

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0863212	(X3) Date Survey Completed 06/24/2019
Name of Provider or Supplier Institute Of Reproductive	Street Address, City, State 94 Old Short Hills Rd, Livingston, NJ	
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 an office review of the CASPER reports 153 and 155 and proficiency testing provider reports, the laboratory failed to achieve a score of at least 80% or more in two out of three events for General Immunology and Endocrinology tests with the College of American Pathologists evaluation.</p>
D2084	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing provider reports, the laboratory failed to achieve a score of 80% for General Immunology tests. The findings include: The laboratory scored a 0% in 3-2018 and 1-2019 events with the College of American Pathologists as below: a. Alpha Feto Protein b. Immunoglobulin E (IgE)

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 an office review of the CASPER reports 153 and 155 and Proficiency Testing provider reports, the laboratory failed to achieve a score of 80% for Endocrinology tests. The findings include: The laboratory scored a 0% in 3-2018 and 1-2019 events with the College of American Pathologists as below: a. Cortisol b. Free thyroxine (free T4) c. Triiodothyronine uptake (T3 uptake) d. Triiodothyronine (T3) e. Total Thyroxine

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the laboratory director failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained.