Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0325122	02/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mcdowell Arh	9879 Route 122, Mc Dowell, 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	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
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 proficiency testing desk review of the Certification and Survey Provider

	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 ABO. (Refer to D2162)
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in 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 CASPER-0155 and API 2023 records (2nd and 3rd events), the laboratory failed to achieve satisfactory performance (100%) for two (2) of (2) consecutive testing events in the specialty of Immunohematology for ABO. 1. A review of the CASPER-0155 report revealed the following: ABO 2023- 2nd Event The laboratory received an unsatisfactory score of 60%. ABO 2023- 3rd Event The laboratory received an unsatisfactory score of 0% 2. A review of proficiency testing records from API 2023 confirmed the above findings.
D2163	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g) 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 CASPER-0155 and API records 2022 (3rd event) and 2023 (2nd and 3rd events), the laboratory failed to achieve an overall testing event score of satisfactory performance (100%) for three (3) of four (4) events in the specialty of Immunohematology for ABO/RHO. 1. A review of the CASPER-0155 report revealed the following: ABO/RHO 2022- 3rd Event The laboratory received an unsatisfactory score of 90%. ABO/RHO 2023- 2nd Event The Laboratory received an unsatisfactory score of 80%. ABO/RHO 2023- 3rd Event The Laboratory received an unsatisfactory score of 0%. 2. A review of proficiency testing records from API 2022 and 2023 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 proficiency testing desk review of the CASPER-0155 Individual

	Laboratory Report and API 2022 (3rd event) and 2023 records (2nd and 3rd events), 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 proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and API 2022 (3rd event) and 2023 records (2nd and 3rd events), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. (Refer to 2163)