Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0678186	04/18/2018
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to ensure the proper storage of BD Veritor and Henry Schein Rapid Strep test kits. The findings were: 1. Direct observation made in the computer room on 04/18/2018 at 1615 hours revealed no method to monitor the room temperature. 2. Further observations revealed 1 opened box of BD Veritor Influenza A & B test kit and 1 opened box of Henry Schein Rapid Strep test kit located in an overhead cabinet. 3. Review of the manufacturer's instructions for the BD Veritor (8087667(13) 2017-10) under "Storage and Handling" stated, "Kits may be stored at 2-30 degrees Celsius ..." 4. Review of the manufacturer's instructions for the Henry Schein OneStep Strep A Dipstick Test (DN 1155800607) under, "Storage and Stability" stated, "The kit can be stored at room temperature or refrigerated (2-30 degrees Celsius)." 5. Review of patient test logs from March and April 2018 revealed the following patients were tested for Strep A when the temperature of the room where the test kit was stored was not monitored: Patient ID 32982 Date: 04/10/2018 Patient ID 34871 Date: 03/05/2018 Patient ID 22320 Date: 03/05/2018 Patient ID 22345 Date: 03/01/2018 6. Review of patient testing logs from February and March 2018 revealed the following patients were tested for Influenza A & B when the temperature of the room where the test kit was stored was not monitored: Patient ID (not legible) Date: 03/05/2018 Patient ID (not legible) Date: 03/05/2018 Patient ID 3756 Date 03/01/2018 Patient ID 42349 Date: 03/01/2018 Patient ID 22664 Date: 02 /27/2018 Patient ID 93066 Date: 02/27/2018 Patient ID 31953 Date: 02/20/2018

	Patient ID 1158 Date: 02/20/2018 Patient ID 7036 Date: 02/15/2018 Patient ID 3657 Date: 02/15/2018 Patient ID 11487 Date: 02/13/2018 Patient ID 10953 Date: 02/13 /2018 Patient ID (not legible) Date: 02/11/2018 Patient ID (not legible) Date: 02/11 /2018 Patient ID (not legible) Date: 02/11/2018 7. The laboratory was asked to provide documentation of monitoring the room temperature where BD Veritor and Henry Schein Rapid Strep A test kits were stored. No documentation was provided 8. An interview with testing personnel one as listed on Form CMS-209 on 04/18/2018 at 1630 hours in the hallway confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute's (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same number of times it tests patient samples. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing Policy" stated, "PT specimens are to be treated the same as patient samples..." 2. Review of the laboratory's hematology API proficiency testing records from 2016 (event 3) and 2017 (events 1, 2, and 3) revealed the following specimens met the laboratory's repeat criteria. The laboratory did not test the proficiency testing sample the same number of times it would routinely test a patient: 2017 (event 1) ID: HEM-03 Flag: AF Not repeated 2017 (event 2) ID: HEM-07 Flag: TM Not repeated 2017 (event 2) ID: HEM-08 Flag: AF Not repeated 2017 (event 2) ID: HEM-10 Flag: AF, TM Not repeated 3. The laboratory was asked to provide documentation of testing the proficiency testing samples the same number of times it tested patients. No documentation was provided. 4. An interview with testing personnel one as listed on Form CMS-209 at 1130 hours in the laboratory confirmed the findings. He revealed that for an AF (aspiration failure), he would, "Definitely repeat the sample." Key: CMS - Centers for Medicare and Medicaid Services
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of patient test results, and staff interview, it was revealed the laboratory failed to follow its own policy to perform repeat testing for verification of CBC (complete blood count) results. The findings were: 1. A review of the laboratory's policy titled "Policy For Repeating CBC Tests" revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following range." RBC Less than 4.0 or Greater than 6.0 million WBC Less than 4.0 or Greater than 11.0

