Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0325122	03/14/2025
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 (PT) scores obtained from the national database and verified with the PT 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] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate 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 (PT) desk review of the Certification and Survey

	Provider Enhanced Reporting (CASPER)-0155 Individual Laboratory Profile Report and American Proficiency Institute (API) proficiency testing 2024 (3rd event) and 2025 (1st event) records, the laboratory failed to successfully participate in a PT program. The laboratory failed to successfully participate in the subspecialty of Toxicology for Phenobarbital for 2 consecutive testing events. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(f) (f) Failure to achieve satisfactory performance for the same analyte or test 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 (PT) desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Individual Laboratory Report and American Proficiency Institute 2024 (3rd event) and 2025 (1st event) records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in 2 consecutive testing events in the subspecialty of Toxicology for the analyte Phenobarbital The findings include: 1. Review of the Casper -0155 Individual Laboratory Profile Report revealed the following: Toxicology 2024- 3rd Event The laboratory received an unsatisfactory score of 60% for Phenobarbital. Toxicology 2025- 1st Event The laboratory received an unsatisfactory score of 0% for Phenobarbital. 2. A PT desk review from API 2024 and 2025 PT records confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 Individual Laboratory Report and American Proficiency Institute 2024 (3rd event) and 2025 (1st event) records, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful PT participation in the subspecialty of Toxicology for Phenobarbital testing for 2 consecutive events. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) 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 (PT) desk review of the Certification and Survey

	Provider Enhanced Reporting (CASPER)-0155 Individual Laboratory Report and American Proficiency Institute 2024 (3rd event) and 2025 (1st event) records, the laboratory director failed to ensure that the PT samples were tested as required under Subpart H during 2 consecutive testing events. Refer to D2118.