

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2167145	(X3) Date Survey Completed 02/25/2021
Name of Provider or Supplier Mrh Medical Grp-Premier Diabetes & Medical Clinic	Street Address, City, State 2394 Mccullough Blvd, Belden, MS	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Qualigen Fast Pack IP #2 calibration records from installation on 4/21/20 and interview with testing personnel (TP) #1 listed on the CMS (Center for Medicare & Medicaid Services) form at 2:00 pm on the day of survey, the laboratory failed to perform calibration on Vitamin D every 30 days and TSH (thyroid stimulating hormone) every 14 days as required by the manufacturer. Findings include: 1. Review of the Qualigen Fast Pack TSH package insert indicates that the assay must be calibrated every 14 days or with each new lot of reagent. Review of the Qualigen Fast Pack Vitamin D package insert indicates that the assay must be calibrated every 30 days or with each new lot of reagent. 2. Review of the Qualigen Fast Pack IP #2 calibration records for TSH from 4/21/20 through the day of survey revealed a calibration was performed on 4/21/2020. The next documented calibration was performed on 11/5/2020. These dates exceed the 14 day calibration requirement by the manufacturer. 3. Review of the Qualigen Fast Pack IP #2 calibration records for Vitamin D from 4/21/20 through the day of survey revealed a calibration was</p>

performed on 4/21/2020. The next documented calibration was on 12/18/2020. Calibration was performed on 1/5/21 and again on 2/11/21. The period from 4/21 until 12/18/2020 and the period from 1/5 until 2/11/21 exceed the 30 day calibration requirement by the manufacturer. 4. Interview with TP #1 at 2:00 pm on 2/25/21 confirmed that calibration was not performed on the Qualigen Fast Pack IP analyzer #2 for Vitamin D every 30 days and TSH every 14 days as required by the manufacturer's policy.

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 Qualigen Fast Pack IP System records from installation on 4/21 /20 through the day of survey and confirmation with testing personnel #1 at 1:30 pm on 2/25/21, the laboratory failed to perform calibration verification on the Quality Fast Pack System #2 every 6 months for TSH (thyroid stimulating hormone) and Vitamin D. Findings include: 1. Review of the laboratory Qualigen Fast Pack IP records for TSH and Vitamin D from installation on 4/21/20 through the day of survey revealed that a calibration verification had not been performed for either assay since installation. 2. Interview with testing personnel #1 at 1:30 pm on the day of survey confirmed that calibration verification had not been performed for the TSH and Vitamin D assays since installation. This period exceeded the 6 month calibration verification requirement from the manufacturer.