Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0016978	01/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Beckley Appalachian Regional Hospital	306 Stanaford Road, Beckley, 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 Beckley Appalachian Regional Hospital on January 10 and January 11, 2023, 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 found are cited below.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview the laboratory failed to enroll in a commercial proficiency testing (PT) program for the molecular methodology utilized to detect potential pathogenic bacteria, viruses, and parasites on the Biofire FilmArray 2.0 analyzer for 2021 and 2022. Findings: 1. Review of American Proficiency Institute (API) PT records for 2021 and 2022 revealed no enrollment for the Biofire FilmArray Gastrointestinal, Meningitis, and Respiratory panels. No documentation of proficiency testing could be located. 2. An interview with the general supervisor and administrative laboratory director, on 1/10/23 at approximately 10:30 AM, confirmed the lack of PT enrollment for the Biofire Gastrointestinal, Meningitis, Parasite ID, and

	Respiratory panels for 2021 and 2022. 3. An exit interview with the administrative team and the medical laboratory director, on 1/11/23 at approximately 4:00 PM, reiterated and confirmed the findings.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on written policies and procedures, observation, and interview the laboratory failed to follow the established policies and procedures (P&P) to ensure positive identification of patients receiving blood and blood products for 12 of 17 patient specimens examined. Findings: 1. Review of P&P identified "Patient Identification and Specimen Collection for Transfusion Services" stating blood bank specimens are required to have the collector's initials, initials of second staff member verifying that patient's identity, collection date, and collection time. 2. A tour of the blood bank laboratory, 1/10/23 at approximately 4:00 PM, identified the retained, previously tested patient specimens in the refrigerator. 3. An examination of 17 retained patient specimens revealed the following 12 unacceptable specimens: 3 specimens had no time of collection, 2 specimens did not have both sets of initials, 7 specimens had only a printed patient label with no documentation. 4. An interview with the general supervisor, 1/10/23 at approximately 4:00 PM, confirmed the lack of required elements on the blood bank specimens. 5. An exit interview with the administrative team and medical laboratory director, 1/11/23 at approximately 4:00 PM, reiterated and confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of written policies and procedures (P&P) and interview, the

	laboratory failed to establish a complete testing procedure for antibody identification that includes (4) preparation of controls, (7) specific control procedures and acceptability criteria, (8) corrective actions to take when control results fail to meet acceptability criteria , and (9) limitations of the antibody identification test method and actions to take for further testing if required. Findings: 1. Review of P&P revealed an Antibody Identification P&P that lacked all the listed required elements. 2. An interview with the administrative laboratory manager and the general supervisor, 1/10 /23 at approximately 2:50 PM, confirmed the findings.