

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2168465	(X3) Date Survey Completed 09/28/2022
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	A recertification survey was performed on September 26-28, 2022 at Orion Laboratories, LLC - CLIA ID # 19D2168465. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's procedure manual revealed the laboratory did not include detailed instructions for the the following laboratory practices: a) New lot rollover of coagulation reagents to include step by step instructions for verifying new reagents as well as criteria of qualification for "normal donors" to be utilized in reference interval studies. b) Process for documentation of manual cell counts to include duplicate testing of patient and quality control as well as frequency of quality control performance. c) Step by Step processed for staining of slides to be utilized for manual cell differentials and/or peripheral blood smear review, as well as stain acceptability and stability of staining reagents. 2. In interview on September 27, 2022 at 2:40 pm, the Laboratory Manager and Technical Consultant confirmed the laboratory policy and procedure manuals did not specifically address the above laboratory processes.</p>
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:

I. Based on observation during the laboratory tour, review of manufacturer instructions and instrument printouts of patient hematology testing as well as interview with laboratory personnel, the laboratory failed to follow manufacturer's instructions and laboratory procedure for flags appearing on Complete Blood Counts (CBC) for three (3) of three (3) patients reviewed. Findings: 1. Direct observation during the laboratory tour on September 26, 2023 at 10:30am revealed the laboratory use of a Sysmex XN-1000 for hematology analysis. 2. Review of the laboratory's policy revealed the laboratory policy aligns with the manufacturer instructions for flags appearing on complete blood count (CBC) result: a) instrument Platelet (Plt) flag of *Plt Distribution (Dist)* requires the laboratory to "scan for platelet morphology" b) instrument Red Blood Cell (RBC) flag of *Dimorphic* and *RBC Abnormal Distribution (Abn Dist)* requires the laboratory to "Scan for RBC Morphology" 3. Review of patient testing directly from XN-1000 on September 26, 2022 at 2:25pm revealed the laboratory failed to follow the manufacturer instructions and laboratory policy for flagging for the following two (2) patients reviewed: Sample ID: 2209230096 performed September 24, 2022 - Plt Dist with no scan for plt morphology Sample ID: 2209230029 performed September 23, 2022 - Dimorphic & RBC Abn Dist flags with no scan for RBC morphology performed. 4. Interview with with testing personnel and laboratory manager on September 26, 2023 at 3pm confirmed the patients identified above were reported without microscopic review confirming Sysmex instrument flags. II. Based on observation during laboratory tour, review of manufacturer instructions, patient results and quality control as well as interview with personnel, the laboratory failed to perform Prothrombin Time Test (PT) within four (4) hours of collection as required by manufacturer for ten (10) of seventeen (17) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on September 26, 2022 at 9:58 am revealed the laboratory utilizes Sysmex CA660 Coagulation analyzer for Prothrombin Time (PT) testing. 2. Review of the Sysmex CA660 operator's manual under specimen storage revealed for PT testing "samples should be analyzed within four (4) hours of collection". 3. Review of patient records for PT testing from June 15, 2022 - June 30, 2022 revealed the following ten (10) of seventeen (17) patients reviewed were not tested within four (4) hours of collection as required by the manufacturer: a) Patient P9987195 collected on June 15, 2022 at 9:30 am and received at 04:52 pm - exceeding the four (4) hours required by manufacturer by three (3) hour twenty two (22) minutes b) Patient P9986288 collected on June 16, 2022 at 1:40 pm and received on June 17, 2022 at 10:02 am - exceeding the four (4) hours required by manufacturer by sixteen (16) hour twenty two (22) minutes c) Patient P9987324 collected on June 17, 2022 at 8:32 am and received at 07:01 pm - exceeding the four (4) hours required by manufacturer by six (6) hour twenty nine (29) minutes d) Patient P9987411 collected on June 16, 2022 at 3:00 pm and received on June 17, 2022 at 11:03 am - exceeding the four (4) hours required by manufacturer by sixteen (16) hour three (3) minutes e) Patient P9987435 collected on June 17, 2022 at 11:50 am and received at 07:08 pm - exceeding the four (4) hours required by manufacturer by three (3) hour eighteen (18) minutes f) Patient P9987437 collected on June 17, 2022 at 11:56 am and received at 06:59 pm - exceeding the four (4) hours required by manufacturer by three (3) hour three (3)

