

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1010918	(X3) Date Survey Completed 11/13/2018
Name of Provider or Supplier City Medical	Street Address, City, State 30581 Stephenson Hwy, Madison Heights, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain the temperature charts for 12 (November to December 2016 and January to October 2017) of 24 months reviewed to ensure proper operation of the laboratory testing instruments and the storage of reagents and quality control material. Findings include: 1. On November 13, 2018 at 11:45 AM, record review of the monthly temperature charts for the room temperature, humidity, refrigerator, and freezer readings the laboratory did not retain the following months a follows: a. 2016 - November to December b. 2017 - January to October 2. During the interview on November 13, 2018 at 11:45 AM, technical consultant #2 as listed on the CMS-209 confirmed the daily temperature readings and documentation were not retained.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to have a written request for patient testing from an authorized person for three (#1, #2, and #12) of 13 patient charts audited for the endocrinology thyroid stimulating hormone (TSH) and the</p>

prostate-specific antigen (PSA) testing and the toxicology urine drug screen (UDS) testing. Findings include: 1. On November 13, 2018 at 1:50 PM, record review for three of 13 patient charts audited revealed the laboratory was not able to show the surveyor the written request for the laboratory testing as follows: a. patient #1 - TSH b. patient #2 - UDS c. patient #12 - PSA 2. During the interview on November 13, 2018 at 1:50 PM, technical consultant #2 as listed on the CMS-209 confirmed the laboratory did not have a written request for the testing performed and documented.

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 record review and interview, the laboratory failed to perform and document the weekly chemistry FRENED maintenance as required by the manufacturer for five (January, April, May, July, and August) of 24 months reviewed. Findings include: 1. On November 13, 2018 at approximately 1:00 PM, record review of the "FRENED Maintenance Log" revealed the laboratory did not have documentation to show the daily maintenance tasks of: "Power-on Analyzer & view Main Screen, Perform and Print daily System Check, and Wipe Analyzer - dry cloth" were performed on days of operation as follows in 2018: a. January 17 b. April 18 c. May 9 and 21 d. July 6, 18, and 25 e. August 1, 10, and 22 2. During the interview on November 13, 2018 at approximately 1:00 PM, technical consultant #2 as listed on the CMS-209 confirmed the maintenance tasks were not completed and documented as required.

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, the laboratory failed to perform quality control as required for the endocrinology thyroid stimulating hormone (TSH) and prostate-specific antigen (PSA) testing for two (#8 and #11) of 13 patient charts audited. Findings include: 1. On November 13, 2018 at 12:45 PM, record review for the TSH and PSA quality control logs revealed the laboratory did not perform and document at least two levels of controls each day of patient testing for the endocrinology testing as follows: a. TSH b. PSA 2. On November 13 2018 at 12:45 PM when queried, technical consultant #2 as listed on the CMS-209 was not able to provide the surveyor the quality control results for at least two different levels of

	<p>controls for the day of testing for patient #8 and #11. 3. During the interview on November 13, 2018 at 12:45 PM, technical consultant #2 confirmed two levels of controls were not performed and documented and that an individualized quality control plan had not been implemented to decrease the number or frequency of running external controls.</p>
<p>D5803</p>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to 1) produce the patients paper charts for two (#1 and #2) of 13 charts audited and 2) maintain the final tests report for four (#4, #10, #11, and #12) of 13 patient charts audited for the endocrinology thyroid stimulating hormone (TSH) and prostate-specific antigen (PSA) and the toxicology urine drug screen (UDS) testing. Findings include: 1. On November 13, 2018 at approximately 12:35 PM, document review revealed the laboratory did not have the final test report maintained as part of the patient's paper chart as follows: a. no chart 1. patient #1 - TSH 2. patient #2 - UDS b. no results in paper chart 1. patient #4 - PSA 2. patient #10 -TSH and PSA 3. patient #11 - PSA 4. patient #12 - TSH and PSA 2. During the interview on November 13, 2018 at approximately 12:35 PM, technical consultant #2 as listed on the CMS-209 confirmed the patient's paper charts and/or the final test reports were not available to the surveyor for review.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to provide the educational requirements for two (#3 and #4) of five testing personnel who perform moderately complex hematology testing. Refer to D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p>

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, the laboratory failed to ensure that all testing personnel met the educational requirements at 493.1423 for two (#3 and #4) of five testing personnel as listed on the CMS-209 performing moderately complex hematology testing. Findings include: 1. On November 13, 2018 at 9:52 AM, record review for two of five testing personnel credentials revealed the educational requirements for performing moderately complex hematology testing was not met. 2. During the interview on November 13, 2018 at 9:52 AM, technical consultant #2 as listed on the CMS-209 confirmed the educational requirements were not met. 3. On November 13, 2018 at 9:52 AM, the laboratory was given five additional days to supply the necessary educational documents. The documents were not received.