

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2097807	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Precision Clinical Laboratory	Street Address, City, State 11275 E Mississippi Ave, Ste 2wi, Aurora, CO	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's written policies, proficiency testing (PT) records and technical consultant interview, the laboratory failed to enroll in an HHS-approved PT program for the first PT testing event in 2017 for the specialty and subspecialty testing for which it seeks certification. Findings include: a. The laboratory's policy for proficiency testing (#GEN.0011, effective 6-3-16) states, "All sections of Precision Clinical Laboratory shall be enrolled in external proficiency testing surveys for the extent of testing performed as required by regulatory agencies." b. The laboratory tests patient specimens in the specialties/subspecialties of routine chemistry, endocrinology, hematology, and coagulation. c. No documentation existed to show that the laboratory had enrolled in a PT program, so the laboratory received no PT samples to test for the 1st event of 2017. d. On 4-10-18 at around 2 p.m., the technical consultant confirmed he could not provide any documentation that the laboratory had enrolled in a PT program in time to receive and test any PT samples for the 1st event of 2017.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p>

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's written policies, proficiency testing (PT) records, and staff interview, the laboratory failed to ensure PT attestation statements were signed by the appropriate personnel for the hematology and chemistry testing modules in 2017. Findings include: a. The laboratory's policy for proficiency testing (#GEN.0011, effective 6-3-16) states, "The proficiency testing attestation page is signed by the laboratory director or designee and the individual performing the testing." b. The laboratory's written policy (Proficiency Testing Protocol #550) states, "The laboratory director and testing personnel are required to sign/date the attestation page." and, "Ensure to file a copy of the signed attestation statement in the manual, as well." c. Records showed neither the lab director nor any testing personnel had signed the attestation statements for the 2nd and 3rd hematology PT events of 2017 and the 3rd chemistry PT event of 2017. d. On 4/10/18 at around 2 p.m., the technical consultant confirmed the attestation statements had not been signed by appropriate personnel as required by laboratory policy and the federal CLIA regulations.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, proficiency testing (PT) records and staff interview, the laboratory failed to document each step in the testing and reporting of results by not retaining a duplicate copy of the PT results sent to the PT provider for the 3rd event of 2017 and the 1st event of 2018. Findings include: a. The laboratory's policy for proficiency testing (#GEN.0011, effective 6-3-16) for submission of PT results states, "Once entered, a second individual should confirm clerical entry from the final result forms/printouts and print the confirmation of receipt page from the CAP website" and "All PT records and corrective action reports will be retained by the respective sections for at least 2 years." b. PT records for the 3rd event of 2017 (hematology and chemistry modules) and the 1st event of 2018 (hematology module) did not contain a copy of the test results reported to the PT provider. c. On 4/10/18 at around 2 p.m., the technical consultant confirmed the laboratory had not maintained a copy of all records required for proficiency testing in 2017 and 2018 as required by the federal CLIA regulations.

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: Based on a review of proficiency testing (PT) scores and staff confirmation, the laboratory failed to achieve successful PT performance for 2 of 3 consecutive testing events in the subspecialty of Routine Chemistry in 2017 and 2018 (Ref D2097).</p>
D2097	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) scores and staff confirmation, the laboratory failed to achieve an overall successful performance of 80% for 2 of 3 consecutive events in the subspecialty of Routine Chemistry for two analytes in 2017 and 2018. Findings include: Total Cholesterol: 2nd event 2017 = 0% 1st event 2018 = 0% Free Thyroxine (Free T4): 2nd event 2017 = 40% 1st event 2018 = 0%</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality assessment (QA) plan, competency assessment policy, a lack of personnel competency assessment records and staff interview, the laboratory failed in 2017 to follow their written policy to assess the competency of 3</p>

