Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2128012	02/11/2020
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: Based on lack of written procedures for review and interview with the facility personnel, the laboratory failed to have written procedures for testing performed under the specialty of Hematology and the sub-specialties of Routine Chemistry, Endocrinology and Toxicology. Findings include: 1. The laboratory performs approximately 230,000 tests per year under the specialty and sub-specialties listed above. 2. No evidence of an approved procedure manual was presented for review during the survey. 3. The facility personnel acknowledged that they were unaware of the location of the procedure manual.
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 review of the manufacturer's criteria for relative humidity requirements for the environment where the Sysmex hematology analyzer is operated, the humidity range indicated on the laboratory's log sheets and interview with the facility personnel, the laboratory failed to follow manufacturer's instructions for the humidity levels where the Sysmex hematology analyzer is operated. Findings include: 1. The manufacturer's specifications for the relative humidity (RH) are between 40% and 80% with no condensation. 2. The laboratory's logs indicated an acceptable humidity range of between 0% and 80%. 3. The recorded daily humidity range for the laboratory was consistently below 40%; although it could not be determined at the time of the survey how many days in 2019 that the humidity was below the manufacturer's range. 4. The facility personnel acknowledged that they were unaware of the manufacturer's requirements.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of analyzer function check records and interview with the facility personnel, the laboratory failed to perform and document background counts on the Sysmex XS 1000i hematology analyzer each day prior to patient testing. Findings include: 1. The laboratory performs patient testing on the Sysmex XS 1000i hematology analyzer, with an approximate annual test volume of 63,995. 2. No documentation was presented for review during the survey conducted on February 11, 2020 to indicate the laboratory performed and documented the background count performed on the Sysmex XS 1000i analyzer each day prior to patient testing. The laboratory failed to maintain record of the background counts that were performed prior to 2/14/2019. 3. No documentation of the background count was presented for review for patient records reviewed during the survey from 11/07/2018. 4. The laboratory director confirmed that the laboratory failed to produce evidence of background counts performed each day of patient testing that occurred prior to 2/14 /19.
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 lack of calibration verification documentation for the Beckman Coulter AU680 chemistry analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required during 2018. Findings include: 1. The laboratory uses a Beckman Coulter AU680 analyzer to conduct patient testing in the sub-specialty of Routine Chemistry, with an approximate annual test volume of 153,412. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification at least once every six months during 2018, 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. 3. Review of calibration verification documentation revealed the laboratory performed a calibration verification in May 2018, but no other documentation was provided for review to indicate the laboratory performed another calibration verification in 2018. 4. The facility personnel confirmed that the laboratory did not perform a calibration verification every six months in 2018 as required.
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 test performance verification documentation for the Tosoh analyzer and interview with the facility personnel, the laboratory failed to identify errors found in the analytic systems. Findings include: 1. The laboratory began patient testing on the Tosoh analyzer in January 2020. 2. During the survey, review of performance verification documentation for the Tosoh analyzer revealed the laboratory name was listed as "Commonwealth Primary Care Laboratory" on all test validation documentation. 3. No corrective action documentation was presented for review during the survey conducted on February 11, 2020 to indicate the laboratory identified and corrected the error of listing the incorrect laboratory name on the performance verification documentation presented for review for the Tosoh. 4. The facility personnel confirmed that the laboratory failed to identify and correct errors found in the analytic systems as indicated above.

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 facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced from the analyzer to the Laboratory Information System (LIS) and from the LIS into the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs approximately 235,697 patient tests annually under the specialties of Chemistry and Hematology. 2. The laboratory performs testing on the Sysmex XS 1000i, Beckman Coulter AU680, Beckman Coulter DXi 600 and Tosoh analyzers, and the test results are electronically transmitted from the analyzers to the LIS and from the LIS to the EMR. 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the analyzers to the LIS and from the LIS to the patients' EMR. 4. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are electronically transmitted into the LIS and from the LIS to the EMR.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on lack of presentation of a procedure manual for review, the director failed to ensure an approved procedure manual for the testing performed was available for laboratory personnel (See D5401 for findings).