

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2168465	(X3) Date Survey Completed 10/28/2020
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
D0000	AN INITIAL CERTIFICATION SURVEY was conducted on October 26-28, 2020 at Orion Laboratories, LLC - CLIA 19D2168465. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing records and the laboratory's test list, as well as interview with personnel, the laboratory failed to enroll in an approved program to establish and maintain the accuracy of White Blood Cell differential (WBC Diff) and Human Chorionic Gonadotropin (HCG) testing. Findings: 1. Review of the annual test volumes provided by the laboratory revealed the laboratory performs Manual Differentials (WBC Diff) and serum HCG testing. 2. Review of proficiency testing records for 2020 revealed the laboratory did not enroll or participate in WBC Diff or serum HCG in any testing events. 3. Interview with technical consultants on October 26, 2020 at 10:30am confirmed the laboratory was not enrolled for WBC Diff or serum HCG for 2020 proficiency testing.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:
Based on RPR maintenance record review and interview with personnel, the laboratory failed to retain monthly maintenance Rapid Plasma Reagin (RPR) for at least two (2) years for six (6) of six (6) months reviewed. Findings: 1. Review of the ASI RPR Test Kit manufacturer instructions revealed detailed instructions to "perform accuracy check on the needle" prior to dispensing 0.05 ml of antigen suspension for the assay protocol. Further review of the manufacturer instructions for assay protocol state to "rotate at 100 +/- 5 rpm for 8 minutes". 2. Review of the laboratory's RPR policy revealed no detailed instructions for documentation of needle accuracy check or verification of rotator RPM checks. 3. Review of patient testing records for RPRs revealed fifty-one (51) patients were tested from April 2020-October 2020 with no documentation of needle accuracy or RPM verification. 4. In interview on October 27, 2020 at 11:22 am, the Technical Consultant and Testing Personnel stated needle accuracy is performed on each new bottle of antigen suspension and rotator RPM is verified monthly. The Technical Consultant confirmed the policy does not specify maintenance frequency or how this should be documented. Not retain RPR maintenance

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records and interview with personnel, the laboratory failed to verify the accuracy of Hemoglobin (Hgb) A1C at least twice annually. Findings: 1. Review of the laboratory's annual test volumes provided to surveyor revealed the laboratory performs Hgb A1C on the Siemens's Atellica 930. 2. Review of the laboratory's proficiency testing records for 2020 revealed the laboratory did not enroll or participate in HgbA1c to verify the accuracy of testing. 3. In interview on October 26, 2020 at 10:25am the Technical Consultant confirmed the laboratory did not enroll in HgbA1c for 2020 PT but would update enrollment for 2021.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's collection protocol and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain the integrity of blood samples. Findings: 1. Direct observation of specimen processing on October 27, 2020 at 9:55am revealed the laboratory receives blood specimens transported between 2-8 degrees Celsius and no greater than 48 hours from collection. 2. Review of the laboratory's Blood Collection Protocol available to providers

revealed the laboratory did not include specific instructions for transportation or acceptable stability and temperature requirements of blood samples referenced to the laboratory for testing. 3. In interview with Technical Consultants and Laboratory Manager on October 27, 2020 at 1pm, personnel confirmed the Blood Collection Protocol was missing the temperature requirements and stability accepted by the laboratory like the other sample types received.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and interview with personnel , the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Rapid Plasma Reagin (RPR): frequency and documentation of maintenance such as needle accuracy and rotator RPM check, specific location of documentation of quality control performance and testing personnel performing test. b) Quality Control (QC): to include but not limited to establishment of acceptable quality control ranges for analytes with more than one instrument or platform , data used for establishment/reestablishment, establishment of acceptable quality control ranges performed prior to patient testing. 2. In interview on October 27, 2020 at 2pm, the laboratory manager stated this was the first establishment of quality control ranges and the laboratory intends to improve this process. The laboratory technical consultant confirmed RPR and QC policies did not specifically address the above items.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to retain monthly maintenance Rapid Plasma Reagin (RPR) for at least two (2) years for six (6) of six (6) months reviewed. Please refer to D3031 2. The laboratory failed to verify the accuracy of Hemoglobin (Hgb) A1C at least twice annually. Please refer to D5217

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for White Blood Cell differential (WBC Diff) and Human Chorionic Gonadotropin (HCG) prior to patient testing. Please refer to D2003

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of blood samples. Please refer to D5317 2. The laboratory failed to have a complete policy and procedure manual. Please refer to D5403