Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2210993	10/21/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of testing personnel competency assessment records, and staff interviews, the laboratory failed to follow the competency assessment policy for eight of eight competency assessments reviewed that were performed for three of three testing personnel in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 10/21/24 at 9 a.m. revealed the Beckman Coulter AU 480 used for chemistry testing, the Beckman Coulter Access 2 used for immunoassay and chemistry testing, the Tosoh G8 used for performing glycated hemoglobin (Hgb A1c) testing and the Beckman Coulter DxH 560 used for performing patient testing for Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff). 2. A review of the laboratory policy titled "Employee Competency Validation Policy" under section V., number three, item f. revealed the following "Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform." The six required elements were included in the policy. 3. A review of testing personnel competency assessments revealed the following: Testing person one: Annual competency performed on 05/23/23 Direct observation of routine patient test performance did not include the Beckman Coulter DxH 560, the Beckman Coulter Access 2, or the Tosoh G8 instruments. Review of worksheets, QC, PT, and maintenance records did not include the Beckman Coulter AU 480 or the Beckman Coulter Access 2. Direct observation of instrument maintenance and function checks did not include the Beckman Coulter AU 480 or the Beckman Coulter Access 2. Blind

testing did not include the Tosoh G8, the Beckman Coulter AU 480 or the Beckman Coulter Access 2. Assessment of problem solving skills did not include the Beckman Coulter AU 480, the Beckman Coulter Access 2 or the Tosoh G8. Annual competency performed 04/17/24: Blind testing not evaluated for the Beckman Coulter AU 480, the Beckman Coulter Access 2, or the Tosoh G8. Assessment of problem solving skills did not include the Beckman Coulter AU 480, Beckman Coulter Access 2, the Tosoh G8, or the Beckman Coulter DxH 560. Testing person two: Six month competency assessment performed 10/07/22 did not include: Direct observation of routine patient testing not documented for the Tosoh G8 Hgb A1c instrument, the Beckman Coulter DxH 560 CBC w/Diff instrument, and the Beckman Coulter AU 480 chemistry instrument. Review of worksheets, QC, PT and Maintenance records not documented for the Tosoh G8 Hgb A1c instrument or the Beckman Coulter DxH 560 CBC w/Diff instrument. Direct observation of instrument maintenance and function checks not documented for the Beckman Coulter Access 2 instrument, the Tosoh G8 instrument or the Beckman Coulter DxH 560 instrument. Blind testing not evaluated for the Beckman Coulter DxH CBC w/Diff instrument. Assessment of problem solving skills not documented for the Beckman Coulter DxH 560 instrument, the Tosoh G8 instrument or the Beckman Coulter Access 2 instrument. Annual competency performed on 04/28/23 did not include: Direct observation of routine specimen handling and processing for the Beckman Coulter Access and the Tosoh G8 Hgb A1c instrument. Direct observation of instrument maintenance for the Beckman Coulter AU480, the Tosoh G8 Hgb A1c, and the Beckman Coulte rDxH 560 CBC instrument. Blind testing for the Beckman Coulter DxH 560 CBC instrument, the Tosoh G8 Hgb A1c instrument, and the Beckman Coulter Access 2 chemistry and immunoassay instrument. Annual competency performed 10/08/24 did not include: Direct observation of routine specimen handling and processing for the Beckman Coulter CBC instrument and the Tosoh G8 glycated hemoglobin (Hgb A1c) instrument. Review of worksheets, QC, PT and Maintenance Records for Beckman Coulter AU 480 instrument, the Tosoh G8 Hgb A1c instrument, and the Beckman Coulter DxH Complete Blood count (CBC) instrument. Blind testing for the Complete Blood Count. Testing person three: 6 month competency performed on 08/15/22 Direct observation of routine patient test performance not evaluated for the Beckman Coulter AU 480, the Beckman Coulter DxH 560, or the Tosoh G8. Review of worksheets, QC, PT and maintenance records was not evaluated for the Beckman Coulter DxH560, the Beckman Coulter AU480, the Beckman Coulter Access 2, or the Tosoh G8. Direct observation of instrument maintenance and function checks was not evaluated for the Beckman Coulter Access 2, the Beckman Coulter DxH560 or the Tosoh G8. Blind testing was not evaluated for the Beckman Coulter AU 480, the Beckman Coulter Access 2, or the Tosoh G8. Problem solving was not evaluated for the Beckman Coulter DxH 560, the Tosoh G8 or the Beckman Coulter Access 2. Annual competency performed on 02/21/23 Monitoring the recording/reporting of results was not evaluated for the Tosoh G8, the Beckman Coulter AU 480 or the Beckman Coulter Access 