	thousand HCT Less than 30.0 or Greater than 50.0 % HGB Less than 10.0 or Greater than 18.0 mg PLT Less than 150.0 or Greater than 450.0 thousand 2. A random sampling of patient charts from April 2017 revealed the following patients whose CBC results met the laboratory's repeat testing criteria, but the laboratory did not perform the required repeat testing: Date Patient ID Result 04-02-2018 14356 WBC = 14.4 04-04-2018 22083 WBC = 3.2 04-04-2018 DAVY0000 WBC = 2.9 04-05-2018 AREMA001 WBC = 12.6 04-10-2018 PERJU003 WBC = 12.4 04-10-2018 19556 WBC = 11.5 04-10-2018 VALAI000 WBC = 3.2 04-11-2018 JENIS000 WBC = 12.8 04-12-2018 33158 WBC = 11.3 04-13-2018 32355 WBC = 12.5 04-16-2018 6604 WBC = 16.6 04-16-2018 22107 WBC = 14.6 04-16-2018 34460 WBC = 11.9 3. The laboratory was asked to provide documentation of following its own policy to repeat CBC results outside of its defined repeat criteria. No documentation was provided. 4. An interview with testing personnel number 1 as listed on Form CMS-209 on 04/18 /2018 at 1545 hours in the laboratory confirmed the findings. He revealed he didn't realize the criteria was so tight and was repeating results when the results were higher or lower than the values listed. Key: WBC - white blood count CMS - Centers for Medicare and Medicaid Services
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 direct observation, review of laboratory policy, review of manufacturer's instructions, review of the laboratory's calibration verification records from 2017 and 2018 (as of the day of the survey), and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verifications for analytes tested on the Envoy 500 every 6 months. Note: This is a repeat deficiency. The findings were: 1. Based on direct observation in the laboratory refrigerator on 04/18 /2018 at 0920 hours revealed the laboratory performs two levels of quality control for chemistry each day of patient testing on the Envoy 500. Analytes performed on the Envoy 500 are calibrated with 2-point calibrators or less. The laboratory is required to perform calibration verification. 2. Review of laboratory policy titled, "Calibration

	Validation" approved by the laboratory director on 01/16/2013, stated, "It is the policy of this laboratory to validate calibrations: every 6 months, following a complete reagent change, following major preventative maintenance, following replacement of a critical part or when shifts or trends in QC are seen." 3. Review of calibration verification records revealed the laboratory performed calibration verification as follows: June 16, 2017 (as part of initial instrument installation) February 14, 2018 (7 months, 29 days later) 4. The analytes tested on the Envoy 500 were: Alananine transaminase Glucose High density lipoprotein Triglycerides Total cholesterol Total bilirubin Aspartate aminotransferase Alkaline phosphatase Blood urea nitrogen Creatinine Sodium Potassium Chloride Carbon dioxide Calcium Total protein Albumin 5. The laboratory was asked to provide documentation of performing calibration verification on the Envoy every six months. No documentation was provided. 6. An interview with the technical consultant on 04/18/2018 at 1400 hours in the break room confirmed the findings.
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: Based on direct observation, review of the manufacturer's instructions for the Envoy 500 Serum Control Kit (Product No. 55131) chemistry control, review of the laboratory's quality control records from November 2017 to March 2018, and staff interview, it was revealed the laboratory failed to have documentation of establishing its own assay ranges as required by the manufacturer. The findings were: 1. Direct observation made in the laboratory on 04/18/2018 at 1400 hours revealed the following means and ranges were entered into the Envoy 500 chemistry analyzer: Serum Control Kit Lot 6151 Expiration Date: 12-2018 Analyte Mean & Range Mean & Range Control Level 1 Control Level 2 Albumin 4.45 / 4.15-4.75 2.92 / 2.62-3.22 ALP 103 / 84-122 478 / 407-549 T. Bili 0.79 / 0.56-1.02 7.31 / 6.34-8.28 2. A review of the manufacturer's instructions for the Envoy 500 Serum Control Kit under the section titled "Assigned Values and Ranges" stated, "...For routine use it is recommended that each laboratory establishes its own means and acceptable ranges and use the published ranges as a guide." 3. A review of the laboratory's quality control records from November 2017 to March 2018 revealed the laboratory placed the following lot of controls into use: Lot 6151 Expiration Date: 12-2018 4. The laboratory was asked to provide documentation of establishing target values as required by the manufacturer. No documentation was provided. 5. An interview with testing personnel number 1 as listed on Form CMS 209 on 04/18/2018 at 1405 hours in the laboratory revealed the laboratory utilized the manufacturer's means and ranges

	for quality control. When asked if the ranges in the instrument were the manufacturer's ranges or the laboratory's established means and ranges, he stated, "The manufacturer's." This confirmed the findings.