

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0402400	<b>(X3) Date Survey Completed</b>  10/17/2018
<b>Name of Provider or Supplier</b>  Robbinsdale Clinic, Pa	<b>Street Address, City, State</b>  3819 West Broadway, Robbinsdale, MN	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing under the subspecialty of ABO/RHO. Findings are as follows: D2153 - the laboratory failed to obtain a PT score of at least 100 percent for D (Rho) Type testing D2154 - the laboratory failed to obtain an overall testing event score of at least 100 percent for the ABO/RHO Subspecialty D2162 - the laboratory failed to achieve satisfactory analyte PT performance for D (Rho) Type testing in two out of three consecutive events D2163 - the laboratory failed to achieve satisfactory performance for the ABO /RHO Subspecialty in two out of three consecutive events</p>

<p><b>D2153</b></p>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score of at least 100 percent for D (Rho) Type testing which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of D (Rho) Type testing was obtained in the following events. -2018 1st event 80% -2018 2nd event 80%</p>
<p><b>D2154</b></p>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(b)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score of at least 100 percent for the ABO/RHO Subspecialty which resulted in overall unsatisfactory performance in the Subspecialty. Overall unsatisfactory PT performance for the ABO/RHO Subspecialty was obtained in the following API events: -2018 1st event 80% -2018 2nd event 80%</p>
<p><b>D2162</b></p>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory analyte PT performance for D (Rho) Type testing in two out of three consecutive testing events which led to unsuccessful performance for the analyte. API results indicated the laboratory had unsatisfactory performance for D (Rho) Type testing in two out of three consecutive events leading to unsuccessful performance for the analyte. Unsatisfactory PT performance of D (Rho) Type testing was obtained in the following events. -2018 1st event with a score of 80% -2018 2nd event with a score of 80%</p>
<p><b>D2163</b></p>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(g)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for the ABO/RHO Subspecialty in two out of three consecutive testing events which led to unsuccessful PT performance in the Subspecialty. API reports indicated the laboratory had unsatisfactory performance for the ABO/RHO Subspecialty in two out of three consecutive events leading to unsuccessful PT performance for Subspecialty. Unsatisfactory PT performance for the ABO/RHO Subspecialty was obtained in the following API events. -2018 1st event with a score of 80% -2018 2nd event with a score of 80%