

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0666806	<b>(X3) Date Survey Completed</b>  06/01/2022
<b>Name of Provider or Supplier</b>  Baptist Memorial Medical Center	<b>Street Address, City, State</b>  670 N Germantown Pkwy, Suite 18, Cordova, TN	
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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of complete blood count (CBC) quality control (QC) package insert and interview with the technical consultant, the laboratory failed to label CBC QC vials with open date and corrected expiration date in 2022. The findings include: 1. Observation of the laboratory on 06/01/2022 at 9AM revealed quality control vials for performing complete blood count QC labeled as "05-30-22." There was no indication if this was an open date or expiration date. 2. Review of the CBC QC package insert revealed that controls are good for a maximum of 20 times within 35 days after opening. 3. Interview with the technical consultant on 06/01/2022 at 2PM confirmed the laboratory failed to label CBC quality control with open date and corrected expiration date in 2022.</p>
<b>D5469</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- 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</p>

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 review of the laboratory's complete blood count (CBC) quality control (QC) and patient test records, and interview with the technical consultant, the laboratory failed to verify correct control limits were used for two of fifteen lots reviewed. A total of five patients reported during the period the incorrect limits were in use (12/02/2020 to 03/1/2021 and 07/15/2021 to 10/18/2021). The findings include: 1. Review of the laboratory's CBC QC records and patient CBC testing records revealed the following: Lot 079000-in use from 12/02/2020 to 03/01/2021 with incorrect ranges for hematocrit (Package insert = 31.1-37.1% range in use = 32.1-36.1). Patient test record review revealed three patients were reported during the period the incorrect ranges for hematocrit were in use (patient medical record numbers 1C10650437, 1C11546341, 1C1026127). Lot 068200-in use from 07/15/2021 to 10/18/2021 with incorrect ranges for hematocrit (Package insert = 14.8 - 20.2%, range in use = 15.9-21.3%) and hemoglobin (Package insert = 5.4-6.8 gm/dL, range in use=5.8-7.2 gm/dL). Patient test record review revealed two patients were reported during the period the incorrect QC ranges for hematocrit and hemoglobin were in use (patient medical record numbers: 1C10137261, 1C10213000). 2. Interview with the technical consultant on 06/01/2022 at 2PM confirmed the laboratory failed to verify the control limits in use for hematocrit and hemoglobin analytes for two of fifteen lots review with a total of five patients reported during the periods the incorrect ranges were in use.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), testing personnel records and interview with the technical consultant, the laboratory director failed to ensure three of four new testing personnel had documentation of highest level of education prior to performing patient testing. The findings include: 1. Review of the Form CMS 209 revealed four new testing personnel since the last survey. The form indicated they were all performing moderately complex patient testing. 2. Review of testing personnel records revealed no evidence of highest level of education for testing personnel numbers four, five, and seven. 3. Interview with the technical consultant on 06/01

/2022 at 2PM confirmed the lab director failed to ensure three of four new testing personnel had appropriate education prior to performing patient testing. All three perform patient testing for complete blood count.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) records and interview with the technical consultant, the laboratory director failed to perform annual, initial, and six month competency assessments for testing personnel number two and four in 2020, 2021, and 2022 (four of sixteen competencies reviewed). The findings include: 1. Review of competency assessment records revealed the following: TP #2--No annual competency for 2020 or 2021 performed by the lab director/technical consultant. TP #4--No initial or 6 month competency performed by the lab director/technical consultant in 2021 and 2022. 2. Interview with the current technical consultant confirmed testing personnel competencies for TP #2 and TP #4 were not performed by the lab director/technical consultant for TP numbers two and four in 2020, 2021 and 2022.