

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2065842	(X3) Date Survey Completed 06/17/2021
Name of Provider or Supplier Altus Lumberton Hospital, Llc	Street Address, City, State 137 North Lhs Drive, Lumberton, TX	
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: Review of the CMS 209 Laboratory Personnel Report, the American Proficiency Institute (API) proficiency testing records, and staff interview found that the laboratory failed to test proficiency testing samples in the same manner as it routinely tested patient samples in five of five events for Chemistry and 4 of 4 events for Hematology in 2020 and 2021. Findings were as follows: 1. Review of the CMS Report 209 Laboratory Personnel report found the laboratory listed 34 testing personnel performing non waived testing. 2. Review of the American proficiency Institute (API) proficiency testing records for Chemistry and Hematology/Coagulation for the 1st testing event of 2020 through the second testing event of 2021 (3 testing events per year) found that testing person three signed the attestation statements for 5 of 5 Chemistry testing events and four of four Hematology testing events . 3. Interview of the technical consultant conducted June 17, 2021 at 10:20 AM confirmed that testing person three performed all proficiency testing events.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Review of quality control records and interview of facility personnel found that the laboratory failed to have a means of evaluating the accuracy and precision of Chemistry and Coagulation test performance over time for quality control materials tested on the Triage meter (Troponin and D dimer) and the i Stat (Blood gasses and Lactate) . Findings included: 1. Review of laboratory quality control records for the Triage meters in 2021 found no statistical information or graphs available for review that would aid in identifying shifts and trends in quality control performance occurring over time. Quality control material lot numbers used between January and March 2021 for each of the Triage meters were: Meter 00084422 - D dimer Triage Total 5 Control 1 lot C3553AN expiration 2021/03/27- used January 07, 2021 Triage Total 5 Control 2 lot C3577AN expiration 2021/04/22- used January 07, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used January 23, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used January 23, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used February 4, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used February 4, 2021 Triage Total 5 Control 2 lot C3658AN Expiration 2021/08/06 - used February 20, 2010 Triage Total 5 Control 2 lot C3671AN expiration 2021/09/04 - used February 20, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used March 4, 2021 Triage Total 5 Control 2 lot C3671AN expiration 2021/09/04 - used March 4, 2021 Triage Total 5 Control 1 lot C3659AN expiration 2021/08/27 - used March 18, 2021 x2 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used March 18, 2021 x2 Meter 00084422 CKMB and Troponin Triage Total 5 Control 1 lot C3553AN expiration 2021/03/27- used January 12, 2021 Triage Total 5 Control 2 lot C3577AN expiration 2021/04/22- used January 12, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used January 21, 2021 Triage Total 5 Control 2 lot C3577AN expiration 2021/04/22- used January 21, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used January 27, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used January 27, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used February 4, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used February 4, 2021 Triage Total 5 Control 2 lot C3658AN Expiration 2021/08/06 - used February 20, 2010 Triage Total 5 Control 2 lot C3671AN expiration 2021/09/04 - used February 20, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used February 24, 2021 Triage Total 5 Control 2 lot C3670AN expiration 2021/08/21- used February 24, 2021 Triage Total 5 Control 1 lot C3659AN expiration 2021/08/27 - used March 18, 2021 x2 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used March 18, 2021 x2 Triage Total 5 Control 1 lot C3659AN expiration 2021/08/27 - used March 24, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used March 24, 2021 Meter 00081982 - D dimer Triage Total 5 Control 1 lot C3553AN expiration 2021/03/27- used January 07, 2021 Triage Total 5 Control 2 lot C3577AN expiration 2021/04/22- used January 07, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used January 23, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used January 23, 2021 Triage Total 5 Control 1 lot C3654AN expiration 2021/06/04 - used February 4, 2021 Triage Total 5 Control 2 lot C3668AN expiration 2021/06/30- used February 4, 2021 Triage Total 5 Control 2 lot C3658AN Expiration 2021/08/06 -

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