Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2210993	03/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Honeycomb Medical Group,Plc	6401 Poplar Ave, Suite 296, Memphis, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: CITATION ONE: Based on laboratory observation, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), laboratory procedure manual, quality control records, a patient test record, review of laboratory test volumes, and staff interview, the laboratory failed to follow the procedure for frequency of creatinine quality control (QC) testing from January 2, 2025 to March 18, 2026, with a total of approximately 16,639 creatinine tests performed during the review period. The findings include: 1. Laboratory observation on 03/19/26 at 9 a.m. revealed the Beckman Coulter AU480 used for performing general chemistry analyte testing, including serum and urine creatinine. During observation, technical consultant two stated that the laboratory performed runs of patient samples at different times during the day, with the last run occurring in the late afternoon to evening. She also stated that creatinine QC was not performed every eight hours. 2. A review of the Form CMS-116 revealed that the laboratory's hours of operation were from 8:30 a.m. to 8:30 p.m. 3. A review of the manufacturer's creatinine reagent package insert, used as part of the laboratory's procedures, revealed the following: "Run QC at a minimum of every 8 hours." 4. A review of the laboratory's quality control records for the creatinine analyte revealed that creatinine quality control was not performed every eight hours for the following months selected for review: January 2025, March 2025, August 2025, and January 2026. 5. A review of a daily quality control record and a patient test report revealed the following: On 03 /18/26, creatinine QC was verified at 9:50 a.m. QC was not performed again after

	eight hours. Creatinine for patient number 101738 was reported on 03/18/26 at 6:47 p. m. 6. A review of the laboratory's test volumes revealed that approximately 13,695 patient creatinine tests (serum and urine) were performed in 2025, and approximately 2,944 were performed in 2026. 7. Technical consultant two confirmed the survey finding during an interview on 03/19/26 at 3:45 p.m. CITATION TWO: Based on laboratory observation, a review of the laboratory procedure manual, a review of calibration verification documents, a patient test report, staff interview, and electronic mail (email) communication, the laboratory failed to follow the procedure for calibration verification frequency for the Tosoh G8 glycated hemoglobin (Hgb A1c) instrument when calibration verification was not performed when due on 03/15/25 (one of three calibration verifications for the Hgb A1c analyte) with approximately 2,678 patients reported during the gap in calibration verification. The findings include: 1. Laboratory observation on 03/19/26 at 9 a.m. revealed the Tosoh G8 instrument used for performing patient testing for Hgb A1c. 2. A review of the laboratory procedure titled "Tosoh G8 Glycohemoglobin Analyzer" revealed the following: "Calibration verification will be performed every six months using an external source." The laboratory procedure titled "Quality Assurance Policy" under the section titled "A. Instrument Calibration and Calibration Verification" "Calibration Verification with a test of the entire reportable (linear) range is performed whenever one of the following situations occurs:" "Every six months using an external source. The linearity/validation material will be purchased from this external source and data will be submitted to ensure accuracy and precision." 3. A review of the laboratory's calibration verification documentation for the Tosoh G8 instrument revealed that the calibration verification due on 03/15/25 was not performed until 07/14/25. 4. A review of patient identification number 101992 revealed testing for Hgb A1c reported on 05/01/25 during the gap in calibration verification. 5. Technical consultant two confirmed the survey findings during an interview on 03/19/26 at 3:45 p.m. 6. A review of an email from technical consultant two, received on 03/23/26 at 10:35 a.m., revealed that approximately 2,678 patients were tested during calibration verification gap from 03/15/25 to 07/14/25.