minutes g) Patient P9987601 collected on June 20, 2022 at 12:04 pm and received at 05:48 pm - exceeding the four (4) hours required by manufacturer by one (1) hour forty four (44) minutes h) Patient P9981198 collected on June 20, 2022 at 12:41 pm and received at 05:51 pm - exceeding the four (4) hours required by manufacturer by one (1) hour ten (10) minutes i) Patient P9986491 collected on June 21, 2022 at 10:36 am and received at 04:32 pm - exceeding the four (4) hours required by manufacturer by one (1) hour fifty six (56) minutes j) Patient P9987195 collected on June 15, 2022 at 9:30 am and received at 04:52 pm - exceeding the four (4) hours required by manufacturer by three (3) hour fifty two (52) minutes 5. In interview on September 28, 2022 at 02:57 pm, the technical consultant stated the laboratory should not perform testing outside of the timeframe of the manufacturer and that samples should have been poured off the cells if the four hour stability of the manufacturer was exceeded. The technical consultant confirmed there was no policy or documentation to verify this process.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on observation, review of manufacturer instructions and calibration records as well as interview with personnel, the laboratory failed to perform calibration every 6 months as required by the manufacturer for the Sysmex XN-1000 analyzer for 2021-2022. Findings: 1. Observation by the surveyor during the laboratory tour on September 26, 2022 at 10:20am revealed the laboratory utilized the Sysmex XN-1000 Hematology analyzer for the testing of Complete Blood Counts (CBC). 2. Review of the Sysmex XN-1000 manual revealed "Initial calibration is performed during installation by the Sysmex representative. Following installation calibration, the operator is requested to verify the instrument calibration every 6 months or on an 'as needed' basis and maintain good QC practices, to ensure the accuracy of the system." Further review of the laboratory procedure revealed that calibration procedures are to be performed every six months or any time a major component or maintenance is performed. 3. Review of the calibration records for 2021 - 2022 revealed the laboratory performed calibration in February only for years 2021 and 2022. 4. In interview on September 27, 2022 at 3:15pm, the laboratory manager confirmed the laboratory only performed calibrations for the Sysmex XN-1000 once for both 2021 and 2022, and that the second calibration was not performed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of policies, manufacturer's instrument manual, calibration records, and interview with personnel, the laboratory failed to perform calibration verification procedures for Thyroid Peroxidase Antibody (aTPO) at least every six (6) months per manufacturer requirements during 2021 - 2022.

Findings: 1. Observation by surveyor during the laboratory tour on September 24, 2022 at 10:20 am revealed the laboratory utilizes the Siemens Atellica for chemistry testing to include Thyroid Peroxidase Antibody (aTPO). 2. Review of the Atellica instrument calibration records revealed the routine calibration contained only 2 calibration points. Further review of calibration records revealed the laboratory performed no additional calibration for aTPO including 3 or more calibration points covering the reportable range for 2021 and 2022. 3. In interview on September 27, 2021 at 2:49 pm, the Laboratory Manager stated the laboratory performs calibration verification for analytes with 2 calibration points but had missed aTPO as an analyte requiring calibration verification. The laboratory manager confirmed the laboratory did not perform calibration verification for aTPO in 2021-2022.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation during laboratory tour, review of laboratory policies, quality control records and patient test records, as well as interview with laboratory personnel, the laboratory failed to perform two (2) levels of controls prior to patient testing for parathyroid hormone (PTH) testing for two (2) of nineteen (19) days reviewed over two months of patient testing. Findings: 1. Observation by surveyor

