Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306704	03/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Group	490 Dunlop Lane, Clarksville, 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's testing personnel policy/procedure, testing personnel records and interview with technical consultant number two, the laboratory failed to follow its' own testing personnel competency assessment policy when it did not include all six elements for five of twenty-five competency assessments reviewed from 2021 and 2022, and failed to perform interim competency assessment for one of seven semi-annual competencies due. The findings include: 1. Observation of the laboratory on 03/07/23 at 8:10 am revealed the following moderately complex test systems in use for patient testing: Complete blood count with differential performed on the Sysmex XN 330, General chemistry and endocrinology performed on the Siemens Dimension EXL 200, Glycosylated Hemoglobin (Hemoglobin A1c) performed on the Tosoh G8 and a microscope used for performing urine microscopic analysis. 2. Review of the laboratory personnel competency assessment policy revealed that a semi-annual competency would be performed during the first year of testing, and that all six of the required elements as described in subpart M of the Clinical Laboratory Improvement Amendments (CLIA) regulations would be included in the competency assessments performed. 3. Review of testing personnel records revealed the following: Testing person number two competency assessment did not include documentation/assessment of review of worksheets, quality control, proficiency testing and preventive maintenance, blind samples or proficiency testing samples, or problem solving skills for the Sysmex XN-330, Dimension EXL 200, Urine Microscopy, and Tosoh G8 for initial and six month competencies performed in 2021 and annual competency performed in 2022. Testing

	person number three competency assessment did not include documentation /assessment of review of worksheets, quality control, proficiency testing and preventive maintenance, blind samples or proficiency testing samples, or problem solving skills for the Sysmex XN-330, Dimension EXL 200, Urine Microscopy, or Tosoh G8 for the initial competency performed in 2021 and the six month and annual competencies performed in 2022. Testing person number nine did not have a semi-annual competency for performance of complete blood count when due in 2022. 4. Interview with technical consultant number two on 03/07/23 at 3:45 pm confirmed the laboratory failed to follow its' own policy for competency assessment when it did not include all six required competency assessment elements as described in the personnel policy for five of twenty-nine competency assessments reviewed, and failed to perform semi-annual competency assessment for one of seven semi-annual competencies when due.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, and interview with technical consultant number two, the laboratory failed to monitor humidity as required by the manufacturer for three of three moderately complex test systems used for performing complete blood count (CBC), glycosylated hemoglobin (Hemoglobin A1c) and general chemistry and endocrinology tests in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 03/07/23 at 8:10 am revealed the following moderately complex test systems in use for patient testing: Sysmex XN 330 (serial #s 11814 and 11822) for performing CBC to include white blood cell differential Tosoh G8 serial # 16371210 for performing Hemoglobin A1c Siemens Dimension EXL 200 serial # DE271895 for performing general chemistry and endocrinology No device for monitoring humidity was observed in the laboratory. 2. Review of the manufacturer environmental operating requirements revealed the following: Sysmex XN 330 - Humidity range of 20 to 85% Tosoh G8 - Humidity range of 40 to 80% Siemens Dimension EXL 200 Humidity range of 20 to 80% 3. Interview with technical consultant number two on 03/07/23 at 3:45 pm confirmed the laboratory did not monitor humidity in the areas where the CBC, Hemoglobin A1c, and chemistry/endocrinology instruments were in use in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of control manufacturer instructions for use, and interview with technical consultant number two, the laboratory failed to label ten of ten controls observed on the date of the survey with a corrected expiration date. The findings include: 1. Observation of the laboratory on 03/07/23 at 8:40 am revealed multiple controls in use that were labeled with open date, but no corrected expiration date for the following: Complete blood count (CBC) controls XN-L (three levels) Immunoassay plus controls used for performing quality control on multiple chemistry and endocrinology tests (two levels) Multiqual controls used for performing general chemistry quality control (two levels) Pediatric (high) bilirubin control (one level) Hemoglobin A1c controls (two levels) 2. Review of the control manufacturer instructions for use revealed the following: XN-L controls are good for 15 days after opening. Immunoassay Plus controls are good for 14 days after opening. Multiqual controls: "All analytes: 14 days Except: - Alkaline Phosphatase, AST/SGOT, Bilirubin (neonatal) and Bilirubin (Total): 9 days -Bilirubin (Direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK), Phosphorus and Triglycerides: 7 days 3. Interview with technical consultant number two on 03/07/23 at 3:45 pm confirmed the laboratory did not label controls with a corrected expiration date after they were opened for ten of ten controls observed on the date of the survey. She also confirmed the expiration date of the controls changed after opening.