

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0978663	(X3) Date Survey Completed 06/03/2020
Name of Provider or Supplier Scotsdale Women's Center	Street Address, City, State 19305 W 7 Mile Road, Detroit, MI	
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 the Proficiency Testing (PT) data report (CASPER Report 155) and review of the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in immunohematology analyte D (Rho) typing. The laboratory had unsatisfactory scores for the 3rd event 2017, 1st event 2018, 3rd event 2019, and the 1st event 2020. See D2163</p>
D2163	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(g)</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.

This STANDARD is not met as evidenced by:

. Based on record review of the Proficiency Testing (PT) data report (CASPER Report 155) and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the analyte D (Rho) typing which has sustained a subsequent occurrence of unsuccessful participation in the speciality of immunohematology. Findings include: D (Rho) typing PT Event Score 3rd event 2017 0% 1st event 2018 0% 3rd event 2019 80% 1st event 2020 0%