

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0244179	(X3) Date Survey Completed 11/27/2023
Name of Provider or Supplier A Woman's Choice Of Charlotte	Street Address, City, State 421 N Wendover Road, Charlotte, NC	
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 Division of Health Service Regulation (State agency) conducted a proficiency testing desk review survey that was completed on November 20, 2023. As a result of the survey, it was determined that the following Conditions were not met: 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	<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 CMS (Centers for Medicare and Medicaid Services) Casper reports 153D and 155D and desk review of 2021, 2022, and 2023 API (American</p>

Proficiency Institute) proficiency testing results 11/20/23, the laboratory failed to achieve satisfactory performance for D (Rho) type and failed to achieve overall testing event scores of satisfactory for ABO/RHO on four out of five testing events, resulting in unsuccessful participation in proficiency testing. Findings: See the deficiencies cited at D2162 and D2163.

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 desk review of CMS Casper reports 153D and 155D and desk review of 2021, 2022, and 2023 API proficiency testing results 11/20/23, the laboratory failed to achieve satisfactory performance for D (Rho) type on four of five testing events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS Casper reports 153D and 155D and desk review of 2021 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for D (Rho) type on the API 2021 Immunology/Immunochemistry 3rd event. 2. Desk review of CMS Casper reports 153D and 155D and desk review of 2022 proficiency testing results revealed the laboratory failed to participate and received a score of 0% for D (Rho) type on the API 2022 Immunology/Immunochemistry 1st event. 3. Desk review of CMS Casper reports 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory failed to participate and received a score of 0% for D (Rho) type on the API 2023 Immunology/Immunochemistry 1st event. 4. Desk review of CMS Casper reports 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory received a score of 80% for D (Rho) type on the API 2023 Immunology/Immunochemistry 2nd event.

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 desk review of CMS Casper reports 153D and 155D and desk review of 2021, 2022, and 2023 API proficiency testing results 11/20/23, the laboratory failed to achieve overall satisfactory performance for ABO/RHO on four of five testing events, resulting in unsuccessful performance. Findings: 1. Desk review of CMS Casper reports 153D and 155D and desk review of 2021 API proficiency testing results revealed the laboratory received an overall test event score of 0% for ABO/RHO on the API 2021 Immunology/Immunochemistry 3rd event. 2. Desk review of CMS Casper reports 153D and 155D and desk review of 2022 proficiency testing results revealed the laboratory received an overall test event score of 0% for ABO/RHO on the API 2022 Immunology/Immunochemistry 1st event. 3. Desk review of CMS Casper reports 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory received an overall test event score of 0% for ABO

	<p>/RHO on the API 2023 Immunology/Immunochemistry 1st event. 4. Desk review of CMS Casper reports 153D and 155D and desk review of 2023 API proficiency testing results revealed the laboratory received an overall test event score of 80% for ABO /RHO on the API 2023 Immunology/Immunochemistry 2nd event.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on desk review of CMS Casper reports 153D and 155D and desk review of 2021, 2022, and 2023 API proficiency testing results 11/20/23, the laboratory director failed to provide overall management and direction to ensure successful proficiency testing participation. Findings: See the deficiency cited at D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that 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 desk review of CMS Casper reports 153D and 155D and desk review of 2021, 2022, and 2023 API proficiency testing results 11/20/23, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: See the deficiencies cited at D2162 and D2163.</p>