Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2042355	10/03/2018
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on Interview with Testing Personnel (TP) #2 and the American Association of Bioanalysts (AAB) Proficiency Testing (PT) record review, the laboratory failed to enroll in PT Hematology tests on the Beckman Coulter Act diff 2 Analyzer and Chemistry tests run on the Fast Pack IP system in 2018. Findings Include: 1. On the day of survey, 10/03/2018, when the surveyor asked to see ABB PT records, TP#2 stated, " PT has not yet been performed in 2018". Review of past AAB PT records revealed, the last PT performed onsite was event #3 of 2017. 2. Regulated analytes run on the Fast Pack IP system: Free Thyroxine and Thyroid Stimulating Hormone. 3. Regulated analytes run on the Act diff 2 Analyzer: Erythrocyte Count, Hematocrit, Hemoglobin, Platelets count and Cell Identification. 4. TP#2 confirmed that the laboratory was not enrolled in PT program for the tests listed above on 10/03/2018 around 10:15 am.
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 of review of laboratory's procedure manual and interview with the Testing Personnel (TP) #2, the laboratory failed to establish and follow written policy or procedure to assess employee competency from 06/08/2017 to the date of survey for 1 of 2 TP. Findings include: 1. On the day of survey, 10/03/2018, TP#2 could not produce a written policy and procedure to assess CLIA's 6 points of employee competency. 2. From 06/08/2018 to 10/03/2018, 1600 specimen were analyzed. 3. TP#2 confirmed on 10/03/2018 around 10:30 am that a competency assessment policy or procedure did not exist.
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 upon surveyor review of the laboratory procedure manual and interview with the testing personnel (TP) #2, the Hematology procedure manual (1 of 1) failed to meet the applicable requirements under 493.1251 (b) for testing performed on the Beckman Coulter AcT Diff 2. Findings include: 1. On the day of survey, 10/03/2018, review of the Laboratory procedure manual revealed, the manual did not include the areas listed below and was not signed by the laboratory director before use. - Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. - Calibration and calibration verification procedures. - The reportable range for test results for the test system as established or verified in. - Control procedures. - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - Limitations in the test methodology, including interfering substances. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - Pertinent literature references. - The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting

	imminent life threatening results, or panic, or alert values. - Description of the course of action to take if a test system becomes inoperable. 2. TP#2 confirmed the findings above on 10/03/2017 around 10:15 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on tour of Laboratory and interview with the Testing Personnel (TP) #2, the laboratory failed to ensure that 1 of 1 box of Becton Dickinson Ethylenediaminetetraacetic acid (EDTA) Purple Top vacutainer tubes were not used beyond the expiration date. Finding Include: 1. On the day of survey, 10/03/2018, while on a tour of the laboratory, the surveyor observed, 1 of 1 box of Purple Top EDTA vacutainer tubes, Lot # 4156935,used for the AcT diff 2 hematology analyzer, expired 10/2015. 2. In 2017, 100 CBC tests were analyzed. 3. In 2018, 80 CBC tests were analyzed. 4. TP #1 confirmed the above findings on 10/03/218 around 11:50 am. * CBC = Complete Blood Count
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on laboratory tour, observation of Clay Adams Compact II Centrifuge and interview with Testing Personnel (TP) #2, the laboratory failed to document maintenance for the 1 of 1 Clay Adams Compact II Centrifuge. Findings include: 1. On the day of survey, 10/03/2018, the maintenance sticker observed on the Clay Adams Compact II Centrifuge, indicated that the last maintenance on the centrifuge was performed 02/2012 and was to be serviced by 08/2012. 2. The Laboratory could not provide maintenance records from 06/08/2017 to 10/03/2018. 3. The Centrifuge is used for Endocrinology tests run on the Qualigen FastPack IP System. 4. In 2018, 250 patient specimen were analyzed for endocrinology (PSA, Testosterone, Vitamin D., TSH and Free T4). 5. TP #2 confirmed the findings above on 10/03/2018 around 11: 55 am.
