Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0966298	01/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Group Of Ms Dba Trace Urgent	530 Veterans Memorial Drive, Kosciusko, MS	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation on 1-23-18 at 1:30 p.m. of the 50-microliter VWR high-performance pipettor in use for mycoplasma testing on the Meridian Bioscience Illumipro-10 test system, review of the manufacturer's instructions for the pipettor, and confirmation by Technical Consultant #2, the laboratory failed to establish a function check protocol for the pipettor to ensure accurate and reliable mycoplasma test results. Findings include: Review of the laboratory's policies and procedures revealed no written function check protocol for the 50-microliter VWR high-performance pipettor, observed in use for mycoplasma testing on 1-23-18 at 1:30 p.m. Review of the manufacturer's instructions for the VWR high-performance pipettor revealed the manufacturer did not provide a function check protocol. Technical Consultant #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, confirmed the 50-microliter VWR high-performance pipettor has been in use for mycoplasma testing since the Meridian Bioscience Illumipro-10 test system was put in use for patient testing on 10-17-16
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control and patient test logs for mycoplasma testing with the Meridian Bioscience Illumipro-10 mycoplasma test system from 10-17-16 through 12-31-17, lack of documentation of an Individualized Quality Control Plan (IQCP), and confirmation by Technical Consultant #2, the laboratory failed to include a positive and negative control each day of testing from 11-1-16 through 12-31-17, when a total of 251 patient mycoplasma test results were reported. Findings include: Review of quality control and patient test logs for mycoplasma testing with the Meridian Bioscience Illumipro-10 mycoplasma test system from 10-17-16 through 12-31-17 revealed a positive and negative control was documented, as performed, for each mycoplasma test kit on the first day of use and at least every 30 days. There was no documentation of performance of a positive and negative control each day of patient testing from 11-1-16 through 12-31-17, when a total of 251 patient mycoplasma test results were reported. There was no documentation of establishment of an IQCP for mycoplasma testing with the Meridian Bioscience Illumipro-10 Mycoplasma test system. Technical Consultant #2 confirmed that a positive and negative control were not performed each day of patient testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality control and patient test logs for mycoplasma testing from 10-17-16 through 12-31-17 and lack of documentation of an Individualized Quality Control Plan (IQCP), the laboratory director failed to ensure a quality control program was established and maintained for Mycoplasma testing with the Meridian Bioscience Illumipro-10 mycoplasma test system from 11-1-16 through 12-31-17, when a total of 251 patient mycoplasma test results were reported. Refer to D5449 (Failure to include a positive and negative control each day of patient testing).