Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0661760	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Summers County Arh Hospital Laboratory	115 Summers Hospital Road, Hinton, 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, routine recertification survey was conducted at Summers County ARH Hospital Laboratory on April 19th and April 20th of 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the evaluation of results for 5 of 5 College of American Pathologists (CAP) proficiency testing (PT) events in Immunohematology for 2021. Findings: 1. Review of 2021 CAP Immunohematology PT records identified 5 of 5 event results had no documentation of review by the technical supervisor. 2. Review of the 2nd event 2021 identified a score of 80% for the analyte 0855 Antibody Detection. No corrective action could be located. 3. An interview with the general supervisor and laboratory director, on 4/19 /22 at approximately 9:30 AM, confirmed the findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to monitor the storage of room temperature platelets throughout the storage in the lab for 4 of 5 issuances reviewed. Findings: 1. Review of P&P identified a process stating the temperatures of platelets must be monitored and documented at the initial receipt into the laboratory and every 4 hours the unit is kept on the platelet rotator before issuance to the patient. 2. Review of platelets issued to patients from May 2021 thru the date of survey identified 5 units of platelets received into the laboratory and issued to patients: 5/13/21, 6/2/21, 6/4/21(2 units of platelets), 1/22/22. 3. Review of temperature logs revealed 4 of 5 platelet units had no initial temperature recorded and no documentation of temperature every 4 hours as required. 4. An interview with the general supervisor, 4/19/22 at approximately 4:30, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to establish a process to monitor, assess, and correct problems identified in the post analytic systems. Specifically: 1) Ensuring all Individualized Quality Control Plans (IQCP) are evaluated for effectiveness and that quality control (QC) is monitored for performance at specified intervals. Review for the Cepheid Gene Expert and the BioFire Film Array test systems IQCPs identified no documented review and evaluation of effectiveness for 3 of the 3 assays performed on the BiofIre Film Array in 2020 or 2021. 2) Ensuring all proficiency testing (PT) scores are reviewed and corrective action documented. Refer to D5211. 3) Ensuring the documented storage of blood products when received and stored in the laboratory. Refer to D5555. An exit interview with the technical supervisor and laboratory director, on 4/20/22 at approximately 3:30 PM, confirmed the findings.