

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1000954	(X3) Date Survey Completed 12/09/2019
Name of Provider or Supplier Warrenfield Medical Center	Street Address, City, State 14716 W Warren Ave, Dearborn, MI	
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
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Supervisor (TS), the laboratory had broken printers for 3 (Roche Cobas Miras Plus, AVL 9180, and IsoComp I) of 4 analyzers observed. Findings include: 1. An observation by the surveyor on 12/9/19 at 9:10 am revealed the following analyzers equipped with printers were present in the laboratory: a. Cobas Miras Plus chemistry analyzer b. AVL 9180 electrolyte analyzer c. IsoComp I 2. The surveyor requested the laboratory's instrument printouts for quality control, calibrations, and patient testing performed on the analyzers listed above on 12/9/19 at 9:10 am and they were not made available. 3. An interview on 12/9/19 at 9:10 am with the TS confirmed the printers on the analyzers listed above were broken and no longer functioned.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

. The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to establish a procedure for performing electrolyte testing on the AVL 9180 analyzer. Refer to D5401. 2. The laboratory failed to establish a step-by-step performance procedure, preparation of materials procedure, calibration procedure, corrective action procedure, and limitations in test method for Complete Blood Count (CBC) testing. Refer to D5403. 3. The laboratory failed to perform calibration and calibration verification procedures for chemistry and endocrinology testing. Refer to D5439. 4. The laboratory failed to perform hematology controls at least once each day of patient testing. Refer to D5445.

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 record review and interview with the Technical Supervisor (TS), the laboratory failed to establish a procedure for performing electrolyte testing on the AVL 9180 analyzer for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A record review of the laboratory's established procedure manual revealed a lack of procedure to perform the following tests on the AVL 9180 analyzer: a. Chloride b. Sodium c. Potassium 2. An interview on 12/9/19 at 10:30 am with the TS confirmed the laboratory did not have a procedure to perform the tests listed above. ***Repeat deficiency from the 9/2/09 survey***

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 on record review and interview with Technical Supervisor (TS), the laboratory failed to establish a step-by-step performance procedure, preparation of materials procedure, calibration procedure, corrective action procedure, and limitations in test method for Complete Blood Count (CBC) testing for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A record review of the laboratory's established "Automated Hematology" procedure revealed a lack of the following procedural components for CBC testing: a. A step-by-step performance of the procedure, including test calculations and interpretation of results. b. The preparation of materials including reagents, controls, and calibrators. c. Calibration procedure. d. Corrective action procedure. e. Limitations in the test method, including interfering substances. 2. An interview on 12/9/19 at 10:07 am with the TS confirmed the laboratory had not established the procedural components listed above for CBC testing.

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 record review and interview with the Technical Supervisor (TS), the laboratory failed to perform calibration and calibration verification procedures for chemistry and endocrinology testing for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. A review of the laboratory's established procedure titled "Calibration and Calibration Verification" revealed a section stating, "Cobas Mira Plus calibration every 6 months or as needed (example, controls not in range). Gamma counter calibration every six months and background checked before daily use." 2. A record review of the laboratory's calibration and calibration verification documentation revealed a lack of documented calibration verification for the following assays performed by the laboratory: a. Hemoglobin A1C, performed on the Roche Cobas Mira Plus analyzer, b. Thyroid Stimulating Hormone (TSH), performed on the IsoComp I gamma counter c. Free Thyroxine (FT4), performed on the IsoComp I gamma counter d. Vitamin D, performed on the IsoComp I gamma counter 3. When requested on 12/9/19 at 10:15 am, the laboratory was unable to provide the surveyor with calibration verification data for the assays listed above. 4. A record

review of the laboratory's "Immunodiagnostic Systems 25-Hydroxy Vitamin D RIA" package insert revealed a section titled "Calculation of Results" stating, "Prepare a calibration curve on semi-log graph paper by plotting B/Bo% on the ordinate against concentration of 25-hydroxy-Vitamin D on the abscissa. Calculate B/Bo% for each unknown sample and read values off the curve in nmol/L (nM)." 5. A record review of the laboratory's "ImmuChem Coated Tube TSH" package insert revealed a section titled "Calculations" stating, Take the average of the counts of all duplicates. Plot the averaged counts (y-axis) versus the standard concentration (x-axis) on 3 cycle log-log paper. Using the standard curve constructed above, determine the hTSH concentrations of each sample." 6. A record review of the laboratory's "Free T4 Solid Phase Component System" package insert revealed a section titled "Assay Procedure" stating, "The preparation of the standard curve and the clinical determinations must be run simultaneously. Control sera should be run at the same time as patient samples." 7. When requested on 12/9/19 at 10:15 am, the laboratory was unable to provide the surveyor with the standard (calibration) curves for Vitamin D, TSH, and FT4 assays used in the determination of patient test results. 8. An interview on 12/9/19 at 10:15 am with the TS confirmed calibration and calibration verification data was not available for the assays listed above.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(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--
 (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to perform hematology controls at least once each day of patient testing for 1 (patient #12051) of 9 patient charts audited. Findings include: 1. A record review of patient testing results revealed patient #12051 had Complete Blood Count (CBC) testing performed on 3/3/18. 2. A record review of the laboratory's established "Automated Hematology" procedure revealed a section titled "Controls" stating, "Run 3 controls low, normal, high." 3. A record review of the hematology controls revealed a lack of documentation of quality control performed on 3/3/18. 4. An interview on 12/9/19 at 1:35 pm with the TS confirmed no quality control documentation was available for CBC testing on 3/3/18.