2. The laboratory could not provide documentation for the verification of accuracy and that reference range /normal value are appropriate for the laboratory's patient population for the following hematology analytes performed on 1 of 1 Beckman Coulter DxH 520 hematology analyzer from March 2024 to the date of the survey: - White Blood Cell Count - Platelet Count - Red Blood Cell Count - Mean Platelet Volume - Hemoglobin - Neutrophil % - Hematocrit - Lymphocyte % - Mean Corpuscular Volume - Monocyte % - Mean Corpuscular Hemoglobin - Eosinophil % - Mean Corpuscular Hemoglobin Concentration - Basophil % - Red Cell distribution Width - Immature Granulocyte % 3. The LD confirmed the findings above on 6/5/2025 at 2:00 pm.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	(a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with testing personnel #1 (TP), the laboratory failed to perform calibrations on 1 of 1 Beckman Coulter DxH 520 hematology analyzer used to perform complete blood count (CBC) examinations from March 2024 to the date of the survey. Findings Include: 1. The Beckman Coulter DxH 520 manual stated, "calibration is performed every 6 months or when advised by Coulter representative". 2. On the day of the survey, 6/5/2025 at 12:30 pm, the laboratory failed to provide documentation for calibrations performed every 6 months on 1 of 1 Beckman Couler DxH 520 hematology analyzer from March 2024 to the date of the survey. 3. The laboratory performed 100 hematology (CBC) examinations (CMS 116, estimated annual volume). 4. TP #1 confirmed the finding above on 6/5/2025 at 1:30 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 (TP) #1, the laboratory failed to perform calibration verification at least once every six months for 1 of 1 Fast Pack IP chemistry analyzer from 6/14/2023 to the date of survey. Findings include: 1. On the date of survey, 06/05/2025 at 12:00 pm, the laboratory failed to provide calibration verification records performed at least once every 6 months for the

	following analytes tested on 1 of 1 Fast Pack IP chemistry analyzer from 6/14/2023 to 06/05/2025: - Vitamin D - Prostrate Specific Antigen -Thyroid Stimulating Hormone - Free Thyroxine 2. The laboratory performed 250 chemistry examinations in 2024 (CMS 116, estimated annual volume). 3. TP #1 confirmed the findings above on 06/05 /2025 at 01:30 pm. ***REPEAT DEFICIENCY***
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #1, the laboratory failed to include two control materials of different concentrations for endocrinology tests performed on 1 of 1 FastPack IP System chemistry analyzer , at least once each day of patient testing from 06/14/2023 to the date of survey. Findings include: 1. On the day of survey, 6/5/2025, the laboratory failed to provide documentation for the two control materials of different concentrations of QC run at least once a day for endocrinology testing performed on 1 of 1 FastPack IP System chemistry analyzer from 06/14/2023 to 6/05/2025. 2. The laboratory performed 250 chemistry examinations in 2024 (CMS 116 estimated annual volume). 3. TP#1 confirmed the finding above on 6/5/2025 at 12:05 pm.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, lack of documentation, and interview with testing personnel (TP)#1, the laboratory failed to provide documentation of the corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing performed on 1 of 1 Beckman Coulter DxH 520 analyzer from 6/14/2023 to 6/5/2025. Findings Included: 1. On the day of survey, 6/5/2025 at 11:30 AM, review of the laboratory's QC records revealed that the following QC results for hematology testing performed from 6/14/2023 to 6/5/2025 failed to meet the laboratory's established acceptable criteria: Abnormal Low Control Normal Control Abnormal High - 7/24/2024 -7/24 /2024 -7/24/2024 - 11/19/2024 -11/14/2024 -1/28/2025 -12/5/2024 -11/19/2024 -1/29 /2025 - 12/9/2024 -11/27/2024 -2/5/2025 - 1/28/2025 -12/6/2024 -3/27/2025 -1/29 /2025 -12/10/2024 -2/12/2025 -12/13/2024 -3/27/2025 -1/28/2025 -1/31/2025 -3/27 /2025 2. The laboratory reported the following patients when QC did not meet the laboratory's established acceptable criteria: - 1/28/2025 Specimen ID# 10978 - 1/29 /2025 Specimen ID# 1043 - 1/29/2025 Specimen ID # 2208 3. The laboratory could not provide documentation of the corrective actions taken for QC performed on the

	Beckman Coulter DxH 520 that did not meet the laboratory's established acceptable criteria. 4. The laboratory could not provide documentation that the patient test results were evaluated to determine if the results were adversely affected due to QC failures. 5. TP #1 confirmed the findings above on 6/5/2025 at 1:45 PM.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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 lack of documentation and interview with the Laboratory Director (LD), the LD failed to ensure a Quality Assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality for endocrinology and hematology analyses performed for 2 of 2 years from 6/14/2023 to 6/5/2025. Findings include: 1. On the day of the survey, 6/5 /2025, the laboratory failed to provide a QA procedure or documentation for the QA activities performed for 2 of 2 years from 6/14/2023 to 6/5/2025. 2. The LD confirmed above findings on 6/5/2025 at 1:30 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD), the TC failed to assess the competency of 1 of 1 testing personnel (TP) that performed endocrinology and hematology testing from 6/14/2023 to 6/5/2025. Findings include: 1. On the day of survey, 6/5/2025 at 11:00 am, the laboratory failed to provide competency assessment records for 1 of 1 TP (CMS 209 TP#1) that performed endocrinology and hematology testing from 6/14/2023 to the date of the survey. 2. The laboratory performed 250 endocrinology, and 100 hematology examinations in 2024 (CMS 116, estimated annual volume). 3. The LD confirmed the findings above on 6/5/2025 at 1:30 pm.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with testing personnel #1 (TP), the

	Technical Consultant (TC) failed to reevaluate and document the performance of 1 of 1 TP responsible for moderate complexity hematology testing performed on new instrumentation (Beckman Coulter DxH 520) prior to reporting patient test results from March 2024 to the date of survey. Findings include: 1. At the time of survey, 06 /05/2025 at 12:00 pm, the laboratory failed to provide documentation of the reevaluation of performance for 1 of 1 TP (CMS 209 TP#1) that performed complete blood counts (CBC) on new instrumentation (Beckman Coulter DxH 520) implemented by the laboratory prior to reporting patient test results from March 2024 to the date of survey. 2. The laboratory performed 100 hematology examinations in 2024 (CMS 116, estimated annual volume). 3. TP #1 confirmed the above findings on 6/5/2025 at 12:30 pm.