

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0690739	(X3) Date Survey Completed 02/29/2024
Name of Provider or Supplier Highland Community Hospital	Street Address, City, State 130 Highland Parkway, Picayune, MS	
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
D5401	<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 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's Policy and Procedure Manual for Blood Bank, the Blood Bank Transfusion Service Testing record from 6/3/2022 through 2/28/2024, and interview with General Supervisor #6, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory personnel failed to follow the laboratory's "ABO/Rh and Weak D Testing" procedure for two cord blood tests performed during twenty-one months of testing. Findings include: 1. Review of the laboratory's Policy and Procedure Manual for Blood Bank revealed the "ABO/Rh and Weak D Testing" procedure states, "Testing for a weak D is not required for all negative anti-D immediate spin reactions except for cord bloods, which always require a weak D test for negative reactions with Anti-D." 2. Review of the Blood Bank Transfusion Service Testing record from 6/3/2022 through 2/28/2024 revealed the laboratory personnel failed to perform weak D testing on the following two cord blood samples when a negative reaction was obtained with Anti-D testing: 12/6/2023-Patient Medical Record #20680582. 12/13/2023-Patient Medical Record #20616090. 3. In an interview on 2/28/2024 at 5:00 p.m., General Supervisor #6 confirmed that weak D testing was not performed on these two patient cord blood samples.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all</p>

personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records, new analyzer verification records and the CMS 209 personnel form, the laboratory director failed to ensure two of seventeen testing personnel, responsible for moderate complexity testing, received the appropriate training and demonstrated that they could perform all testing operations reliably, to provide and report accurate results, on new analyzers put in use in 2023. Findings include: 1. Review of personnel records and new analyzer verification records since 6/2/2022 revealed Testing Personnel #18, date of hire November 2022, listed on the CMS 209 personnel form, had no documentation of training or documentation of performance of testing operations for the following four Beckman Coulter analyzers, in use for eight months from 6/27/23 through the day of the survey, 2/29/24: DxC 700AU and AU 480 for routine chemistry testing; DxI 600 and Access II for immunoassay testing. 2. Review of personnel records and new analyzer verification records since 6/2/2022 revealed Testing Personnel #20 had no documentation of training or documentation of performance of testing operations, since this individual's date of hire in September 2023, for the Instrumentation Laboratories (IL) ACL TOP 350 coagulation system, put in use 4/12/23, and ACL Elite coagulation system, put in use 4/20/23, or for the following Beckman Coulter analyzers put in use on 6/27/23: DxC 700AU and AU 480 for routine chemistry testing; DxI 600 and Access II for immunoassay testing.