Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0935401	03/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to retain QC records for tests performed on the Envoy 500 analyzer from January 2018 to the date of survey. The finding includes: 1. The QC records for Sodium, Chloride, Total Protein, Total Iron were not retained from 4/1/18 - 4/30/2018. 2. The QC records for low-density lipoproteins, Creatine Kinase, Uric Acid, Cholesterol, Direct bilirubin, Total Iron, were not retained from 1/1/18 - 9/18/18. 3. The TP # 1 listed on the CMS form 209 confirmed on 3/27/19 at 10:00 AM that the QC records were not retained. b) Based on the lack of Calibration Records (CR) records and interview with the TP, the laboratory failed to retain CR for tests performed on the Envoy 500 analyzer from 4/11/17 to the date of survey. The TP # 1 listed on the CMS form 209 confirmed on 3/27/19 at 11:00 am that the CR were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they

	received an unacceptable score in Chemistry with Medical Laboratory Evaluation (MLE) in the 1st event of 2018. The findings include: 1. There was no evaluation documented when the laboratory received an unacceptable grade for Iron sample CH-1 - 5, Creatine Kinase CH-2 - 5, Uric Acid CH-1, CH-2, CH-4, Cholesterol CH-2 - 5, in 1-2018. 2. There was no documented evidence the laboratory evaluated the failures. 3. The TP#1 confirmed on 3/24/18 at 10:20 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Insert, observation of the Quality Control (QC) material, and interview with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Hematology Control vials from August 2018 to the date of survey. The findings include. 1. The MPI for Eightcheck -3WP X-TRA Controls stated that QC vials for Hematology expired 14 days after opening if stored at 2 to 8 degrees Celsius. 2. The TP was not aware that QC vials expired 14 days after opening. 3. The TP #1 on CMS form 209 confirmed on 3/27/19 /19 at 10:30 am the laboratory failed to put new expiration dates on the control vials.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures were performed on the Sysmex XP 300 analyzer from August 2018 to the date of survey. The finding includes: 1. There was no documented evidence Accuracy and Reportable Range Verification was performed. 2. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 11:15 am that PS records were performed.
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 the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to ensure two levels of QC was required in range on each day of patient testing for Chemistry tests performed on the Envoy +500 from 12/4/18 to the date of survey. The findings include: 1. A review of the QC records revealed that controls were out of range as follows: a. 12/4/18 - Blood urea nitrogen low control . b. 12/11/18- Carbon dioxide low control. c. 12/18/18 - Creatine Kinase low control d. 12/20/18 - Serum Glutamic-Oxaloacetic Transaminase low and high control. e. 12/28/18 - Serum Glutamic-Oxaloacetic Transaminase high control. f. 12/28/18 - Blood urea nitrogen high control. g. 2/1/19 - Calcium low control h. 2/26 /19 - Blood urea nitrogen high control. 2. Approximately one to three patients were run and reported each with one level of QC in range. 3. The TP#1 listed on CMS form 209 confirmed on 3/27/19 at 10:50 am that laboratory failed to have to ensure two levels of QC was required in range on each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: a) Based on surveyor review of Quality Control (QC) records, Manufacture's Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Hematology testing performed on the Sysmex XP300 analyzer from August 2018 to the date of survey. The TP #1 lisetd on CMS form 209 confirmed on 3/27/2019 at 12: 00 pm that the QC materials were not verified before putting in use. b) Based on surveyor review of Quality Control (QC) records, Manufacture's Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Routine Chemistry testing performed on the Envoy 500+ analyzer from 4/11/17 to the date of survey. The TP #1 lisetd on CMS form 209 confirmed on 3/27/2019 at 12:00 pm that the QC materials were not verified before putting in use.
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 an surveyors review of the laboratory's records, procedures and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 4/11/17 to the date of the survey. 1. The LD failed to ensure PT results were reviewed. Cross Refer to D6018. 2. The LD failed to ensure a Quality Control program was maintained. Cross Refer to D6020. 3. The LD failed to ensure a Quality Assessment program was maintained. Cross Refer to D6021. 4. The LD failed to establish a Competency Assessment procedure with the applicable elements. Cross Refer to D6103.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Control (QC) program was maintained for Hematology and Chemistry Testing from 4/11/17 to the date of survey. The findings include: 1) The PM stated that "Levy-Jennings charts for all analytes must be printed at the end of month for review by the Technical Supervisor and/or Director". 2) Levy Jennings Charts for Total Protein, Albumin, Globulin, Creatine Kinase, Blood urea nitrogen, Creatinie, Date range 1/1/18 - 7/31/2018 had not QC results for 9/18/2018. 3) There was no evidence of monthly QC review. 4) The TP #1 listed on CMS from 209 confirmed on 3/27/19 at 11:00 am that a QC program was not maintained.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Assurance (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was maintained from 4/11/17 to the date of survey. The findings include: 1. The QA procedure stated the Technical Supervisor and or Laboratory Director will complete a "Monthly review tracking sheet". 2. The QA procedure stated the Technical Supervisor and or Laboratory Director will complete a "Case study review". 3. The QA procedure stated "Quality Assurance meeting - The Laboratory Director, Technical Supervisor and all Technical Staff will meet quarterly to assess the performance of the laboratory" 4. The QA procedure stated "Semi-Annually: Split samples analysis. The Laboratory will send 5 samples to an outside laboratory using the same or similar methodology to ascertain the reliability of the results" 5. The QA procedure stated that "Annually: Reference Range review Reference Ranges for assays performed in lab must be reviewed annually and/or with any instrument change or change in the patient population" 6. There was no documented evidence that a above procedures were completed. 7. The TP #1 listed on CMS form 209 confirmed on 3/27/19 at 11:50 am that the laboratory did not maintain the QA program.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the elements for TP from 4/11/17 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 3/27/19 at 10:30 am that a CA procedure was not established.