Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2167145	11/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mrh Medical Grp-Premier Diabetes & Medical Clinic	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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing event records and confirmation with Technical Consultant/Lab Director (TC/LD), the laboratory failed to retain all proficiency records to include but not limited to results, attestation statements, submitted results and analyzer printouts for six of seven proficiency testing events. Findings include: 1. Review of the 3rd event of 2022, the 2nd and 3rd events of 2023 and the 1st, 2nd and 3rd events of 2024 proficiency testing records revealed the laboratory did not retain the following: a. Report sheets and submitted result sheets for the 1st event of 2024. (1 of 6 events report sheets not retained) b. Attestation statements for the 2nd and 3rd events of 2023 and 1st, 2nd and 3rd of 2024. (5 of 6 events attestation statements not retained) c. Analyzer printouts for the 3rd event of 2022, 2nd and 3rd of 2023 and 1st and 2nd of 2024 (5 of 6 events analyzer printouts not retained) d. Proficiency graded results for the 2nd event of 2024 (1 of 6 graded results not retained.) 2. Interview with TC/LD on 11/6/2024 at 10:00 a.m. confirmed that the listed proficiency records were not retained after completion of each proficiency event.
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 Endocrinology records, and confirmation with the Laboratory Director (LD)/Technical Consultant (TC) and testing personnel (TP) #1 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory testing personnel failed to perform the calibration verification on the Qualigen for Free T4 for four of four sixth-month calibration verification procedures due. Findings include: 1. Review of the Qualigen Fast Pack records for Free T4 from 10/11/2022 through 11/6/2024, revealed a calibration verification was not performed on Free T4 every 6 months as required by the manufacturer. Four of four sixth-month calibration verifications were not performed. 2. Interview with the LD/TC and TP #1 on 11/6/2024 at 2:00 p.m., confirmed the calibration verification on Free T4 had not been performed every 6 months as required by the manufacturer.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, the Centers for Medicare and Medicaid Services (CMS) data system CASPER report 0155D and interview with the Laboratory Director (LD)/Technical Consultant (TC) and testing personnel (TP) #1, the TC failed to ensure the laboratory enrolled and participated in an HHS approved proficiency testing (PT) program for Free T4, TSH (thyroid stimulating hormone) and Testosterone performed on the Qualigen Fast Pack analyzer for the 1st event of 2023 and 2nd event of 2024. Findings include: 1. Review of the laboratory proficiency records from 2022 through 2024, and the CMS database casper report revealed: A. The laboratory did not enroll and participate in proficiency testing for the 1st event of 2023. There were no PT records available the day of survey and no PT scores in the CMS database for the 1st event of 2023. The laboratory failed to enroll and participate in 1 of 7 PT events. B. The laboratory did not participate in the 2nd PT event of 2024. On the day of survey TP #1 provided the unsubmitted endocrinology results in the API database for the 2nd event of 2024 but failed to

	submit the results for grading. The laboratory scored 0% for nonparticipation. The laboratory failed to participate in 2 of 7 PT events. 2. The LD/TC and TP #1 confirmed in an interview on 11/6/2024 at 10:00 a.m., that the laboratory did not enroll and participate in the 1st PT event of 2023, nor did they participate in the 2nd PT event of 2024 for Endocrinology testing (Free T4, TSH and Testosterone). The laboratory is under a cease testing sanction as of the day of the survey.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory testing records and interview with the Laboratory Director/Technical Consultant (LD/TC), the technical consultant (TC) failed to document the review of the Qualigen Fastpack analyzer's quality controls, maintenance and temperature logs from 10/13/2022 through 11/06/2024. Findings Include: 1. Review of laboratory records from 10/12/2022 through 11/6/2024 revealed no documented review by the TC for the following records: a. Laboratory temperature logs (room, refrigerator, freezer, humidity) from 5/1/2024 through 10/31/2024 b. Free T4 quality control (QC) from 10/10/2022 through 9/11/2024 and calibrations from 12 /29/2022 through 10/29/2024 c. Testosterone QC from 11/14/2022 through 6/24/2024 and calibrations from 12/6/2022 through 10/29/2024 and calibration verification on 7 /25/2023 c. TSH calibrations from 12/27/2022 through 10/29/2024 2. Interview with LD/TC on 11/6/2024 at 2:00 p.m. confirmed there was no available documentation of review of these records by the technical consultant during these time frames.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the Laboratory Director/Technical Consultant LD/TC, the technical consultant failed to evaluate the performance for one of two testing personnel at least annually for moderate complexity testing. Findings include: 1. The surveyor reviewed moderate testing personnel records form 10/11/2022 through 11/6/2024 including competency evaluations and the CMS 209 personnel form. 2. Testing Personnel #2 had no annual competency/evaluation for 2023 or 2024: 3. The LD/TC just assigned to this position confirmed in an interview on 11/6/2024 at 2:00 p.m., there was no annual competency evaluation documented as performed by the previous TC for TP #2 (1 of 2 TP) for the years 2023 and 2024.