

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2066156	(X3) Date Survey Completed 09/28/2022
Name of Provider or Supplier Regional Med Extended Care Hospital, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, review of testing personnel records, and interview with the respiratory therapy manager, the laboratory failed to ensure proficiency testing was performed by the same personnel who perform patient testing in 2020, 2021, and 2022 when eight of eight events were performed by one testing person. The findings include: 1. Review of the laboratory's CAP PT attestation statements revealed the performance of arterial blood gas proficiency testing by one testing person for eight of eight events reviewed from 2020, 2021, and 2022 (2020 events one, two, and three; 2021 events one, two and three; and 2022 events one and two). 2. Review of testing personnel records revealed there were nineteen personnel who perform arterial blood gas testing. 3. Interview on 09/28/22 at 3:45 pm with the respiratory therapy manager confirmed the laboratory failed to ensure arterial blood gas proficiency testing was performed by personnel who routinely perform patient arterial blood gas testing in 2020, 2021 and 2022.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a</p>

function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory area, lack of records and interview with the respiratory therapy manager, the laboratory failed to verify the accuracy of its' thermometers in 2020, 2021, and 2022. The findings include: 1. Observation on 09/28/22 at 10:00 am of the laboratory area where blood gas instruments, reagent cartridges, controls and calibration verification materials were stored revealed uncertified thermometers in use for monitoring temperatures of the room and the refrigerator. 2. There was a lack of records verifying the accuracy of the temperature monitoring devices (thermometers). 3. Interview on 09/28/22 at 3:45 pm with the respiratory therapy manager confirmed the laboratory failed to verify the accuracy of its' thermometers that were being used to monitor the storage/operating temperature of blood gas instruments, reagent cartridges, controls and calibration verification materials in 2020, 2021, and 2022.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the respiratory therapy manager, the laboratory director failed to ensure job descriptions for lab director, clinical consultant, technical consultant, and testing personnel in 2022. The findings include: 1. Review of personnel records revealed the following: No lab director job description. No job description for the clinical consultant position. No job description for the technical consultant position. No job descriptions were present for twelve of twelve testing personnel records reviewed. 2. Interview on 09/28/22 at 3:45 pm with the respiratory therapy manager confirmed the laboratory director failed to ensure written job descriptions for the positions of lab director, clinical consultant, technical consultant and testing personnel.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b)

The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, personnel college degrees and transcripts, and interview with the respiratory therapy manager, four of five personnel performing technical consultant duties did not have the required education to perform the duties. The findings include: 1. Review of laboratory records including proficiency testing, quality control, quality assessment and testing personnel competency assessments revealed technical consultant duties performed by five personnel. 2. Review of documentation of highest level of education revealed four of the five did not have the required education as defined in the regulations to perform the technical consultant duties. Duties performed by the four who did not meet the regulatory education requirement included signing attestation statements and performing competency assessments in 2020, 2021 and 2022. 3. Phone interview with the respiratory therapy manager on 10/04/2022 at 3:30 pm confirmed four of five personnel performing signing of attestation statements and competency assessments did not have the required minimum education to perform the technical consultant duties.