

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2108023	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Planned Parenthood Of Illinois Ottawa	Street Address, City, State 612 Court St, Ottawa, IL	
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 review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the immunohematology blood group/Rhesus factor (ABO/RHO) and Rhesus factor immune globulin, anti-D (D (RHO)) testing during events 1 and 3 of 2021. See D2162 and D2163.</p>
D2162	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p>

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 review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for Rhesus factor immune globulin, anti-D (D (RHO)) testing during events 1 and 3 of 2021. Findings Include: 1. Review of the CASPER Report 0155D revealed that the initial unsuccessful PT performance occurred during API PT events 1 and 3 of 2021, as listed below.

IMMUNOHEMATOLOGY EVENT -1, 2021 D (RHO), 80% Unsatisfactory EVENT -3, 2021 D (RHO), 80% Unsatisfactory 2. Interview with the API PT representative on 2-01-2022, at 8:08 AM confirmed the unsuccessful PT performance for D (RHO) testing in events 1 and 3 of 2021.

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 review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for immunohematology blood group/Rhesus factor (ABO/RHO) during events 1 and 3 of 2021. Findings Include: 1. Review of the CASPER Report 0155D revealed that the initial unsuccessful PT performance occurred during API PT events 1 and 3 of 2021, as listed below.

IMMUNOHEMATOLOGY EVENT -1, 2021 ABO/RHO, 80% Unsatisfactory EVENT -3, 2021 ABO/RHO, 80% Unsatisfactory 2. Interview with the API PT representative on 2-01-2022, at 8:08 AM confirmed the unsuccessful PT performance for ABO/RHO testing in events 1 and 3 of 2021.