Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661760	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Summers County Arh Hospital Laboratory	**Street Address, City, State** 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
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 a review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory manager, the laboratory failed to enroll in an approved program for Microbiology and Routine Chemistry for the 1st and 2nd testing events of 2020 and no other testing was performed to establish and maintain the accuracy of the testing procedures, in accordance with 493.1236 (c)(1). Findings: 1. A review of 2019 and 2020 API PT records identified no enrollment for Microbiology- Bacteriology PT of the Film Array BioFire GI panel, Respiratory panel, and Meningitis panel for testing events 1 and 2 of 2020. 2. A review of 2019 and 2020 API PT records identified no enrollment for Chemistry- Core Chemistry and Hematology PT of Respiratory Therapy testing pCO2, pH, pO2, Carboxyhemoglobin, Hemoglobin (Blood Oximetry), Methemoglobin, and Oxyhemoglobin for testing events 1 and 2 of 2020. 3. A review of the PT records for the API Microbiology and Core Chemistry 2020 testing events (1 and 2), identified an investigation and corrective action documentation by the laboratory to enroll testing in PT and the receipt of the order for the PT for all testing that was not enrolled, except for the Meningitis panel on the FilmArray BioFire. 4. During an interview with the laboratory manager, on 9/15/2020 at approximately 12:00 PM, the laboratory manager stated that

	no enrollment for PT had been performed for Respiratory Therapy and BioFire FilmArray testing in 2020 and no other testing was performed to establish and maintain the accuracy of the tests.
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 a review of the laboratory quality control (QC) records and patient testing log book for Immunohematology, the laboratory failed to perform and document QC for ABO, antibody screening, and crossmatch testing for 4 days of patient testing from March 1, 2020 thru September 16, 2020. Findings: 1. A comparative review of the Immunohematology patient testing log and the daily QC worksheets from March 1, 2020 thru September 16, 2020, identified 4 separate instances of patient testing without documentation that QC had been performed for that 24 hour period. a. On 9/8 /2020 a patient retype was performed and no QC was documented. QC was documented as performed 9/09/2020 and 09/05/2020. b. On 5/8/2020 2 patients were tested for ABO, Rh, Antibody screening, and 2 units were crossmatched for each patient. No QC was documented. QC was documented as performed 5/06/2020 and 05 /11/2020. c On 4/02/2020 2 units of RBCs were retyped and no QC was documented. QC was documented as performed 4/01/2020 and 4/06/2020. d. On 3/28/2020 1 patient had an ABO, Rh, Antibody screening, and a 2 unit crossmatch performed. No QC was documented. QC was documented as performed 3/27/2020 and 3/29/2020. 2. During an interview with the laboratory manager, on 9/16/2020 at approximately 10: 40 AM, the laboratory manager reviewed the patient testing log book and the QC daily records for Immunohematology. The laboratory manager stated that no QC was documented as performed within 24 hours of the 4 identified incidences (9/8/2020, 5/8 /2020, 4/2/2020, and 3/28/2020).