Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0677467	03/10/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on a review of the Cobas Integra 400 Plus User Manual, a review of the laboratory's maintenance records from July 2019 to November 2020, and staff interview, it was revealed the laboratory failed to have documentation of completing the manufacturer-required maintenance procedures for 12 of 16 months from July 2019 to November 2020 on the Cobas Integra 400 Plus chemistry analyzer. Findings include: 1. A review of the Cobas Integra 400 Plus User Manual (Version 2.4, 2006) revealed the following required maintenance procedures: Weekly: a) System Power Off/Power On b) Clean ISE tower automatically c) Backup Database d) Clean probes and splash guard e) Clean wash station f) Clean instrument Monthly: a) Clean waste

box fitting b) Clean ISE tower manually 2. A review of the laboratory's maintenance records from July 2019 to November 2020 revealed the laboratory failed to have documentation of completing the following maintenance procedures listed above for the following 12 months: a) July 2019: - weekly maintenance procedures (a, b, c, d, e, f) for week 1 - weekly maintenance procedures (a, b, c, d, e, f) for week 2 - weekly maintenance procedures (a, b, c, d, e, f) for week 3 - weekly maintenance procedures (a, b, c, d, e, f) for week 4 b) August 2019: - weekly maintenance procedures (a, b, c, d, e, f) for week 3 - monthly maintenance procedures (a and b) c) September 2019: - weekly maintenance procedures (c, e, f) for week 2 - weekly maintenance procedures (a, c, e, f) for week 4 - monthly maintenance procedure (b) d) November 2019: - weekly maintenance procedures (c, e, f) for week 3 e) December 2019: - weekly maintenance procedures (c, e, f) for week 1 - monthly maintenance procedures (a and b) f) January 2020: 4 of 6 weekly maintenance procedures for week 4 (c and e) - monthly maintenance procedure (b) g) February 2020: - weekly maintenance procedures (a, b, c, e, f) for week 1 - weekly maintenance procedures (a, c, e, f) for week 2 - weekly maintenance procedures (a, b, c, e, f) for week 3 - weekly maintenance procedures (a, b, c, e, f) for week 4 - monthly maintenance procedure (b) h) March 2020: - weekly maintenance procedures (c, e, f) for week 1 - weekly maintenance procedures (a, b, c, d, e, f) for week 2 - weekly maintenance procedures (a, b, c, d, e, f) for week 3 - weekly maintenance procedures (a, b, c, e, f) for week 4 i) July 2020: - weekly maintenance procedures (c, e, f) for week 1 - weekly maintenance procedures (a, b, c, e, f) for week 2 - weekly maintenance procedures (a, b, c, d, e, f) for week 3 - monthly maintenance procedure (b) j) September 2020: - weekly maintenance procedures (a, b, c, d, e, f) for week 3 k) October 2020: - weekly maintenance procedures (a, c, d, e, f) for week 1 - weekly maintenance procedures (a, c, e, f) for week 3 - weekly maintenance procedures (a, b, c, d, e, f) for week 4 - monthly maintenance procedure (b) l) November 2020: - weekly maintenance procedures (a, c, e, f) for week 2 - monthly maintenance procedure (b) 3. An interview with the laboratory director on 3/10/21 at 1:25 p.m. in the office, after review of the records, confirmed the above findings. II. Based on a review of the Operator's Manual for the Cobas e 411 analyzer, a review of the laboratory's maintenance records from April 2019 to July 2020, and staff interview, it was revealed the laboratory failed to have documentation of completing the manufacturer-required maintenance procedures for 9 of 15 months from April 2019 to July 2020 on the Cobas e 411 analyzer. Findings include: 1. A review of the Operator's Manual (Version 2.1, 2014) for the Cobas e 411 analyzer revealed the following: "Provide the system with proper maintenance and care to ensure consistent and accurate functioning. Modifying or omitting the maintenance procedures may result in the loss of performance or reliability of the system, which are the responsibility of the operator." 2. Further review of the Operator's Manual for the Cobas e 411 analyzer revealed the following manufacturer-required maintenance procedures: - Weekly: a) Clean incubator and aspiration station b) Clean sipper probe - Every 2 weeks: a) Clean rinse stations b) Perform liquid flow cleaning - Monthly: a) Replace pinch valve tubing 3. A review of the laboratory's maintenance records for the Cobas e 411 analyzer from April 2019 to July 2020 revealed the laboratory failed to have documentation of completing the following maintenance procedures listed above for the following 9 months: a) April 2019: - monthly maintenance procedure (a) b) July 2019: - weekly maintenance procedures (a and b) for week 4 - monthly maintenance procedure (a) c) August 2019: - every 2 weeks maintenance procedure (a) for week 2 - monthly maintenance procedure (a) d) September 2019: - weekly maintenance procedure (a) for week 2 - every 2 weeks maintenance procedure (a) for week 2 - every 2 weeks maintenance procedure (a) for week 4 - monthly maintenance procedure (a) e) October 2019: - weekly maintenance procedure (b) for week 2 - weekly maintenance procedure (a and

	b) for week 3 - every 2 weeks maintenance procedure (a) for week 2 - monthly maintenance procedure (a) f) November 2019: - weekly maintenance procedure (a) for week 2 - weekly maintenance procedure (b) for week 4 - monthly maintenance procedure (a) g) February 2020: - weekly maintenance procedure (a) for week 2 - weekly maintenance procedure (a) for week 3 - monthly maintenance procedure (a) h) March 2020: - weekly maintenance procedure (a) for week 2 - weekly maintenance procedure (a) for week 3 - weekly maintenance procedure (a) for week 4 - monthly maintenance procedure (a) i) July 2020: - weekly maintenance procedure (b) for week 2 - weekly maintenance procedure (b) for week 3 - every 2 weeks maintenance procedure (a) for week 3 - monthly maintenance procedure (a) 4. An interview with the laboratory director on 3/10/21 at 1:25 p.m. in the office, after review of the records, confirmed the above findings.
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 a review of the laboratory's quality control and calibration records, a review of the laboratory's calibration verification (linearity) records for the Cobas Integra 400 Plus chemistry analyzer from 2019 to 2020, and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification procedures at least every 6 months in 2020 on 16 of 16 analytes run on the Cobas Integra 400 Plus chemistry analyzer. Findings include: 1. A review of the laboratory's quality control and calibration records for the Cobas Integra 400 Plus chemistry analyzer (Serial Number: 402648) revealed the following 16 analytes were calibrated using 2 calibrators and the laboratory tested 2 levels of quality control once a day for each analyte, thus calibration verification was required at least every 6 months: Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase (ALP) AspartateTransaminase (AST) Total Bilirubin Total Calcium Chloride Total Cholesterol HDL Cholesterol Creatine Glucose Potassium (K) Sodium (NA) Total Protein Triglyceride Blood Urea Nitrogen (BUN) 2. A review of the calibration verification (linearity) records from 2019 and 2020 revealed the following dates when

	a calibration verification was performed for the above listed analytes: 5/13/19 12/2/19 10/21/20 Elapsed time between calibration verifications on 12/2/19 and 10/21/20: 10 months 20 days 3. The laboratory director was asked for documentation of a calibration verification being performed on the Cobas Integra 400 Plus chemistry analyzer for the 16 analytes between 12/2/19 and 10/21/20. No documentation was provided. 4. An interview with the laboratory director on 3/10/21 at 1:15 p.m. in the office, after review of the records, confirmed the above findings.