

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0323855	(X3) Date Survey Completed 02/06/2024
Name of Provider or Supplier Harlan Arh	Street Address, City, State 81 Ballpark Road, Harlan, 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	<p>The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The laboratory was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider</p>

	<p>Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2023 records (2nd and 3rd events), 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)</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and API records 2023 (2nd and 3rd events), the laboratory failed to achieve an overall testing event score of satisfactory performance (100%) for two (2) of two (2) consecutive testing events in the specialty of Immunohematology for Compatibility Testing. 1.A review of the CASPER-0155 report revealed the following: Compatibility Testing 2023- 2nd Event The Laboratory received an unsatisfactory score of 80%. Compatibility Testing 2023- 3rd Event The Laboratory received an unsatisfactory score of 60%. 2. A review of proficiency testing records from API 2023 confirmed the above findings.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and API 2023 records (2nd and 3rd events), the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6089)</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and API 2023 records (2nd and 3rd events), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. (Refer to 2181)</p>