

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0701946	(X3) Date Survey Completed 03/04/2019
Name of Provider or Supplier O L Matthews Md	Street Address, City, State 3011 W Grand Blvd Suite 466, Detroit, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: . Based on operator's manual review, record review, and interview with the technical consultant (TC), the laboratory failed to follow manufacturer's instructions for the instrument flag for five (#1602, #1606, #1610, #1611, and #1613) of 14 patient samples run on February 16, 2019. Findings include: 1. Record review of patient testing performed revealed the flag "SS" for five of 14 patient samples run on February 16, 2019. The operator's manual states "SS: The assay was cancelled because of insufficient sample. If this flag appears when there is an enough sample, either the sample nozzle or the sample detection sensor may be faulty. If this problem occurs frequently, contact the service department." a. #1602 - thyroid stimulating hormone (TSH), tape reported "SS" error, resulted out on final report as 0.0 b. #1606 - prostate specific antigen (PSA), tape reported 1.31 ng/ml with the error "Sample Shortage Detected", resulted 1.31 ng/ml on the final report c. #1610 - PSA tape reported "SS" error, resulted out on final report as 0.0 d. #1611 - PSA tape reported "SS" error, resulted out on final report as 0.0 e. #1613 - TSH tape reported "SS" error, resulted out on final report as 0.0 2. On March 2, 2019 at approximately 11:45 AM when queried, the TC stated there was no documentation that specimens were rerun prior to reporting. 3. During the interview on March 2, 2019 at approximately 11:45 AM, the TC confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical consultant (TC), the laboratory failed to perform the chemistry calibration curve for the thyroid stimulating hormone (TSH) testing for one (January 12, 2019) of five days of patient testing reviewed. Findings include: 1. Record review of patient testing performed on January 12, 2019 revealed the flag "NC" on control 1 (C1) and three (#1201, #1204, and #1206) of four patients for the TSH. The operator's manual states "NC: No result was obtained because there was no calibration curve for the item or lot. Alternatively, the concentration could not be calculated because the calibration curve has expired 60 days ago or earlier. In these cases, create a calibration curve and recalculate to obtain a result." 2. On March 2, 2019 at approximately 12:00 PM when queried, the TC stated there was no documentation that specimens were rerun prior to reporting. 3. During the interview on March 2, 2019 at approximately 12:00 PM, the TC confirmed the above findings.

D5800

POSTANALYTIC SYSTEMS
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

The laboratory failed to meet applicable postanalytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to have the patient's correct spelling of their name on the final test report. Refer to D5801. 2. The laboratory failed to provide accurate and reliable patient test results. Refer to D5801.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical

consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

. Based on record review, quality control (QC) review, and interview with the technical consultant, the laboratory director failed to ensure the overall operation of the laboratory was maintained for the analytic and postanalytic systems and that accurate results were reported. Findings include: 1. The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: a. The laboratory failed to follow manufacturer's instructions for the chemistry TOSOH AIA 360 instrument flags. Refer to D5411. b. The laboratory failed to label two (diluent and wash) of three bottles on the TOSOH AIA 360 chemistry/endocrinology instrument with the preparation and/or expiration date when first put into use. Refer to D5415. c. The laboratory failed to perform the chemistry calibration curve for the thyroid stimulating hormone (TSH) testing. Refer to D5437. d. The laboratory failed to test at least two levels of control material each day of patient testing for the endocrinology thyroid stimulating hormone (TSH) testing. Refer to D5447. 2. The laboratory failed to meet applicable postanalytic system requirements and correct identified problems. Findings include: a. The laboratory failed to have the patient's correct spelling of their name on the final test report. Refer to D5801. b. The laboratory failed to report accurate and reliable results. Refer to D5801. 3. During the interview on March 2, 2019 at approximately 12:00 PM, the TC confirmed the above findings.