Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0307709	01/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Murfreesboro Medical Clinic	1272 Garrison Dr Floors 1-3, Murfreesboro, 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 review of the laboratory procedure manual, employee personnel records for 2018 and 2019 and interview with the Technical Consultant, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Interview on January 30, 2020 at 3:00 p.m. with the Tecnical Consultant confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, laboratory records, and interview with the lead testing personnel, the laboratory failed to verify the accuracy of histopathology procedures in 2019 and 2020. The findings include: 1) Observation of the laboratory on January 30, 2020 at 8:30 a.m. revealed a designated area in the laboratory for reading of histopathology slides. 2) Review of patient test reports (patient numbers one and four) revealed final patient test reports for histopathology read on June 25, 2019 and January 10, 2020, respectively. 3) Review of laboratory records revealed no records were present for twice a year verification of accuracy of histopathology procedures in 2019 and 2020. 4) Interview with the lead testing personnel on January 30, 2020 at 3:30 p.m. confirmed the laboratory failed to perform twice a year verification of accuracy for histopathology procedures in 2019 and 2020.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) records for Microbiology and interview with the Technical Consultant the laboratory failed to check each batch of media for sterility for Strep Select media in 2018 and 2019. The findings include: 1. Review of the Microbiology QC records revealed the laboratory failed to perform sterility checks for each batch/lot number of Strep Select media in 2018 and 2019. 2. Interview with the Technical Consultant on January 30, 2020 at 1:30 pm confirmed the laboratory failed to check each batch of media for sterility for Strep Select media in 2018 and 2019.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with the lead testing personnel, the laboratory failed to compare results between two instrument platforms that report the same analyte (Clostridium difficile) in 2018, 2019, and 2020. The findings include: 1) Observation of the laboratory on January 30, 2020 at 8:30 a.m. revealed two instrument platforms in use for performing and

	reporting Clostridium difficile testing (Biofire Torch and Meridian Illumigene). 2) Review of laboratory records revealed no twice a year comparison was performed between the two instruments in 2018, 2019, or 2020. 3) Interview with the lead testing personnel on January 30, 2020 at 3:30 p.m. confirmed the laboratory reports Clostridium difficile from both the Biofire Torch and Meridian Illumigene instruments and failed to compare results between the two instruments in 2018, 2019, and 2020.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of proficiency testing records and interview with the lead testing personnel, the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for the Clostridium difficile analyte performed on the Meridian Illumigene instrument in 2018, 2019, and 2020. The findings include: 1) Observation of the laboratory on January 30, 2020 at 8:30 a.m. revealed the Meridian Illumigene instrument in use for patient testing for Clostridium difficile assay. 2) Review of the laboratory's proficiency testing records revealed no records were available showing enrollment/participation in proficiency testing for the Meridian Illumigene Clostridium difficile assay in 2018, 2019 or 2020. 3) Interview with the lead testing personnel on January 30, 2020 at 3:30 p.m. confirmed the laboratory director failed to ensure enrollment in proficiency testing for the Clostridium difficile test performed on the Meridian Illumigene instrument in 2018, 2019, and 2020. The lead testing personnel confirmed the instrument was in use for patient testing during 2018, 2019, and 2020.