Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2128012	12/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Group Laboratory	5005 S Ash Ave Suite A-2, Tempe, AZ	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of established Quality Assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. The laboratory's established QA policy and form titled 'Quality Assessment Review Form and Checklist' states, "Annually, one activity for each of the following processes will be reviewed for the patient testing process. A detailed account of a problem may also be documented on the Monitoring Quality Assessment form." The QA form monitors the following: Patient Test Management, Quality Control, Proficiency Testing, Comparison of Test Results, Personnel, Complaint Investigations, and QA Review. 2. No QA documentation was provided for review during the survey conducted on 12/15/2022 to indicate the laboratory documented QA activities on an annual basis during 2020, 2021 and 2022 (through the date of the survey) to monitor, assess and, when indicated, correct problems identified in the general laboratory systems. 3. The testing personnel interviewed on 12/15/22 at 12:50pm confirmed the laboratory failed to provide documentation of annual QA reports to monitor, assess and correct problems identified with the general laboratory systems.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of control and calibration material and interview with the testing personnel, the laboratory used controls and calibrators past the expiration date. Findings include: 1. The laboratory performs patient testing in the specialties of Diagnostic Immunology and Chemistry, with an approximate annual test volume of 126,240 in those specialties. The laboratory utilizes the Beckman Coulter AU680 and DXI600 analyzers for the testing. 2. During the survey conducted on December 15, 2022, direct inspection of the reagents, control and calibration materials in use at the time of the survey for the analyzers indicated above revealed the following expiration dates: - ISE Reference Solution, lot# M104520, expiration date of 9/30/22 - Access SARS-CoV-2 IgG II reagent boat, lot# 234088, expiration date of 11/30/22 - DRI pH Detect control pH 3.6, lot# 74394022, expiration date of 11/30/22 - DRI pH Detect control pH 11.5, lot# 74394023, expiration date of 11/30/22 - DRI Creatinine Detect 20.0 mg/dL Calibrator, lot# 74437068, expiration date of 9/30/22 - DRI pH Detect pH 11.0 Calibrator, lot# 74186499, expiration date of 4/30/22 - DRI Creatinine Detect Calibrator, lot# 74437067, expiration date of 9/30/22 - DRI Opiate Urine Calibrator 1, lot# 74229258, expiration date of 8/31/22 - DRI Opiate Urine Calibrator 3, lot# 74229262, expiration date of 8/31/22 - DRI Negative Urine Calibrator, lot# 73980992, expiration date of 6/30/22 - Cedia Multi-Drug Calibrator, lot# 74174431, expiration date of 8/31/22 - Cedia DAU Negative Calibrator, lot# 73939225, expiration date of 6 /30/22 3. The total number of patients tested using the expired reagents, controls and calibrators could not be determined at the time of the survey. 4. At approximately 11: 45am on 12/15/22, the testing personnel interviewed confirmed that the expired reagents, controls and calibrators indicated above were in use at the time of the survey
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) policies and procedures and interview with the testing personnel, the laboratory failed to follow established QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems, specifically problems identified with the using reagents, controls and calibrators past the expiration date. Findings include: 1. During the survey conducted on 12/15/22, the laboratory presented a binder for review labeled, "AU680 Drug Screen Tests". It is the practice of the laboratory to complete a log in the binder to track the name, lot#, and expiration dates of reagents, controls and calibrators used by the laboratory on the Beckman Coulter AU680 analyzer. 2. The laboratory failed to document any information in the log referenced above after 5/23/2019 with regard to the reagents, controls and calibrators used for the drug screen tests performed on the AU680 analyzer. 3. The laboratory failed to follow their established QA process indicated above to monitor, assess and correct problems identified in the analytic

	systems, as evidenced by the number of expired test materials in use on the AU680 analyzer at the time of the survey. See D5417 for findings. 4. The testing personnel interviewed on 12/15/22 at 12:40pm confirmed the laboratory failed to follow established QA policies and procedures to monitor, assess and correct problems identified with the analytic systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the testing personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The laboratory performs patient testing using the Sysmex XS-1000i hematology analyzer, Beckman Coulter AU680 and DXI 600 chemistry and immunology analyzers, TOSOH analyzer, and the Applied Science Quant Studio 3 analyzer, with an approximate annual test volume of 160,038. 2. The test results from the analyzers listed above are electronically interfaced into the Laboratory Information System (LIS), LabDaq. 3. No documentation was presented for review during the survey conducted on December 15, 2022 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced into the LIS. 4. The testing personnel interviewed on 12/15/22 at 12:15pm confirmed the laboratory failed to have a system in place to verify the accuracy of the patient test results that are electronically sent from the analyzers to the LIS.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one testing personnel who performs testing in the specialties of Diagnostic Immunology, Chemistry and Hematology and interview with the general supervisor, the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one testing personnel who performs patient testing in the

	specialties of Diagnostic Immunology, Chemistry and Hematology. 2. The general supervisor interviewed on 12/15/22 at 9:20am confirmed the laboratory failed to have documentation of initial training for the testing personnel indicated above.