

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0889009	<b>(X3) Date Survey Completed</b>  01/23/2020
<b>Name of Provider or Supplier</b>  Precision Medical Laboratories	<b>Street Address, City, State</b>  5901 W Olympic Blvd, Ste 501, Los Angeles, CA	
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>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 CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and interview with testing staff, it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialty of Endocrinology constituting unsuccessful PT performance. (See D2107)</p>

**D2087**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing records and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the third quarter 2019 (Q3-2019) for Free Thyroxine. The findings included: a. Q3-2019 API reported 40% proficiency score for Free Thyroxine : Sample # Reported Expected Mean Value Result CH-12 1.2 1.3 - 1.9 1.63 CH-14 1.9 2.1 - 3.0 2.52 CH-15 2.1 2.4 -3.3 2.82 b. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory performed approximately 400 patient for Free Thyroxine tests, when the proficiency testing scores were unsatisfactory. d. The TS and TP confirmed (January 23, 2020 at 12:00) that the laboratory received the above unsatisfactory proficiency testing scores.

**D2107**

**ENDOCRINOLOGY**

CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test 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 the American Proficiency Institute (API) proficiency testing records and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to achieve satisfactory performance for Prolactin in two consecutive testing events. The findings included: a. The laboratory stated that they are enrolled in the American Proficiency Institute (API) proficiency testing. b. API reported proficiency score for Prolactin first event 2019 (Q1-2019) 67% and for the second event 2019 (Q2-2019) zero (0%). c. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported approximately 825 patient Prolactin tests during the period that Prolactin proficiency scores were unsatisfactory. d. The TS and TP confirmed (January 23, 2020 at 11:45) that the laboratory received the above unsatisfactory proficiency testing scores.