2 Review of worksheets, QC, PT and maintenance records not documented for the Tosoh G8, the Beckman Coulter AU 480, or the Beckman Coulter Access 2 Direct observation of instrument maintenance and function checks not documented for the Beckman Coulter DxH560, the Beckman Coulter Access 2 or the Tosoh G8. Blind testing not evaluated for the Beckman Coulter DxH 560. Assessment of problem solving skills not documented for the Beckman Coulter AU480, the Beckman Coulter Access 2, or the Beckman Coulter DxH 560. Annual competency performed on 02/19/24 Direct observation of routine patient test performance was not documented for the Tosoh G8, the Beckman Coulter AU 480, or the Beckman Coulter DxH 560. Direct observation of instrument maintenance and function checks was not evaluated for the Tosoh G8, the Beckman Coulter AU 480, or

	the Beckman Coulter Access 2 instruments. Blind testing was not evaluated for the Tosoh G8, the Beckman Coulter AU 480, or the Beckman Coulter Access 2. Assessment of problem solving skills was not evaluated for the Beckman Coulter AU480, the Beckman Coulter Access 2, the Beckman Coulter DxH 560 or the Tosoh G8. 4. Technical consultants one and two confirmed the survey findings during an interview on 10/21/24 at 2:30 p.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient CBC w/Diff records, the manufacturer's instructions for use, lack of procedure and staff interview, the laboratory failed to have a procedure to follow for actions to take when CBC w/Diff results were flagged by the instrument. The findings include: 1. Observation of the laboratory on 10/21/24 at 9:00 a.m. revealed the Beckman Coulter DxH 560 used for patient testing for CBC w/Diff. 2. A review of two patient CBC w/Diff reports from 10 /21/24 revealed the following: The instrument printout for patient specimen identification number 1102124755 was flagged with "PLT1: Debris." A "R" flag was listed next to the platelet and mean platelet volume parameters. The instrument printout for patient specimen identification number 1102124727 was flagged with "PLT3: PLT/RBC Overlap." A "R" flag was listed next to the platelet and mean platelet volume parameters. The instrument message/flags did not cross in the laboratory information system to be included in the patient results. 3. A review of the Beckman Coulter DxH 560 instructions for use revealed the following: "Flags, codes, and messages are evaluated when the sample is analyzed. Review the results and pay close attention to any flags, codes, or messages that are intended to alert you to issues with results or with the instrument." "In all cases, follow your laboratory's policy for reviewing results." Messages are displayed in the Messages box on the Sample Analysis-Patient Results screen. Messages are generated when specimen results meet certain conditions or an event occurs that may affect the operation of the system, the quality of results, or when operator intervention is required. Messages may be accompanied by R (Review) flags, other flags or codes. "R" = Review results The message for "PLT1:Debris", "PLT R", and "MPV R" was described as "Interference

	with smaller platelets. Interference at the left side of the PLT histogram is between channel 0 and the CP1 threshold. The message for PLT3: PLT/RBC Overlap, "PLT R" and "MPV R" was described as "PLT and RBC populations are overlapped between the CP3 and CP3-2 thresholds. Other messages/parameters/Flag and descriptions included: "Dimorphic RBC / RDW R, RDW-SD R / Evidence of the presence of at least two populations of red cells." "Cellular Interference / WBC R, Diff % R, Diff# R, PLT R / Poor separation between WBC populations and interference below the lymphocytes area. Abnormal Diff appears with this message when a CD is ordered." "Low Diff Events / Diff% R, Diff# R / The scatter plot total number of cells is less than 500. "Large Cells, Differential percent and number flagged with "R", High number of events in the Large Immature Cell area. Abnormal Diff appears with this message when a CD is ordered." "Suspect Diff / Pattern varies from a normal differential. Suspect Diff appears when Abnormal Diff is present." 4. The laboratory did not have a procedure to follow for actions to take when CBC w /Diff results were flagged by the instrument. 5. Technical consultant one confirmed the survey findings during an interview on 10/21/24 at 4:30 p.m. Word Key: Diff=White Blood Cell Differential MPV=Mean Platelet Volume PLT= Platelet RDW=Red Cell Distribution Width WBC = White Blood Cell %=Percent #=number
