

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0313761	<b>(X3) Date Survey Completed</b> 06/10/2021
<b>Name of Provider or Supplier</b> Baptist Minor Medical Center	<b>Street Address, City, State</b> 3295 Poplar Ave, Suite 105, Memphis, 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>D0000</b>	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This requirement is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209) and the Aspen Web database, and interview with the laboratory liaison, the laboratory failed to notify the state agency of change in laboratory director within 30 days in 2020. The findings include: 1. Review of the Form CMS-209 and the Aspen Web database revealed the name of a laboratory director that did not match the laboratory director of record in the Aspen Web database. 2. Interview with the laboratory liaison on June 10, 2021 at 1:00 pm confirmed the laboratory failed to notify the state agency of the change in laboratory director in 2020. The current director began performing lab director duties on March 1, 2020.
<b>D5200</b>	<b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230  Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
The laboratory failed to detect and correct problems with complete blood count quality control in 2019, 2020, and 2021. (Refer to D5293)

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment policy, quality control and quality assessment records, and interview with the laboratory liaison, the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with complete blood count (CBC) quality control (QC) in 2019, 2020 and 2021. The findings include: 1. Review of the laboratory's quality assessment plan revealed "This laboratory has established the following goals for our Quality Assessment Program. We intend to: 1. Evaluate the effectiveness of our written policies and procedures; 2. Identify problems in our laboratory and apply corrective action." 2. Review of the laboratory's quality control records and quality assessment monitoring forms revealed the following: QC lot numbers 069100, 079100 and 089100 with an expiration date of 05.06.2019 in use through 08.01.2019 with patient testing performed (patient number one-performed 7.31.19). No control package insert was available for lots 069100, 079100, and 089100. Quality assessment records for May and June 2019 revealed no evidence that the issues with controls used past the expiration date or the lack of quality control package insert was detected or corrected. No quality assessment documents were present for July 2019. QC lot numbers 067800, 077800, and 087800 with an expiration date of 09.14.20 in use on 08.11.2020. No QC package insert was present. Patient number two tested on 08.11.2020. No corrective action was performed for the lack of QC package insert. QC lot number 069000, 079000, and 089000 with an expiration date of 03.01.2021 in use through 03.04.2021 with patient testing performed on 03.02.2021 (patient numbers six and seven). Quality assessment records for the month of March 2021 revealed no evidence that the issue was detected or corrected. QC lot numbers 067800, 077800, and 087800 in use beginning 5.27.2021 until current date with patient testing performed (patient number five on 06.07.2021). The ranges used for quality control limits were incorrect. The laboratory used the ranges for AcT Diff instead of the AcT Diff2. Quality assessment records for the month of May 2021 revealed no evidence that the issue was detected or corrected. Quality assessment form for May 2021 revealed "Parameters, lot numbers, and expiration dates for new controls were updated in the analyzer and verified by manager and/or laboratory director monthly." Indicated as "yes" with no corrective action performed.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in

accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

The laboratory failed to have a technical consultant who met regulatory qualification requirements (Refer to D6034); the individual functioning as the technical consultant failed to resolve technical problems and apply corrective actions (Refer to D6043).

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on review of quality assessment records, personnel competency records, laboratory director personnel records, and interview with laboratory liaison, the laboratory director performed technical consultant duties without meeting regulatory requirements for training or experience in 2020 and 2021. The findings include: 1. Review of the laboratory's quality assessment records revealed the laboratory director signature on quality assessment records beginning March 2020 until present. 2. Review of testing personnel competency records revealed the laboratory director signature on testing personnel competency assessment records in 2020 and 2021. 3. Review of the laboratory director personnel records revealed no evidence of laboratory training or experience. 4. Interview with the laboratory liaison on June 10, 2021 at 1pm confirmed personnel records for the laboratory director did not include any evidence of laboratory training or experience. The laboratory director did not meet the regulatory requirements for training or experience, but was performing technical consultant duties in 2020 and 2021.

**D6043**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality assessment policy, quality control and quality assessment records, and interview with the laboratory liaison, the laboratory's technical consultant failed to resolve technical problems and apply corrective actions for problems with complete blood count (CBC) quality control in 2019, 2020 and 2021 for four out of five dates selected for review. The findings include: 1. Review of the laboratory's quality assessment plan revealed "This laboratory has established the following goals for our Quality Assessment Program. We intend to: 1. Evaluate the effectiveness of our written policies and procedures; 2. Identify problems in our laboratory and apply corrective action." 2. Review of the laboratory's quality control

records and quality assessment monitoring forms revealed four out of five dates selected for review had problems with lack of package inserts, controls used past expiration dates, and problems with quality controls limits in use. The quality assessment monitoring forms did not indicate that the issues were identified or that corrective action was performed. The quality assessment monitoring forms for the dates selected had been reviewed and signed by the laboratory director who was performing the functions of the technical consultant. 3. Interview with the laboratory liaison on June 10, 2021 at 1pm confirmed the laboratory's technical consultant failed to identify and correct problems with CBC quality control in 2019, 2020, and 2021. Issues were detected for four out of five dates selected.