

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2168465	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Orion Laboratories, Llc	Street Address, City, State 6300 Corporate Boulevard, Baton Rouge, LA	
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: No deficiency details available.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
No deficiency details available.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

An on-site follow-up survey was performed as Orion Laboratories, LLC, CLIA ID 19D2168465, on December 17, 2024. Based on review of the laboratory's personnel training records, performance specification records, and interview with personnel, the Laboratory Director failed to ensure three (3) of three (3) Testing Personnel had complete training documentation for blood bank (ABO type and antibody screen) testing. Findings: 1. In interview on December 17, 2024 at 9:35 am, the Laboratory Manager stated the laboratory brought on blood bank ABO type and antibody screen testing after their previous inspection. 2. Review of the laboratory's performance specification records for the blood bank testing revealed the Laboratory Director approved the laboratory's studies on September 24, 2024. 3. Review of training records revealed hands-on training, quality control and antibody screening were not included. The laboratory had documentation of a written test for Testing Personnel 2 and Testing Personnel 3 prior to patient testing. 4. In interview on December 17, 2024 at 5:00 pm, the Laboratory Manager confirmed she did not have training records for herself or complete training records for Testing Personnel 2 and 3.