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: Based on observation of the laboratory, a review of the Beckman Coulter operator's manual, a review of the DxH 560 maintenance records, and staff interview, the laboratory failed to perform maintenance as required by the Beckman Coulter DxH 560 manufacturer for 24 of 24 months reviewed from 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on 10/21/24 at 9 a.m. revealed the Beckman Coulter DxH 560 used for patient testing for CBC w/Diff. 2. A review of the Beckman Coulter DxH 560 operators manual revealed the following required maintenance: Every 1,000 cycles or biweekly, whichever comes first for "Performing a Bleach Cycle." Monthly: "Cleaning the WBC bath filter." 3. A review of the monthly maintenance records for the DxH 560 instrument revealed the task of performing a bleach cycle every 1,000 samples or bi-weekly was not documented for 24 of 24 months reviewed from October 2022 to September 2024; the monthly task of cleaning the WBC bath filter was not documented for 20 of 24 months reviewed (October 2022, November 2022, December 2022, January 2023, February 2023, March 2023, April 2023, May 2023, June 2023, July 2023, August 2023, September 2023, November 2023, February 2024, March 2024, April 2024, May 2024, June 2024, July 2024, and August 2024). 4. Technical consultant one confirmed the survey findings during an interview on 10/21/24 at 4:30 p.m.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on laboratory observation, a review of quality control records and staff interview, the laboratory failed to ensure it verified the manufacturer's quality control (QC) ranges for the current lots of chemistry and immunoassay controls. The findings include: 1. Observation of the laboratory on 10/21/24 at 9:00 a.m. revealed the Beckman Coulter AU480 and the Beckman Coulter Access 2 used for performing patient testing for Chemistry and Endocrinology. Controls observed for use in the laboratory for the two systems were Biorad assayed quality control products (Multiqual lots number 45981 and 45983, Immunoassay Plus lot numbers 85381 and 85383, and Liquicheck Specialty Immunoassay Control lot numbers 1003701 and 1003703). 2. A review of the Biorad QC package inserts for all control products revealed the following statement: "The mean values and corresponding +/-3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product." 3. A review of the manufacturer's 3SD range and the laboratory's QC range in the laboratory information system for selected analytes revealed the laboratory used the manufacturer's 3SD range as a 2SD laboratory range for the following analytes: Multiqual: Glucose: Level one-Lot 45981 Biorad package insert 3SD range = 53.7-65.8 mg/dL Laboratory 2SD range = 54-65 mg/dL Level three-Lot 45983 Biorad package insert 3 SD range = 320-386 mg/dL Laboratory 2SD range used = 320-386 mg/dL Sodium Level one-Lot 45981 Biorad package insert 3SD range = 108-118 mmol/L Laboratory 2SD range used = 108-118 mmol/L Level three-Lot 45983 Biorad package insert 3 SD range = 151-163 mmol/L Laboratory 2SD range = 151-163 mmol/L Potassium Level one-Lot 45981 Biorad package insert 3SD range = 2.33-2.72 mmol/L Laboratory 2SD range used = 2.3-2.7 mmol/L Level three-Lot 45983 Biorad package insert 3 SD range = 6.97-7.7 mmol/L Laboratory 2SD range = 6.97-7.7 mmol/L Chloride Level one-Lot 45981 Biorad package insert 3SD range = 71.1-79.6 mmol/L Laboratory 2SD range used = 71-79 mmol/L Level three-Lot 45983 Biorad package insert 3 SD range = 112-123 mmol/L Laboratory 2SD range = 112-124 mmol/L Alanine aminotransferase Level one-Lot 45981 Biorad package insert 3SD range = 20.9-36.3 U/L Laboratory 2SD range used = 21-37 U/L Level three-Lot 45983 Biorad package insert 3 SD range = 118-206 U/L Laboratory 2SD range = 118-206 U/L Calcium Level one-Lot 45981 Biorad package insert 3SD range = 5.28-6.56 mg/dL Laboratory 2SD range used = 5.2-6.6 mg/dL Level three-Lot 45983 Biorad package insert 3 SD range = 12.2-14.2 Laboratory 2SD range = 12.2-14.2 mg/dL Aspartate Aminotransferase Level one-Lot 45981 Biorad package insert 3SD range = 22.7-47.8 U/L Laboratory 2SD range used = 23-47 U/L Level three-Lot 45983 Biorad package insert 3 SD range = 133-306 U/L Laboratory 2SD range = 133-307 U/L Immunoassay Plus: Thyroid Stimulating Hormone Level one-Lot 85381 Biorad package insert 3SD range = .631-.835 uIU/mL Laboratory 2SD range used = .631 - .835 uIU/mL Prostate Specific antigen Level one-Lot 85381 Biorad package insert 3SD range = .324-.463 ng/mL Laboratory 2SD range used = ..32-.46 ng/mL Free Thyroxine Level one-Lot 85381 Biorad package insert

	3SD range = .653-.930 uIU/mL Laboratory 2SD range used = .631-.835 uIU/mL Specialty Immunoassay Vitamin D Level one-Lot 1003701 Biorad package insert 3SD range = 10.2-26.1 ng/mL Laboratory 2SD range used = 10.2-26.2 Level three-Lot 10033703 Biorad package insert 3 SD range = 86.1- >120 ng/mL Laboratory 2SD range = 96.1-136 ng/mL Word Key: mg/dL = milligrams per deciliter mmol /L=millimoles per liter ng/mL=nanograms/milliliter SD = Standard Deviation U /L=Units/Liter uIU/mL = milli-international units per liter 4. Technical consultant one confirmed the survey findings during interview on 10/21/24 at 4:30 p.m.