Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0701946	08/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
O L Matthews Md	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document proficiency testing samples on the daily worksheet and retain the instrument printouts for six (3rd event 2016, 1st - 3rd events 2017, and 1st - 2nd events in 2018) of six events reviewed for the routine chemistry and endocrinology proficiency testing samples. Findings include: 1. On August 1, 2018 at 10:41 AM, record review of the American Proficiency Institute (API) graded proficiency testing documents revealed the laboratory did not document the proficiency testing samples on the daily worksheet and maintain the TOSOH chemistry analyzer printouts for six (3rd event 2016, 1st - 3rd events 2017, and 1st - 2nd events in 2018) of six events reviewed. 2. During the interview on August 1, 2018 at 10:41 AM, testing personnel #1 as listed on the CMS-209 confirmed the proficiency testing samples were not documented on the daily worksheet and the TOSOH instrument printouts were not maintained.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	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. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain the daily quality control records and the testing patient results for 19 (January 2017 to July 2018) of 19 months of operation for the TOSOH chemistry analyzer. Findings include: 1. On August 1, 2018 at 12:12 PM, record review of the daily worksheets revealed for 19 (January 2017 to July 2018) of 19 months of operation, the laboratory did not retain the instrument printouts from the TOSOH with the quality control and patient test results. 2. On August 1, 2018 at 12:12 PM when queried, testing personnel #1 as listed on the CMS-209 was unable to provide the surveyor the instrument printouts. 3. During the interview on August 1, 2018 at 12:12 PM, testing personnel #1 confirmed the daily quality control data and patient test results was not retained.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure that verification of performance specifications were performed and evaluated for the new chemistry TOSOH analyzer. Refer to D5421. 2. The laboratory failed to perform and document calibration verification for the chemistry prostate specific antigen (PSA) and the carcinoembryonic antigen (CEA) testing on the TOSOH analyzer at least once every six months. Refer to D5439. 3. The laboratory failed to test at least two levels of control material each day of patient testing for the chemistry and endocrinology testing. Refer to D5447.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	. Based on record review and interview, the laboratory failed to demonstrate the accuracy, precision, reportable ranges, and verify the normal ranges for the TOSOH chemistry and endocrinology testing for 19 (January 2017 to July 2018) of 19 months of operation. Findings include: 1. On August 1, 2018 at 12:20 PM, record review for the TOSOH chemistry/endocrinology instrument revealed there was no documentation to show the accuracy, precision, reportable ranges, and the verification of normal ranges were performed and documented for 19 of 19 months of operation before reporting patient test results. 2. During the interview on August 1, 2018 at 12:2 PM, testing personnel #1 as listed on the CMS-209 confirmed the performance verification documentation was not available on the day of the survey.
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, the laboratory failed to perform and document calibration verification for the chemistry prostate specific antigen (PSA) and the carcinoembryonic antigen (CEA) testing on the TOSOH analyzer at least once every six months for three (two events in 2017 and one event in 2018) of three six month events. Findings include: 1. On August 1, 2018 at 12:20 PM, lack of records for the calibration verification of the PSA and CEA revealed the laboratory did not perform and document the calibration verification on the TOSOH analyzer as least once every six months for three (two events in 2017 and one event in 2018) of three events. 2. During the interview on August 1, 2018 at 12:20 PM, testing personal #1 as listed on the CMS-209 confirmed the calibration verification was not completed at least every six months in 2017 and 2018. ***Repeat Deficiency from August 6, 2014 survey***
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 test at least two levels of control material each day of patient testing for the chemistry and endocrinology testing for one (#10) of ten patient charts audited on the day of the survey. Findings include: 1. On August 1, 2018 at 1:30 PM, record review of the daily worksheets revealed the laboratory did not have any documentation to show the quality control for the following tests were performed before testing and reporting patient results for one (#10) of ten patient charts audited : a. chemistry - carcinoembryonic antigen (CEA), lipid profile (total cholesterol, high density lipoprotein (HDL), triglycerides, and low density lipoprotein (LDL) b. endocrinology - free thyroxine (FT4) and thyroid stimulating hormone (TSH) 2. On August 1, 2018 at 1:30 PM when queried, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor the quality control results. 3. During the interview on August 1, 2018 at 1:30 PM, testing personnel #1 confirmed the quality control records were not available on the day of the survey.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to have 1) the final chemistry and endocrinology report for two (#6 and #8) of ten patient charts audited and 2) the laboratory failed to establish a system to ensure the computer generated calculations for the low density lipoprotein (LDL) and the very low density lipoprotein (VLDL) and patient test results were periodically checked for accuracy for two (July 2016 to July 2018) of two years of testing. Findings include: 1. On August 1, 2018 at 1:20 PM, document review for two (#6 and #8) of ten patient charts audited revealed the final patient test reports was not available in the patient's paper chart as follows: a. #6 - no thyroid stimulating hormone (TSH) test report in chart b. #8 - no lipid profile (cholesterol [total], high density lipoprotein (HDL), triglycerides, LDL, and VLDL, carcinoembryonic antigen, and TSH 2. On August 1, 2018 at 1:30 PM, document review revealed the laboratory was resulting two (LDL and VLDL) computer generated calculation results in the patient's final report. There was no documentation to show the calculations and patient test results were periodically checked for accuracy for two (July 2016 to July 2018) of two years. 3. During the interview on August 1, 2016 at 1:20 and 1:30 PM, testing personnel #1 as listed on the CMS-209 confirmed the final chemistry and endocrinology test result was not

	included in the patient's paper chart, the LDL and VLDL calculations, and patient test results were not periodically checked for accuracy.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to detect an incorrect laboratory test result reported out for two (#2 and #9) of ten patient charts audited. Findings include: 1. On August 1, 2018 at 1:10 PM, record review for two (#2 and #9) of ten patient charts audited revealed the final laboratory test result in the patient's paper chart was not the same result as recorded on the daily worksheet as follows: a. #2 - carcinoembryonic antigen test b. #9 - prostate specific antigen 2. During the interview on August 1, 2018 at 1:10 PM, testing personnel #1 as listed on the CMS-209 confirmed the final laboratory test report in the patient's paper chart did not match the result reported on the daily worksheet.