Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 18D0684548	**(X3) Date Survey Completed** 02/27/2023
Name of Provider or Supplier Whitesburg Arh	**Street Address, City, State** 240 Hospital Rd, Whitesburg, KY	
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	Based on desk review of proficiency testing (PT) from 2021 through 2022 the laboratory failed to meet the following conditions resulting a non-initial unsuccessful PT participation: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6076 - HIGH COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1441
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each

	specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialty of Immunohematology for Compatibility Testing. (Refer to D2181).
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Report and American Proficiency Institute (API) 2021 records (3rd event) and 2022 records (1st, 2nd and 3rd events), the laboratory failed to achieve satisfactory performance of 100% for four of four testing events in the specialty of Immunohematology for Compatibility Testing. 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report revealed the following: Immunohematology 2021 3rd event Laboratory received an unsatisfactory score of 80% for the Compatibility Testing analyte. Immunohematology 2022 1st Event Laboratory received an unsatisfactory score of 80% for the Compatibility Testing analyte. Immunohematology 2022- 2nd Event Laboratory received an unsatisfactory score of 80% for the Compatibility Testing analyte. Immunohematology 2022- 3rd Event Laboratory received an unsatisfactory score of 80% for the Compatibility Testing analyte. 2. A proficiency testing desk review from API 2022 proficiency testing records confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing results revealed the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2181