

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0929149	<b>(X3) Date Survey Completed</b>  12/20/2021
<b>Name of Provider or Supplier</b>  Planned Parenthood South Atlantic	<b>Street Address, City, State</b>  700 South Torrance Street, Charlotte, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020, and 2021 Eldon Card RhD QC(quality control) records and review of the Immucor Panoscreen QC assay sheets, the laboratory failed to discard control materials that had exceeded the expiration date and was used for testing. Findings: Random review of 2019, 2020, and 2021 RhD QC records and review of QC assay sheets revealed the Immucor Panoscreen positive control lot number 198509 and negative control lot number 398509 expired on 11/26/21, and was used for testing on 11/30/21.</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, review of TP (testing personnel) training</p>

records, staff interview, absence of documentation 12/20/21, and email communication 12/30/21, the laboratory failed to verify the manufacturer's performance specifications for the Anti-D Rh(Rhesus) slide typing Doctor's kit DKS RhD Eldon card test that was put into use in November 2019. Findings: Review of training records revealed TP#3 and TP#5 were trained for RhD testing blood slide typing on 7/31/19. Review of laboratory's patient and quality control records and interview with the Nursing director at approximately 11:15 am 12/20/21 revealed the laboratory began Rh(D) patient testing using the Eldon Cards November 2019. There was no documentation available to indicate the laboratory had verified the performance specifications of accuracy and precision for the Doctor's kit DKS RhD Eldon Card slide test before testing and reporting Rh(D) patient results. The nursing director stated at approximately 11:15 am on 12/20/21 that she was unsure where the verification for the Eldon Card Rh(D) testing was located. Email communication with the Nursing director on 12/30/21 confirmed the laboratory failed to document the verification of the Rh(D) testing before patient testing began.