

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0325122	(X3) Date Survey Completed 02/16/2021
Name of Provider or Supplier Mcdowell Arh	Street Address, City, State 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
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 desk review of chemistry proficiency testing results from the American Proficiency Institute (API) proficiency testing agency on 2/16/2021, the laboratory failed to successfully participate in two (2) consecutive chemistry testing events. See D2087 and D2096</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte</p>

in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on the desk review of proficiency testing results from the American Proficiency Institute, the laboratory failed to attain an overall satisfactory score of at least eighty percent (80 %) in two (2) Chemistry testing events. Findings include: The facility scored Zero percent (60 %) in the second (2nd) testing event of 2020 and scored Zero percent (60 %) in the third (3rd) testing event in 2020.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(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 desk review of Chemistry proficiency testing results from the American Proficiency Institute testing agency on 02/16/2021, the laboratory failed to successfully achieve satisfactory performance for the Human Chorionic Gonadotropin (HCG) certified analyte in two (2) consecutive testing events. Findings include: 1. The laboratory failed to achieve a satisfactory performance for the Human Chorionic Gonadotropin (HCG) in the second (2) testing event of 2020. 2. The laboratory failed to achieve a satisfactory performance for the Human Chorionic Gonadotropin (HCG) in the third (3) testing event of 2020