

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0683776	(X3) Date Survey Completed 04/21/2021
Name of Provider or Supplier Broaddus Hospital	Street Address, City, State # 1 Health Care Drive, Philippi, WV	
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
D0000	An announced, on site, recertification survey was performed at Broaddus Hospital on April 20 and 21, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve a satisfactory score of at least 80% for the analytes 0585 TSH and 0595 TY in 1 of 3 American Proficiency Institute (API) 2020 testing events for Endocrinology. Findings: 1. API testing documentation identified the following unsatisfactory scores for the 2nd 2020 testing event: - 0% for 0585 TSH - 0% for 0595 TY 2. CASPER Report 0155D confirmed the API scores of 0% for 0585 TSH and 0595 TY. 3. The technical supervisor confirmed the findings on 4/20/2021 at approximately 10:00 am.</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve an overall test</p>

event score of 100% for the American Proficiency Institute (API) in 1 of 3 2020 testing events for Immunohematology. Findings: 1. API documentation identified a score of 80% for Immunohematology (blood bank) Compatibility testing in the 3rd 2020 testing event. a. SER-11 reported as NOT COMPATIBLE b. Expected result for SER-11 was COMPATIBLE 2. CASPER Report 0155D confirmed the 80% unsatisfactory performance for Compatibility testing. 3. The laboratory manager confirmed the findings on 4/20/2021 at approximately 10:15 AM.

D3015

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

This STANDARD is not met as evidenced by:
Based on record review and interview the laboratory failed to perform and document external quality control (QC) in Immunohematology for 4 of 41 days of patient testing reviewed from January 1, 2020 thru April 21, 2021. Findings: 1. Immunohematology QC was reviewed from January 1, 2020 thru April 21, 2021. 2. Immunohematology patient testing log was reviewed from January 1, 2020 thru April 21, 2021. 3. Documentation revealed that 4 of 41 days (7/1/2020, 8/14/2020, 12/21/2020, 2/27/2021) of patient testing in Immunohematology had no external QC performed and documented. 4. The laboratory manager confirmed the findings April 21, 2021 at 9:35 am.