

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111832	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Women's Choice Of Bergen County Pa	Street Address, City, State 200 Grand Avenue, Suite 101, Englewood, NJ	
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
D2155	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to submit ABO Rho(D) Groups and D(Rho) Typing results to the American Association of Bioanalysts (AAB) in event 2, 2022. The TC confirmed on 5/31/2023 at 11:00am the laboratory failed to submit PT results to AAB.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to retain all PT records for Nonchemistry event Q1- 2021 performed with the American Association of</p>

	<p>Bioanalysts (AAB) at the time of survey. The TC confirmed on 5/31/23 at 10:45 am that all records for event Q1- 2021 were not retained.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Laboratory Temperature Logs (LTL) and interview with the Technical Consultant (TC), the laboratory failed to monitor and document Room temperature, where Rhesus (Rh) tests are performed from 10/04/19 to the date of survey. The TC confirmed on 5/31/23 at 11:35 am that Room temperature was not documented .</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor lack of Maintenance Records and interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance of the Centrifuge used for Rhesus (Rh) testing from 10/4/19 to the date of survey. The TC confirmed on 5/31/23 at 11:15 am the laboratory failed to perform and document maintenance on the centrifuge.</p>
<p>D5469</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be</p>

established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Consultant (TC), the laboratory failed to verify Panoscreen QC material before use for Rhesus (Rh) tests from 10/4/19 to the date of survey. The TC confirmed 5/31/23 at 11:15 am that QC material was not verified before putting in use.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual and interview with Technical Consultant (TC) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 10/04/19 to the date of survey. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use. 2. The TC confirmed on 5/31/23 at 10:45 am that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.