

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0303802	<b>(X3) Date Survey Completed</b>  10/28/2021
<b>Name of Provider or Supplier</b>  Medical Center Barbour	<b>Street Address, City, State</b>  820 W Washington Street, Eufaula, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control records for qualitative Clostridium difficile (C. diff) testing performed on the Meridian Bioscience illumigene C. difficile platform and an interview with the Technical Supervisor (also the Laboratory Manager), the laboratory failed to perform QC each day of patient testing in 2018-2021, in the absence of an IQCP (Individualized Quality Control Plan). The findings include: 1. A review of the Meridian Bioscience illumigene C. difficile QC records revealed positive and negative QC was only performed when a new test kit lot number was opened on 7/5/2018, 10/4/2018, 2/22/2019, 5/23/2019, 9/3/2019, 1/23/2020, 5/6/2020, 9/23/2020, 12/2/2020, 5/24/2021, and 9/28/2021. 2. During an interview on 10/28 /2021 at approximately 2:15 PM, the surveyor asked if Meridian Bioscience illumigene C. difficile QC was run each day of patient testing. The Technical Supervisor stated the testing personnel performed QC whenever a new lot number or shipment of C. diff test kits were opened, as per manufacturer's instructions. The surveyor explained whenever the manufacturer's requirements were less stringent than the CLIA requirement of positive/negative QC each day of patient testing, the laboratory had the option of developing and implementing an IQCP. The Supervisor confirmed the laboratory had not implemented an IQCP. Each test kit contained 50 C. diff tests; QC was only run when the kit was first opened, and the other 48 tests were used for patient tests on days when QC was not performed. .</p>

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on reviews of personnel files and an interview with the Technical Supervisor (also the Laboratory Manager), the Technical Consultant failed to perform and document the semi-annual competency evaluations for three of six new Testing Personnel (TP) in the Main Laboratory, and one of two new TP in the Respiratory Therapy Laboratory. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) for the Main Laboratory personnel revealed six new TP were hired since the previous survey on 6/28/2018. TP #4, TP #8 and TP #9 were recently hired in 2021; the other three had been employed for more than a year, as follows: A) TP #3: Hired and trained in May 2019; there was no competency assessment performed until 6/1/2020. B) TP #5: Hired and trained in February 2019; there was no competency assessment performed until November 2020. C) TP #7: Hired and trained in August/September 2018; there was no competency assessment performed until 8/3/2019. 2. A review of the Form CMS-209 (Laboratory Personnel Report) for the Respiratory Therapy Laboratory revealed two new TP hired since the previous survey on 6/28/2018. TP #5 was hired in October 2021. TP #4 was trained on 4/18/2020, however no competency assessment was performed until 4/8/2021. 3. During an interview on 10/27/2021 at 11:15 AM, the surveyor requested the semi-annual competency evaluations for the above testing personnel hired in 2018-2020. The Technical Supervisor stated semi-annual competency evaluations were not performed because she did not know this was a CLIA requirement. SURVEYOR ID# 32558 Licensure and Certification Surveyor