Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D2296523	**(X3) Date Survey Completed** 05/29/2024
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	An Initial survey was performed at Orion Laboratories, CLIA ID 19D2296523, on May 29, 2024. Orion Laboratories was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1415 CONDITION: Laboratories performing moderate complexity testing; Clinical Consultant
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, review of laboratory polices and patient test records, as well as interview with personnel, the laboratory failed to follow their policy for hematology slide review for one (1) of ten (10) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the laboratory utilized a Sysmex XN 550 hematology analyzer for hematology testing. 2. Review of the laboratory's "Manual Differential & Slide Review" policy section "Criteria for Slide Review" revealed the following: a) "Includes review of WBC's, RBC's, and PLTS" b) "The following are Instrument flags which will prompt tech to perform a Slide Review:...PLT ABN Dist" 3. Review of the instrument printout for patient ID E623501 revealed an "*" flag for the MPV result. 4. In interview on May 29, 2024 at 2:38 p.m., the Laboratory Director stated the "*" flag indicated platelet abnormal distribution and a slide review for morphology should be performed. 5. Review of the patient final report revealed the patient did not have a morphology review performed as required by laboratory policy. 6. In interview on May 29, 2024 at 2:38 p.m., the Laboratory Director confirmed a morphology review was not performed on the patient identified above.

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 the laboratory's policies and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have complete policies and procedures for: a) The course of action to take if a test system becomes inoperable b) When to refer samples to an outside facility based on white blood cell differential, red blood cell morphology, and platelet morphology results 2. In interview on May 29, 2024 at 2:34 p.m., the Laboratory Director confirmed the laboratory did not have the policies identified above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, as well as interview with personnel, the laboratory failed to follow manufacturer's instructions for the staining of hematology blood smears for manual differential. Findings: 1. Observation by the surveyor during the laboratory tour on May 29, 2024 at 1025 a.m. revealed the laboratory utilized Protocol Wright Stain for staining of hematology blood smears for white blood cell manual differential. 2. Review of the manufacturer's package insert "Protocol Wright Stain Procedure" revealed the following: - Fix slide in Methyl Alcohol (30 - 60 seconds). - Flood slide with 1 mL of Wright Stain and allow to stain for 1 - 2 minutes. - Add 1.5 mL of pH 6.4 Diluted Buffer (see below) to the stain-covered slide. Make sure to completely cover the slide with buffer. - Mix the stain and buffer together by gently rocking the slide for 1 minute. Allow the mixture to stand on

	slide for an additional 2 minutes. - Rinse the slide with deionized water and allow to air dry. 3. In interview on May 29, 2024 at 10:49 a.m., Testing Personnel 1 stated she allows blood smears to air dry and uses tap water to rinse them. She confirmed she does not use Methyl Alcohol to fix the slides and does not use deionized water to rinse the slides.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: I. Based on observation by surveyor, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of two (2) of three (3) rooms where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the storage and draw station rooms had the following specimen collection devices stored without monitoring of the room temperature: a) Storage room - BD Vacutainer SST Blood Collection Tubes - manufacturer's storage requirements 4 - 25 degrees Celsius - Greiner bio-one Vacuette Tube K2EDTA - manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer Serum Blood Collection Tubes - manufacturer's storage requirements 4 - 25 degrees Celsius - BD Vacutainer Urinalysis Urine Tube- manufacturer's storage requirements 4 - 25 degrees Celsius b) Draw Room - BD Vacutainer SST Blood Collection Tubes - manufacturer's storage requirements 4 - 25 degrees Celsius - Greiner bio-one Vacuette Tube K2EDTA - manufacturer's storage requirements 4 - 25 degrees Celsius 2. Review of 2024 temperature logs revealed no documentation of temperature monitoring for the storage or draw station rooms. 3. In interview on May 29, 2024 at 10:32 a.m., the Laboratory Director confirmed the laboratory did not monitor the room temperature of the rooms identified above. II. Based on observation, review of laboratory temperature records and manufacturers' instructions for use, as well as interview with personnel, the laboratory failed to define acceptable temperature limits within the manufacturer's required ranges for the refrigerator where Hematology controls are stored. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the laboratory stored the following Hematology quality control material in the refrigerator: a) Sysmex XN Check L1, L2, L3 - manufacturer's storage requirements 2 - 8 degrees Celsius 2. Review of the laboratory's 2024 temperature logs for the refrigerator revealed the laboratory defined the acceptable temperature limits as 2 - 10 degrees Celsius which exceeded the manufacturers' acceptable upper limit. 3. In interview on May 29, 2024 at 12:15 p.m., the Laboratory Director confirmed the laboratory's refrigerator temperature range exceeded the manufacturer's limits as identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, the laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the following expired items: a) Sysmex SLS Sulfolyser, Lot A3005, expiration date 4/11/2024, quantity two (2) bottles 2. In interview on May 29, 2024 at 10:45 a.m.., Testing Personnel 1 confirmed the items identified above were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for the Sysmex XN 550 hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the laboratory utilized a Sysmex XN 550 hematology analyzer for hematology testing. 2. Review of the Sysmex XN 550 validation records revealed the laboratory did not include the following: - Operator variance as part of precision - Reference range 3. In interview on May 29, 2024 at 12:43 p.m., the Laboratory Director confirmed the laboratory did not include documentation for the studies identified above when validating the Sysmex XN 550 analyzer. II. Based on observation by surveyor, review of validation records, and interview with personnel, the laboratory failed to have complete performance verification studies for hematology manual differential testing. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2024 at 10:25 a.m. revealed the laboratory utilized a Wright Stain for hematology manual differential testing. 2. Review of validation records revealed the laboratory did not perform validation studies to include: - Precision - Accuracy - Reference Range 3. In interview on May 29, 2024 at 116 p.m., the Laboratory Director confirmed the laboratory did not perform validation studies for manual differential testing.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Findings: 1. The laboratory failed to have complete performance verification studies for the Sysmex XN 550 hematology analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance verification studies for hematology manual differential testing. Refer to D5421 II.
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 the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow manufacturer's instructions for the staining of hematology blood smears for manual differential. Refer to D5411. 2. The laboratory failed to monitor the room temperature of two (2) of three (3) rooms where laboratory supplies were stored. Refer to D5413 I. 3. The laboratory failed to define acceptable temperature limits within the manufacturer's required ranges for the refrigerator where Hematology controls are stored. Refer to D5413 II. 4. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to follow their policy for hematology slide review for one (1) of ten (10) patients reviewed. Refer to D5401. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403.
D6056	CLINICAL CONSULTANT

	CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to ensure the position of Clinical Consultant was employed based on requirements for moderate complexity testing. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS 209) and personnel records as well as interview with personnel, the laboratory failed to ensure the Clinical Consultant met the education qualification required. Findings: 1. Review of the Laboratory Personnel Report (CMS 209) revealed the laboratory listed Personnel 1 as serving as the Clinical Consultant. 2. Review of the laboratory's personnel records revealed Personnel 1 did not meet the qualification of education for the position of Clinical Consultant. 3. In interview on May 29, 2024 at 11:20 a.m., the Laboratory Director stated she was unaware she did not meet the qualifications for Clinical Consultant.