

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2296523	(X3) Date Survey Completed 12/19/2025
Name of Provider or Supplier Orion Laboratories	Street Address, City, State 5131 O'Donovan Drive, Suite 100, 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	A Recertification survey was performed at Orion Laboratories, CLIA ID 19D2296523, on December 19, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu and policies and interview with personnel, the laboratory failed to have a complete policy for reflexing patient</p>

samples to a reference laboratory for manual differential testing: Findings: 1. Review of the laboratory's test menu revealed the laboratory performed automated white blood count (WBC) differentials, but did not perform manual WBC differentials. 2. In interview on December 15, 2025 at 10:00 a.m., the Laboratory Director stated if a patient sample requires a manual differential based on analyzer flags, error codes, and /or patient results, it is sent to a sister facility. She further stated rules were built in the Laboratory Information System (LIS) to alert the technologist a sample needs to be sent out for further testing. 3. Review of the laboratory's policy "Complete Blood Count, Reticulocyte Count" revealed the laboratory did not include criteria for referring patient samples to an outside facility for manual differential testing, but did include instructions for reviewing slides in the section "Potential Flags and Laboratory Interpretation Guidelines" to include the following: a) "Abnormal, WBC Abn Scattergram" * "Asterisk (*) next to results: Verify WBC, differential and PLT results by repeat analysis. If rerun does not resolve the issue, scan the slide for abnormal cells or platelet clumping." b) "IG Present" - "When this message is present, review a smear to detect any clinically relevant findings and report the analyzer differential results if none are detected. The presence of any potential immature granulocytes, toxic granulation or vacuolation, or any other abnormal cells should be referred to parent high-complexity laboratory or submitted for Hematopath review." 4. In interview on December 19, 2025 at 11:01 a.m., the Laboratory Director confirmed the laboratory did not have a complete policy as identified above.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)**

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation, review of the manufacturers' storage requirements and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for three (3) of three (3) rooms where the laboratory stored supplies. Findings: 1. Observation by surveyor during the laboratory tour on December 19, 2025 at 10 a. m. revealed the laboratory stored specimen collection supplies in three (3) rooms to include the following: a) Storage Room *BD Vacutainer Urinalysis urine tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius *Greiner Bio-One 3ml K2E K2EDTA - Manufacturer's storage requirements: 4-25 degrees Celsius *BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements: 4-25 degrees Celsius b) Main Lab *BD Vacutainer Urinalysis urine tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius c) Draw Room *BD Vacutainer Urinalysis urine tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius *Greiner Bio-One 3ml K2E K2EDTA - Manufacturer's storage requirements: 4-25 degrees Celsius *BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements: 4-25 degrees Celsius 2. Review of the laboratory's room temperature logs "Orion Laboratories Temperature/Humidity Log"

from January 2025 through November 2025 revealed the laboratory defined the acceptable room temperature limits for the three (3) rooms identified above as 20-30 degrees Celsius which exceeded the manufacturers' upper temperature limits. 3. In interview on December 19, 2025 at 11:50 a.m., the Laboratory Director confirmed the laboratory's acceptable room temperature limits exceeded the manufacturers' required limits as identified above.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation, review of the laboratory's maintenance logs and patient test records, as well as interview with personnel, the laboratory failed to perform maintenance as required by the manufacturer for one (1) of forty-seven (47) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 19, 2025 at 10 a.m. revealed the laboratory utilized the Sysmex XN 550 analyzer for complete cell count (CBC) testing. 2. Review of the laboratory's maintenance log "XN 550 Maintenance Checklist" revealed the following required weekly task: * "Auto Rinse with Cell Clean." 3. Review of the laboratory's XN 550 maintenance logs from January 2025 through November 2025 revealed the laboratory did not perform weekly maintenance from September 21, 2025 through September 27, 2025. 4. In interview on December 19, 2025 at 11:50 a.m., the Laboratory Director confirmed maintenance was not performed as identified above. 5. Review of the laboratory's CBC patient test records from September 21, 2025 through September 27, 2025 revealed the laboratory tested two hundred twenty-seven (227) patients.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on observation, review of the manufacturer's storage requirements and the laboratory's temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained between 4-25 degrees Celsius as required by the manufacturers for supplies stored in the laboratory, storage, and draw rooms for sixteen (16) of eighty (80) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 19, 2025 at 10 a.m. revealed the laboratory stored specimen collection supplies in three (3) rooms to include the following: a) Storage Room *BD Vacutainer Urinalysis urine

tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius *Greiner Bio-One 3ml K2E K2EDTA - Manufacturer's storage requirements: 4-25 degrees Celsius *BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements: 4-25 degrees Celsius b) Main Lab *BD Vacutainer Urinalysis urine tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius c) Draw Room *BD Vacutainer Urinalysis urine tube no additive - Manufacturer's storage requirements: 4-25 degrees Celsius *Greiner Bio-One 3ml K2E K2EDTA - Manufacturer's storage requirements: 4-25 degrees Celsius *BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements: 4-25 degrees Celsius

2. Review of the laboratory's room temperature logs "Orion Laboratories Temperature /Humidity Log" revealed the laboratory defined the acceptable room temperature limits for the three (3) rooms identified above as 20-30 degrees Celsius which exceeded the manufacturers' upper temperature limits. 3. Review of the laboratory's temperature logs January 2025 through November 2025 revealed the room temperature exceeded the manufacturer's upper temperature limits on the following dates, but no corrective action was performed: a) Storage room January 23, 2025: Temperature documented as 25.9 degrees Celsius b) Main Lab January 8, 2025: Temperature documented as 25.1 degrees Celsius January 23, 2025: Temperature documented as 27.9 degrees Celsius March 25, 2025: Temperature documented as 25.9 degrees Celsius c) Draw Room: January 2, 2025: Temperature documented as 29.6 degrees Celsius January 3, 2025: Temperature documented as 25.9 degrees Celsius January 7, 2025: Temperature documented as 29.3 degrees Celsius January 8, 2025: Temperature documented as 28.7 degrees Celsius January 9, 2025: Temperature documented as 29.6 degrees Celsius January 10, 2025: Temperature documented as 26.6 degrees Celsius January 13, 2025: Temperature documented as 25.5 degrees Celsius January 14, 2025: Temperature documented as 25.1 degrees Celsius January 16, 2025: Temperature documented as 25.7 degrees Celsius January 17, 2025: Temperature documented as 26.1 degrees Celsius January 20, 2025: Temperature documented as 26.6 degrees Celsius January 23, 2025: Temperature documented as 25.7 degrees Celsius January 30, 2025: Temperature documented as 28.3 degrees Celsius January 31, 2025: Temperature documented as 28.0 degrees Celsius February 6, 2025: Temperature documented as 25.9 degrees Celsius February 10, 2025: Temperature documented as 26.7 degrees Celsius 4. In interview on December 19, 2025, the Laboratory Director confirmed the room temperature readings identified above exceeded the manufacturers' room temperature upper limits and the laboratory did not perform corrective actions.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu and patient test records and interview with personnel, the laboratory failed to include the name of the reference laboratory

where manual differential testing was performed for one (1) of 1 (one) patient final test reports reviewed. Findings: 1. Review of the laboratory's test menu revealed the laboratory performed complete cell count (CBC) with automated differential testing. 2. In interview on December 15, 2025 at 10:00 a.m., the Laboratory Director stated if a patient sample requires a manual differential it is sent to a reference laboratory. 3. Review of a random patient final report (Accession 01381-LA-25336) revealed a manual differential was performed by an outside facility; however, the laboratory did not include the name and address of the reference laboratory on the final patient report. 4. In interview on December 19, 2025 at 10:58 a.m., the Laboratory Director confirmed the laboratory did not include the name and address of the reference laboratory as identified above.

D6014

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

(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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to perform maintenance as required by the manufacturer for one (1) of forty-seven (47) weeks reviewed. Refer to D5429. 2. The laboratory failed to perform corrective actions when the room temperature was not maintained between 4-25 degrees Celsius as required by the manufacturers for supplies stored in the laboratory, storage, and draw rooms for sixteen (16) of eighty (80) days reviewed. Refer to D5781.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.