during laboratory tour on September 26, 2022 at 10:26 am revealed the laboratory utilizes the Siemens Atellica with BioRad Immunoassay quality control. 2. Review of the laboratory's quality control policy for chemistry testing revealed the laboratory is to perform two (2) levels of quality controls within acceptable range prior to patient testing for chemistry testing performed on the Siemens Atellica, including PTH. 3. Review of patient testing and PTH quality control records for February 2022 and August 2022 revealed the laboratory did not perform two (2) levels of controls for the following two (2) out of nineteen (19) days reviewed: Sample ID: 2208080155 performed August 09, 2022: Controls Level 1 and Level 2 not performed within 24 hours Sample ID: 2202100018 performed February 10, 2022: Controls Level 1 and Level 2 not performed within 24 hours 4. In interview on September 27, 2022 at 3:30 pm, the laboratory manager confirmed the above patients were tested without 2 levels of quality control prior to patient testing.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedure, test menu, Quality Control (QC) and patient records, and interview with personnel, the laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for thirteen (13) of forty eight (48) days reviewed. Findings: 1. Review of the test menu provided to the surveyor by laboratory staff revealed the laboratory performed manual Rapid Plasma Reagin (RPR) patient testing. 2. Review of the laboratory's Quality Control Procedures revealed "External Quality Controls are performed each day of use, prior to or parallel with patient testing." 3. Review of the Quality Control (QC) and patient records from July 2022 through September 2022 revealed the laboratory did not document external reactive and non-reactive controls each day of patient testing for the following thirteen (13) of forty eight (48) testing days reviewed: a) July 1, 2022: 5 patients performed with no quality control documented b) July 6, 2022: 4 patients performed with no quality control documented c) July 7, 2022: 3 patients performed with no quality control documented d) July 8, 2022: 4 patients performed with no quality control documented e) July 11, 2022: 2 patients performed with no quality control documented f) July 21, 2022: 1 patient performed with no quality control documented g) July 22, 2022: 1 patient performed with no quality control documented h) July 27, 2022: 1 patient performed with no quality control documented i) August 1, 2022: 1 patient performed with no quality control documented j) August 8, 2022: 3 patients performed with no quality control documented k) August 15, 2022: 2 patients performed with no quality control documented l) August 20, 2022: 1 patient performed with no quality control documented m) August 24, 2022: 1 patient performed with no quality control documented 4. In interview on September 27, 2022 at 1:20 pm, the laboratory manager confirmed the laboratory external reactive and non-reactive controls was not documented for the above identified patients. The laboratory manager also stated all manual tests have quality control performed with patient testing, but the quality control is recorded in the LIS.

D5451

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control and patient testing records as well as interview with laboratory personnel, the laboratory failed to include a titered control for reactive RPR testing for one (1) of thirteen (13) patients. Findings: 1. Review of the laboratory's policy for RPR testing revealed additional titer quality control required for any reactive patient RPR. 2. Review of RPR patient test records from July - September 2022 revealed the laboratory failed to perform a negative and a known titered control for the following one (1) of thirteen (13) reactive RPR tests performed: Patient 2207140201 performed on July 15, 2022. 3. Interview with the laboratory manager and technical consultant on September 27, 2022 at 2pm confirmed the above reactive RPR did not have titer quality control documented with patient testing.

D5543

HEMATOLOGY

CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, patient and quality control records as well as interview with laboratory personnel, the laboratory failed to perform quality control every 8 hours of patient testing for manual cell counts. Findings: 1. Review of the laboratory procedure manual for manual cell counts revealed quality control (QC) to be performed every 8 hours of patient testing for all cell counts performed with a hemocytometer. 2. Review of patient testing and quality control records from April 2021 - July 2021 revealed the following three (3) of twenty (20) patients performed without QC every 8 hours: a) P9942728 b) P994744 c) P36692 3. Interview with the technical consultant on September 26, 2022 at 2pm confirmed the above identified patients did not have documented quality control performed within 8 hours of patient testing. II. Based on review of laboratory policy, patient and quality control records as well as interview with laboratory personnel, the laboratory failed to perform quality control and patient testing for manual cell using a hemocytometer in duplicate. Findings: 1. Review of the laboratory policy revealed performance of testing by hemocytometer procedure did not specify a required frequency of duplicate counts. 2. Review of patient testing and quality control records from April 2021 - July 2021 revealed the following three (3) of twenty (20) patients performed by hemocytometer were not counted in duplicate: a) P9942728 b) P994744 c) P36692 3. Interview with the technical consultant on September 26, 2022 at 2pm revealed the laboratory does perform counts in duplicate, but the duplicate count is documented outside of the LIS.

The technical consultant confirmed the LIS does not reflect duplicate count of quality control or patient testing.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation during laboratory tour, review of laboratory policies and records, as well as interview with personnel, the laboratory failed to perform instrument comparison testing of two (2) Atellica instruments at least twice annually. Findings: 1. Observation by surveyor during the laboratory tour on September 26, 2022 at 10 am revealed the laboratory utilizes the following two (2) Siemens Atellica instruments (930 & 1300) for a variety of patient testing. 2. Review of the laboratory's records revealed the laboratory performed instrument correlations in September of 2022, but did not have documentation of comparison of the two Atellica analyzers for the first half of 2022. 3. In interview on September 27, 2022 at 10:33 am the technical consultant confirmed the laboratory did not perform the instrument correlations of the Atellicas twice in 2022.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on direct observation of refrigerator temperatures, review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for sixty five (65) of eighty four (84) days reviewed from July - September 2022. Findings: 1. Direct observation by surveyor of specimen accessioning on September 23, 2023 at 11am revealed the temperature documentation of accessioning room refrigerator temperature chart was retained on the front of the refrigerator. 2. Further review of the laboratory policy and procedure as well as the temperature documentation of the accessioning room refrigerator had an acceptable temperature range of 2-8 degrees Celsius. The following sixty five (65) of eighty four (84) days had documented temperatures outside of the laboratory's acceptable ranges: July 3, 2022: Min temperature documented -14 degrees Celsius July 4, 2022: Min temperature documented -14 degrees Celsius July 5, 2022: Daily temperature documented 1 degrees Celsius July 6, 2022: Daily temperature documented 1 degrees Celsius July 7, 2022: Daily temperature documented 1 degrees Celsius July 8, 2022: Daily temperature documented -5 degrees Celsius July 9, 2022: Min temperature documented -10 degrees Celsius July 10, 2022: Min temperature documented -10 degrees Celsius July 11, 2022: Daily temperature documented -1 degrees Celsius July

12, 2022: Daily temperature documented -3 degrees Celsius July 13, 2022: Daily temperature documented -3 degrees Celsius July 15, 2022: Daily temperature documented -1 degrees Celsius July 17, 2022: Min temperature documented -3 degrees Celsius July 18, 2022: Daily temperature documented 0 degrees Celsius July 19, 2022: Daily temperature documented 0 degrees Celsius July 22, 2022: Daily temperature documented 0 degrees Celsius July 24, 2022: Min temperature documented -8 degrees Celsius July 25, 2022: Daily temperature documented 1 degrees Celsius July 27, 2022: Daily temperature documented -7 degrees Celsius July 30, 2022: Min temperature documented -12 degrees Celsius August 4, 2022: Daily temperature documented 0 degrees Celsius August 5, 2022: Daily temperature documented -6 degrees Celsius August 6, 2022: Daily temperature documented -2 degrees Celsius August 8, 2022: Daily temperature documented 0 degrees Celsius August 9, 2022: Daily temperature documented -2 degrees Celsius August 11, 2022: Daily temperature documented -1 degrees Celsius August 12, 2022: Daily temperature documented 0 degrees Celsius August 13, 2022: Daily temperature documented 1 degrees Celsius August 14, 2022: Min temperature documented -7 degrees Celsius August 15, 2022: Daily temperature documented 0 degrees Celsius August 16, 2022: Daily temperature documented -1 degrees Celsius August 18, 2022: Daily temperature documented 1 degrees Celsius August 19, 2022: Daily temperature documented 1 degrees Celsius August 20, 2022: Daily temperature documented -2 degrees Celsius August 21, 2022: Min temperature documented -5 degrees Celsius August 22, 2022: Daily temperature documented 1 degrees Celsius August 23, 2022: Daily temperature documented -2 degrees Celsius August 25, 2022: Min temperature documented -5 degrees Celsius August 26, 2022: Daily temperature documented -3 degrees Celsius August 27, 2022: Daily temperature documented 0 degrees Celsius August 28, 2022: Daily temperature documented -2 degrees Celsius August 29, 2022: Daily temperature documented -3 degrees Celsius August 30, 2022: Daily temperature documented -3 degrees Celsius September 1, 2022: Daily temperature documented -2 degrees Celsius September 2, 2022: Daily temperature documented -3 degrees Celsius September 3, 2022: Daily temperature documented 1 degrees Celsius September 4, 2022: Min temperature documented -8 degrees Celsius September 5, 2022: Min temperature documented -8 degrees Celsius September 7, 2022: Daily temperature documented 1 degrees Celsius September 8, 2022: Min temperature documented -8 degrees Celsius September 9, 2022: Min temperature documented -8 degrees Celsius September 11, 2022: Min temperature documented -8 degrees Celsius September 14, 2022: Daily temperature documented 0 degrees Celsius September 15, 2022: Daily temperature documented 0 degrees Celsius September 16, 2022: Daily temperature documented -1 degrees Celsius September 17, 2022: Daily temperature documented -1 degrees Celsius September 18, 2022: Min temperature documented -8 degrees Celsius September 20, 2022: Daily temperature documented -1 degrees Celsius September 21, 2022: Daily temperature documented 0 degrees Celsius September 24, 2022: Daily temperature documented 0 degrees Celsius 3. In interview on September 24, 2022, accessioning personnel stated the temperatures are documented each day on the temperature chart reviewed. Further interview on September 24, 2022 at 2pm, the laboratory manager and technical consultant confirmed the temperatures documented were outside the laboratory acceptable ranges, but that these were recorded in error by accessioning staff using the min/max thermometer.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of records, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory has a quality assessment process in place; however, the following deficient practices were not identified: a. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 b. The laboratory failed to follow manufacturer's instructions and laboratory procedure for flags appearing on Complete Blood Counts (CBC) for three (3) of three (3) patients reviewed. Refer to D5411 I. c. The laboratory failed to perform Prothrombin Time Test (PT) within four (4) hours of collection as required by manufacturer for ten (10) of seventeen (17) patients reviewed. Refer to D5411 II. d. The laboratory failed to perform calibration every 6 months as required by the manufacturer for the Sysmex XN-1000 analyzer for 2021-2022. Refer to D5437. e. The laboratory failed to perform calibration verification procedures for Thyroid Peroxidase Antibody (aTPO) at least every six (6) months per manufacturer requirements during 2021 - 2022. Refer to D5439. f. The laboratory failed to perform two (2) levels of controls prior to patient testing for parathyroid hormone (PTH) testing for two (2) of nineteen (19) days reviewed over two months of patient testing. Refer to D5447. g. The laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for thirteen (13) of forty eight (48) days reviewed. Refer to D5449. h. The laboratory failed to include a titered control for reactive RPR testing for one (1) of thirteen (13) patients. Refer to D5451. i. The laboratory failed to perform quality control every 8 hours of patient testing for manual cell counts. Refer to D5543 I. j. The laboratory failed to perform quality control and patient testing for manual cell using a hemocytometer in duplicate. Refer to D5543 II. k. The laboratory failed to perform instrument comparison testing of two (2) Atellica instruments at least twice annually. Refer to D5775. l. The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for sixty five (65) of eighty four (84) days reviewed from July - September 2022. Refer to D5785. 2. Interview with the technical consultant of the laboratory on September 27, 2022 at 2pm confirmed the above identified deficient practices were not identified by the laboratory's quality assessment activities.

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 observation by surveyor, review of manufacturer's instructions, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to

perform quality control and patient testing for manual cell using a hemocytometer in duplicate. Refer to D5543 II. 2. The laboratory failed to perform Prothrombin Time Test (PT) within four (4) hours of collection as required by manufacturer for ten (10) of seventeen (17) patients reviewed. Refer to D5411 II. 3. The laboratory failed to perform calibration every 6 months as required by the manufacturer for the Sysmex XN-1000 analyzer for 2021-2022. Refer to D5437. 4. The laboratory failed to perform calibration verification procedures for Thyroid Peroxidase Antibody (aTPO) at least every six (6) months per manufacturer requirements during 2021 - 2022. Refer to D5439. 5. The laboratory failed to perform instrument comparison testing of two (2) Atellica instruments at least twice annually. Refer to D5775. 6. The laboratory failed to perform corrective actions for refrigerator temperatures that exceeded the acceptable range for sixty five (65) of eighty four (84) days reviewed from July - September 2022. Refer to D5785.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to follow manufacturer's instructions and laboratory procedure for flags appearing on Complete Blood Counts (CBC) for three (3) of three (3) patients reviewed. Refer to D5411 I. 2. The laboratory failed to perform two (2) levels of controls prior to patient testing for parathyroid hormone (PTH) testing for two (2) of nineteen (19) days reviewed over two months of patient testing. Refer to D5447. 3. The laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for thirteen (13) of forty eight (48) days reviewed. Refer to D5449. 4. The laboratory failed to include a titered control for reactive RPR testing for one (1) of thirteen (13) patients. Refer to D5451. 5. The laboratory failed to perform quality control every 8 hours of patient testing for manual cell counts. Refer to D5543 I.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation by surveyors, review of laboratory records, and interview with

personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.

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 a complete procedure manual was available to all personnel. Refer to D5401.