

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2017356	<b>(X3) Date Survey Completed</b> 01/09/2024
<b>Name of Provider or Supplier</b> Altus Baytown Hospital	<b>Street Address, City, State</b> 1626 W Baker Road, Baytown, TX	
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>	An announced survey of the laboratory was conducted on 01/09/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form CMS (Centers for Medicare and Medicaid) 209, personnel records, policies/procedures and staff interview the laboratory failed to document competency assessment for one of two clinical consultants employed by the facility. Findings included: 1. Review of submitted Form CMS 209 revealed the laboratory employed two clinical consultants. 2. Review of personnel records revealed Clinical Consultant number 1 (as indicated on submitted Form CMS 209) did not have documentation of competency assessment. 3. Review of policy "Lab2.0 - Quality Control Program" (effective date: 2024-01-07) revealed the policy did not address competency assessment for Clinical Consultant or Technical Consultant positions. 4. In an interview on 01/09/2024 at 1035 hours in the conference room, the laboratory's Testing Person number 1 (as indicated on submitted Form CMS 209) confirmed the findings.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL 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</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures and staff interview, the laboratory failed to define one of one procedure/protocol for when the laboratory cannot perform proficiency testing (PT) due to technical difficulties, or alternate means for assessing test accuracy after technical difficulties have been resolved, in order to comply with the requirement of at least twice yearly PT/test accuracy verification of results.

Findings included: 1. Review of policy "Lab2.0 - Quality Control Program" (effective date: 2024-01-07) revealed the policy did not address protocols for when the laboratory cannot perform proficiency testing (PT) due to technical difficulties, or alternate means for assessing test accuracy after technical difficulties have been resolved to ensure compliance with the frequency of PT/test accuracy verification regulatory requirements. 2. In an interview on 01/09/2024 at 1105 hours in the conference room, the laboratory's Testing Person number 1 (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid