Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0677467	02/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Health Laboratory Inc	9100 Southwest Freeway, Suite 114 A, Houston, TX	

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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Review of American Proficiency Institute (API) proficiency testing (PT) records from 2018 and 2019, patient test results and confirmed with interview, the laboratory failed to verify the accuracy of Glycated hemoglobin (HgbA1c) twice annually either through enrollment in proficiency testing or method comparison studies. Findings were: 1. Review of the API testing records revealed the laboratory enrolled in proficiency testing records for the 2019 test events for the test HgbA1c. 2. Review of the verification studies for HgbA1c revealed the laboratory performed method comparison in 03/2018. No documentation was available for review of the second assessment in 2018. HgbA1c patient testing began in April 2018 with an annual volume of 1700 tests. 3. An interview with the primary testing person on 2/26/19 at 1100 hours confirmed the above findings. She stated that since they missed the cutoff to enroll for PT, they were unable to perform the PT and they were unaware they should perform twice annual the accuracy assessment. This is a repeat deficiency from the survey with date 04/26/17.
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: Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5421, D5439
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 a review of the chemistry verification studies, and verified by interview the laboratory failed to perform a complete verification study for Glycated Hemoglobin (HgbA1c) on the Roche integra 400 plus chemistry analyzer. Findings were: 1. A review of the Roche Integra 400 plus chemistry analyzer verification studies revealed no documentation of a normal patient ranges study for the analyte HgbA1c. 2. An interview with the primary testing person on 02/26/19 at 1100 hours confirmed the above findings. This is a repeat deficiency from the survey with date 04/26/17.
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 review of chemistry records and interview of facility personnel, the laboratory failed to document every 6 month calibration verifications on all required analytes for Roche cobas e411 and cobas integra 400 plus. Findings were: 1. Review of chemistry records revealed no documentation of calibration verification studies in 2018 on the following analytes performed on the Roche COBAS e411 clinical chemistry analyzer and calibrated with fewer than 3 calibrators: TSH, TT4, TU 2. Review of chemistry records revealed no documentation of calibration verification studies in 2018 on the following analytes performed on the Roche Integra 400 plus clinical chemistry analyzer and calibrated with fewer than 3 calibrators: Alanine Aminotransferase, Albumin, Alkaline Phosphatase, Aspartate Aminotransferase, Total Bilirubin, Calcium, chloride, Total Cholesterol, HDL Cholesterol, Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglycerides, Urea Nitrogen, Uric Acid. 3. Interview of the primary testing person on 02/26/19 at 1300 hours in the laboratory confirmed the above findings. This is a repeat deficiency from the survey with date 04 /26/17. key: TSH - Thyroid Stimulating Hormone TT4 - Thyroxine TU - Thyroid hormone uptake
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records, calibration records, and confirmed in interview, the laboratory quality assessment policies and procedures failed to to monitor & evaluate the overall quality of the analytic systems. (refer to D5421, D5439).
D5817	TEST REPORT CFR(s): 493.1291(i) If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory test reports and confirmed in interview with the laboratory director, the laboratory report for the Glycated Hemoglobin (HgbA1c) did not identify the laboratory facility where the tests had been performed for 5 of 10 test reports sent to the reference lab. Findings include: 1. A random review of the HgbA1c from February 2019 sent to a reference lab revealed 10 HgbA1c tests were sent to the reference laboratory for testing. For 5 of 10 patient test reports for the HgbA1c, the report did not identify the laboratory facility where the testing was performed. Accn# 52578 52582 52583 52584 52587 2. An interview with the primary testing person on 2 /26/19 at 1345 in the office confirmed the above findings. She acknowledged that the final report should have the name and address of the reference laboratory.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, test list and confirmed in interview, the laboratory did not have an established and written policy/procedure for verifying and documenting their LIS (laboratory information system) calculated test result as it is interfaced with their Roche Integra 400 plus chemistry analyzer to ensure accuracy. Findings included: 1. The laboratory's procedure manual did not include a policy/procedure for verifying calculated test results from the LIS as it was interfaced with the Roche Integra 400 plus chemistry analyzer. 2. The laboratory's test list included the following calculated test results obtained from the test menu: LDL (calculated); vLDL; Chol/HDL ratio. 3. An interview with the primary testing person on 2/26/19 at 1340 hours acknowledged that "There is not a policy or procedure for checking the calculated test results." She was unaware that she needed to verify the calculated results. According to records, the laboratory's patient total test volume was 12000 tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, quality assessment records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. (Refer to D6013, D6021)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the laboratory's test system records and interview of facility personnel it was revealed that the laboratory director failed to ensure verification studies were complete for chemistry testing on the Roche Cobas chemistry analyzer before reporting patient test results. (Refer to D5421)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure a quality assurance program was developed to prevent repeat deficiencies. Refer to D5217, D5421, D5439