

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0203526	(X3) Date Survey Completed 12/04/2018
Name of Provider or Supplier Planned Parenthood Sepa	Street Address, City, State 8 South Wayne Street, West Chester, PA	
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	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 review of the CASPER Report 155 and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analyte: D (RHO) which is of the specialty Immunohematology. The laboratory had unsatisfactory scores for the 3rd event of 2017 and the 2nd event of 2018. See D2162.
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 a review of the CASPER Report 0155D and performance evaluations from the proficiency testing organization American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in a proficiency testing program approved by CMS for the analyte: D(RHO) which is in the specialty of Immunohematology in which the laboratory is certified under CLIA. The laboratory had unsatisfactory scores for the 2nd event of 2017 and 2nd event of 2018 for the analyte listed above. Findings include: 1. AAB 2017 Event 2 for D (RHO), the score was 0%. 2. AAB 2018 Event 2 for D (RHO), the score was 0%.