

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2066156	<b>(X3) Date Survey Completed</b>  10/23/2019
<b>Name of Provider or Supplier</b>  Regional Med Extended Care Hospital, Llc	<b>Street Address, City, State</b>  890 Madison Ave 4th Floor Turner Tower, 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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 proficiency testing (PT) records and interview with the laboratory manager, the laboratory failed to retain all PT records for at least two years. The findings include: 1. Review of the PT records for 2018 and 2019 revealed the laboratory failed to retain the instruction booklet, submitted records for the whole blood glucose, the pH, PCO2 and PO2 analytes, and the signed attestation sheets. 2. Interview with the laboratory manager on October 23, 2019 at 11:30 a.m. confirmed that the laboratory failed to retain all PT records for 2018 and 2019.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals and interview with the laboratory manager, the laboratory failed to have procedures for the verification of performance specifications for the arterial blood gas (ABG) instrument, the ABG instrument validation of the Individualized Quality Control Plan (IQCP) procedure, twice per year comparison of instrument procedure, the updated EPOC instrument</p>

instructions for quality control, the qualifications, duties and responsibilities for testing personnel. The findings include: 1) Review of the laboratory procedure manuals revealed the following processes were not written procedures: verification of performance specifications for the ABG instrument, twice per year comparison of instrument procedure, the ABG instrument validation of the Individualized Quality Control Plan (IQCP) procedure, the updated EPOC instrument instructions for quality control, the qualifications, duties and responsibilities for testing personnel. 2) Interview on October 23, 2019 at 12:20 p.m. with the laboratory manager confirmed there were no written procedures for the following: verification of performance specifications for the ABG instrument, the ABG instrument validation of the Individualized Quality Control Plan (IQCP) procedure, twice per year comparison of instrument procedure, the updated EPOC instrument instructions for quality control, the qualifications, duties and responsibilities for testing personnel. CITATION NUMBER TWO: Based on review of the EPOC ABG manufacturer's instructions and the ABG records, and interview with the laboratory manager, the laboratory failed to perform the thermal quality assessment (QA) twice per year, in 2018 and 2019. The findings include: 1) Review of the EPOC ABG manufacturer's instructions revealed the thermal QA is to be performed twice per year. 2) Review of the ABG records revealed the twice per year thermal QA was not included in 2018 and 2019. 3) Interview on October 23, 2019 at 2:40 p.m. with the laboratory manager confirmed the thermal QA was not performed twice per year in 2018 and 2019.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of employee personnel records for 2018 and 2019 and interview with the manager, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency. The findings include: 1) Review of 18 of 18 employee personnel records for 2018 and 2019 revealed documentation of the six required criteria of competency that include: 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 were not included in the competency assessments. 2) Interview with the manager on October 23, 2019, at 11:30 a.m. confirmed the competency for testing personnel evaluated during 2018 and 2019 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).