Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306704	02/13/2020
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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to define quality control ranges for the current lot number of glycated hemoglobin (Hb A1c) controls. (Refer to D5469)
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 observation of the laboratory, interview with the obstetrics/gynecology supervisor, review of patient test reports, the laboratory procedure manual, and interview with technical consultant number one, the laboratory failed to have procedures for performing fern test and whiff test in 2020. The findings include: 1) Observation of the laboratory area in the obstetrics/gynecology area on February 13, 2020 at 9:00 a.m. revealed a microscope in use for patient testing for wet prep and potassium hydroxide (KOH) testing. 2) Interview on February 13, 2020 at 9:10 a.m. with the area supervisor revealed the providers report fern testing. 3) Review of KOH test reports for patient numbers thirteen, fourteen, and fifteen for KOH testing

	revealed "Whiff" test reported. 4) Review of the laboratory procedure manual revealed no procedures were present for performing fern testing and whiff testing. 5) Interview with technical consultant number one on February 13, 2020 at 5:00 pm. confirmed there were no procedures for performing fern test and whiff test in 2020.
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 and interview with technical consultant number one, the laboratory failed to label saline container with lot number and expiration date in 2020. The findings include: 1) Observation of the laboratory space in the obstetrics/gynecology area on February 13, 2020 at 9:00 a.m. revealed a bottle labeled "Nacl 0.9%" in use for patient wet prep testing. There was no lot number or expiration date on the vial. 2) Interview with technical consultant number one on February 13, 2020 at 9:30 a.m. confirmed the saline used for performing patient wet prep testing was not labeled with lot number and expiration date in 2020.
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 observation of the laboratory, review of quality control (QC) records, and interview with technical consultant number one, the laboratory failed to define the QC ranges for glycated hemoglobin (Hb A1c) for the current lot in use. The findings include: 1) Observation of the laboratory on February 13, 2020 at 8:45 a.m. revealed the Tosoh G8 instrument in use for patient testing for Hb A1c. 2) Observation of the laboratory on February 13, 2020 at 4:45 p.m. revealed QC lot number 7097 (levels one and two) in use for monitoring QC for the Tosoh G8 instrument. 3) Review of the current QC lot in the laboratory information system (LIS) revealed a different lot number and QC ranges configured in the LIS. 4) Interview with technical consultant number one on February 13, 2020 at 5:00 p.m. confirmed the laboratory failed define

	the QC ranges for the current lot of QC for the Tosoh G8 instrument, resulting in the use of incorrect QC limits for the current QC lot (levels one and two). The current lot (7097) began sometime after December 5, 2019.