

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1008641	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Flushing Road Internal Medicine & Pediatrics	Street Address, City, State 1201 Flushing Road, Flint, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, procedure review, and interview with Technical Supervisor #2 (TS2), the laboratory failed to keep beverages out of the refrigerator designated for laboratory reagents, quality control, and patient specimens. Findings include: 1. An observation by the surveyor during the laboratory tour on 4/24/19 at 8:55 am revealed a bottle of coffee creamer in the door of the laboratory refrigerator containing patient specimens, quality control, and reagents. 2. A review of the laboratory's procedure manual revealed a policy in the "Lab Rules" section stating, "No eating, drinking, or applying of make up." 3. An interview with TS2 on 4/24/19 at 9:00 am confirmed coffee creamer was present in the laboratory refrigerator.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with Technical Supervisor #1 (TS1), the</p>

laboratory failed to label reagents on the AIA-360 TOSOH analyzer with the preparation dates, expiration dates, and lot numbers. Findings include: 1. During a tour of the laboratory on 4/24/19 at 8:55 am, the surveyor observed a lack of documentation and labeling of preparation dates, expiration dates, and lot numbers for the wash and diluent reagents in use on the AIA-360 TOSOH analyzer. 2. An interview with TS1 on 4/24/19 at 9:06 am confirmed the lack of documentation and labeling of preparation dates, expiration dates, and lot numbers on the above mentioned reagents.

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 Technical Supervisor #1 (TS1), the laboratory failed to perform calibration verification for the Prostate Specific Antigen (PSA) assay for 2 (second event of 2017 and first event of 2018) of 4 testing events at least once every 6 months. Findings include: 1. A record review revealed a lack of documentation of calibration verification for the AIA-360 TOSOH analyzer PSA assay during the second testing event of 2017 and the first testing event of 2018. 2. An interview with TS1 on 4/24/19 at 12:05 pm confirmed the calibration verification was not completed at least every 6 months in 2017 and 2018.

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 record review and interview, the laboratory failed to provide the

educational requirements for 1 (Testing Personnel #1) of 1 who performs moderately complex hematology and chemistry testing. 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 record review and interview with Technical Supervisor #1 (TS1), the laboratory failed to ensure all testing personnel met the educational requirements for 1 (Testing Personnel #1) of 1 testing personnel. Findings include: 1. A record review of credentials for Testing Personnel #1 revealed a lack of documentation of educational requirements for performing moderately complex laboratory testing. 2. During the interview on 4/24/19 at 9:15 am, TS1 confirmed the above findings. 3. The laboratory was given 5 additional days to supply the necessary educational documents. The documents were not received.