

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0867797	(X3) Date Survey Completed 08/09/2021
Name of Provider or Supplier Reproductive Medicine Laboratory Inc	Street Address, City, State 808 Sw 15th Avenue, Portland, OR	
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: Review of the College of American Pathologists (Excel) (CAP) proficiency testing (PT) showed the laboratory had unsuccessful participation for the 3rd event 2020 and 1st event 2021 for the analytes AFP(Tumor Marker) and IGE in General Immunology. Unsuccessful participation for the 3rd event 2020 and 1st event 2021 for the analytes Coritisol, Human chronic gonadotropin, T3 Uptake, Triiodothyronine, and Thyroxine total in Endocrinology. Refer to D2077 and D2100</p>
D2077	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p>

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Review of the College of American Pathologists (CAP) proficiency testing (PT) showed the laboratory had unsuccessful participation for the 3rd event 2020 and 1st event 2021 for the analytes AFP(Tumor Marker) and IgE. Findings include: 1. 3rd event 2020 AFP (Tumor Marker) and IgE = 0% 2. 1st event 2021 AFP (Tumor Marker) and IgE = 0%

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Review of the College of American Pathologists (CAP) proficiency testing (PT) showed the laboratory had unsuccessful participation for the 3rd event 2020 and 1st event 2021 for the analytes Cortisol, Human chronic gonadotropin, T3 Uptake, Triiodothyronine, and Thyroxine total. Findings include: 1. 3rd event 2020, Cortisol, Human chronic gonadotropin, T3 Uptake, Triiodothyronine and Thyroxine total = 0% 2. 1st event 2021, Cortisol, Human chronic gonadotropin, T3 Uptake, Triiodothyronine and Thyroxine total = 0%