Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0304601	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clay County Hospital Laboratory	83825 Highway 9, 1st Floor South Hall, Ashland, AL	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the Respiratory records, and an interview with TP (Testing Personnel) #8, the laboratory failed to retain documentation of daily Respiratory quality control (QC) performed on the Roche Cobas b 221 Respiratory analyzer from the date of the previous survey (7/13/2022) to the current survey (5/8/2024) . The findings include: 1. A review of the Roche Cobas b 221 QC records revealed the laboratory retained the Roche Diagnostics Quality Assurance Reports (peer group evaluations) for each Respiratory QC lot number from August 2022 through to the current 2024 report. There was no evidence of daily Respiratory QC data retained after July 2022. 2. During an interview on 5/8/2024 at 11:27 AM, TP #8 explained they moved into the Respiratory Manager role shortly after the last inspection in 2022. They were not aware they needed to print daily QC. TP #8 confirmed patients are not able to be performed until all three levels of QC are acceptable.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B

	grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the Blood Bank QC (Quality Control) records, a review of the policy and procedure manual, and an interview with the Technical Consultant, the laboratory failed to document Blood Bank QC per the laboratory requirements. This was noted for 1 of 30 days reviewed in October 2022. The findings include: 1. A review of the Blood Bank QC revealed no evidence of ABO and Rh interpretation documentation for 10/22/2022. 2. A further review of the policy and procedure under "Quality Control Testing- Reagents, Equipment" revealed, "...Quality control reactions.... must be documented in the Blood Bank Log." 3. During an interview on 5/7/2024 at 1:53 PM, The Technical Consultant confirmed the above findings.