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 interview with testing personnel (TP) #2 and review of laboratory records, the laboratory failed to perform calibration verification on the Qualigen FastPack IP System analyzer (1 of 1) from 06/08/2017 to the date of survey. Findings include: 1. On the day of survey, 10/03/2018, According to the Qualigen FastPack IP System analyzer operator's manual reviewed at the time of inspection, calibration verification must be performed on the analyzer once every 6 months. 2. TP #2 was unable to provide documentation of calibration verification of Qualigen FastPack IP System from 06/08/2017 to 10/03/2018. 3. From 06/08/2017 to 10/03/2018, around 250 patient specimen were analyzed for endocrinology (PSA, Testosterone, Vitamin D., TSH and Free T4). 4. On 10/03/2018, TP #2 confirmed the findings above around 12: 10 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records and interview with the Testing Personnel (TP) #2, the laboratory failed to include two control materials of different concentrations for endocrinology tests performed on the FastPack IP System (1 of 1), at least once each day for patient testing from 06/08/2017 to the date of survey. Findings include: 1. On the day of survey, 10/03/2018, it was revealed the laboratory did not run two control materials of different concentrations of QC at least once a day for endocrinology testing performed on the FastPack IP System instrument from 06/08/2017 to 10/03/2018. 2. From 06/2017 to 10/2018, 300 specimen were analyzed. 3. TP#2 confirmed the finding above on 10/03/2018 around 12:05 pm.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Laboratory record review and interview with Testing Personnel (TP) # 2, the laboratory failed to have a written Quality Assessment policy or procedure, that assesses the laboratories Preanalytical, Analytical and Postanalytical system activities from 2017 to the time of survey. Findings include: 1. On the day of survey, 10/03 /2018, TP#2 could not provide the surveyor with a quality assurance/assessment policy or quality assurance/assessment documentation records from 06/2018 to 10 /2018. 2. The laboratory did not run two control materials of different concentrations of QC at least once a day for endocrinology testing performed on the FastPack IP System instrument from 06/08/2017 to 10/03/2018. 3. The Laboratory Director failed to ensure testing personnel were competent before running patient testing. 4. TP #2 confirmed the findings above on 10/03/2018 around 10:55 am.
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, review of laboratory records, and interview with testing personnel #2, the laboratory director failed to provide overall management and direction in accordance with 493.1407 for a moderate complexity laboratory. Refer to: D5209, D5403, D5417, D5439, D5447 and D5791. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Interview with Testing Personnel (TP) #2 , and review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, the laboratory failed to enroll in PT Hematology tests on the Beckman Coulter Act diff 2 Analyzer and Chemistry tests run on the Fast Pack IP system in 2018. Refer to: D2000 .
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 of review of laboratory's procedure manuals, review of testing personnel credentials and interview with the Testing Personnel (TP) #2, the technical consultant (Laboratory Director) failed to document the performance of TP (1 of 2) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens, from 06/08/2017 to the date of survey. Findings include: 1. On the day of survey, 10/03/2018, TP#2 could not produce documentation of competency assessment performed by 12/08/2018, for their semiannual competency during the first year for testing on the AcT diff 2 and the Qualigen Fast pack IP system. 2. From 06/08/2017 to 10/03/2018, 1600 specimen were analyzed. 3. TP#2 confirm on 10/03/2018 around 10:30 pm.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Testing Personnel (TP) #2, the laboratory failed to ensure that each individual performing Moderate Complexity testing is qualified. Refer to: D6065 .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CLIA's Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Testing Personnel (TP) #2, the laboratory failed to ensure that TP (1 of 2) performing Moderate Complexity testing is qualified from 06/08/2017 to the date of survey. Findings Include: 1. The CMS 209 form signed by the Laboratory Director (10/02/2018), lists Individual #2 as a Testing Personnel (TP). 2. On the date of the survey (10/03/2018)

	TP#2 failed to provide her educational credentials for performing Moderate Complexity testing. 3. The TP#2 confirmed the findings above on 10/03/2018 around 10:00 AM.