of 3 testing personnel who perform moderate and high complexity testing using the chemistry, hematology, and coagulation analyzers. Findings include: a. The laboratory's policy for Hematology General Quality (#HEM.0071, effective 5-9-16) states, "Competency assessment is determined after the initial training by consistent satisfactory performance as outlined on the performance appraisal form." b. The laboratory's policy for Coagulation General Quality (#COAG.0019, effective 5-6-16) states, "Competency assessment is determined after the initial training by consistently satisfactory performance as outlined on the performance appraisal form" and, "The supervisor assumes the responsibility for determining that the new employee performs the tasks appropriately." c. The QA plan (Policy/Procedure #530) states, "Documentation of an evaluation every six months during the first year of employment and annually thereafter." d. The policy for Competency Assessment (Policy/Procedure #570) states, "New employees must be evaluated upon hire, at six months, and annually thereafter; other employees must be evaluated annually or whenever a new method or procedure is introduced" and, "Each completed competency assessment will be placed in the employee's permanent file". e. On 4/6/2018, staff found no records of any competency assessments of 3 of 3 testing personnel for any testing they performed in 2017 and 2018. f. On 4/6/2018, testing personnel confirmed they had not been assessed for competency of any testing in the specialties of chemistry, hematology or coagulation. g. On 4/10/2018, competency assessments were found for 3 of 3 testing personnel with the completion date of '4/9/2018'. h. On 4/10/2018 at around 10 a.m., the technical consultant confirmed competency assessments of all testing personnel were not performed in 2017 or in 2018 prior to 4/9/2018.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies, quality assessment (QA) plan, proficiency testing (PT) records, and staff confirmation, the laboratory failed to document the review and evaluation of the scores obtained from PT events of 2016 and 2017. Findings include: a. The laboratory's policy for proficiency testing (#GEN.0011, effective 6-3-16) for evaluation of PT results states, "The evaluation report will be reviewed and signed by the laboratory director, PCL, or section designee." b. The laboratory's QA Plan (Policy/Procedure #530) states, "Ensure a review of graded results is conducted and documented." c. Records showed no one signed the PT results received to document a review of the hematology and chemistry modules for the 3rd event of 2016, the 2nd event of 2017, and the 3rd event of 2017. d. On 4/10/18 at around 2 p.m., laboratory staff stated they were unaware of this requirement and confirmed no one had signed the PT scores received for each of the events in 2016 and 2017.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's written policies, proficiency testing (PT) scores, lack of accuracy verification (comparison testing) documentation and staff interview, the laboratory failed to assess the accuracy of an analyte, specialty and subspecialty for PT scores that do not reflect the laboratory's test performance. Findings include: a. The laboratory's PT policy (Policy/Procedure #550) for ungraded PT analytes states, "When such a situation occurs, the laboratory must perform and document its own verification of accuracy for the analyte, specialty, or subspecialty affected." b. No documentation of accuracy verification existed for the subspecialty of routine chemistry and the specialty of hematology after the laboratory failed to enroll in a PT program for the 1st PT event of 2017 c. No documentation of accuracy verification existed for the analytes of total cholesterol and free thyroxine (Free TY) after receipt of failed PT scores (0% and 40%, respectively) for the 2nd event of 2017. d. No documentation of accuracy verification existed for the subspecialty of routine chemistry after receipt of a 0% PT score for nonparticipation of the 1st event of 2018. e. On 4-10-18 around 2 p.m., the technical consultant stated they were unaware of this regulatory requirement and confirmed no comparison testing was performed to verify the accuracy of these analytes.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's written policies, proficiency testing (PT) records, and staff confirmation, the laboratory failed to review and evaluate unsatisfactory PT results received in 2016, 2017, and 2018. Findings include: a. The laboratory's policy for proficiency testing (#GEN.0011, effective 6-3-16) for evaluation of PT results states, "The section laboratory director or supervisor will promptly initiate investigation of the cause and a plan for corrective action for all samples not listed as acceptable" and "All PT records and corrective action reports will be retained by the respective sections for at least 2 years." b. The laboratory's QA Plan (Policy/Procedure #530) states, "Verify unsuccessful or unsatisfactory PT events are investigated and corrective actions taken. Document findings and actions." c. The laboratory's PT policy (Policy/Procedure #550) states, "Complete the Proficiency Testing Corrective Action form for any PT failures to determine the cause and initiate any corrective action" and, "Document all investigative actions to avoid violating the "two out of three" rule." d. Records showed unsatisfactory PT results were received for the 3rd event of 2016 for thyroxine in the subspecialty of routine chemistry (20%) and for activated partial thromboplastin time (APTT) in the specialty of hematology (40%). No investigation was documented to identify the root cause of these failures and prevent their recurrence. e. Records showed unsatisfactory PT results were received for the 2nd event of 2017 for total cholesterol (0%) and free thyroxine (free T4) (40%). No investigation was documented to identify the root cause of these failures and prevent their recurrence. f. Records showed unsatisfactory PT results were received for the 1st event of 2018 for the entire routine chemistry module (0%). No investigation was documented to identify the root cause of these failures and

prevent their recurrence. g. On 4/10/18 at around 2 p.m., staff confirmed they were unaware whether any investigation of these PT failures had been conducted since no documentation of investigations could be found in the laboratory.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

The laboratory failed in 2017 and 2018 to ensure their written policies were followed on an ongoing basis to monitor, assess, and correct problems in the general laboratory systems. Findings include: a. No QA activities were performed to ensure the laboratory assessed the competency of testing personnel (Ref D5209). b. No QA activities were performed to ensure the laboratory reviewed and evaluated PT scores obtained (Ref D5211). c. No QA activities were performed to ensure the laboratory assessed the accuracy of analytes for PT scores that did not reflect the laboratory's test performance (Ref D5215). d. No QA activities were performed to ensure the laboratory reviewed and evaluated unsatisfactory PT scores received (Ref D5221).

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

The laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems for each specialty and subspecialty of testing performed. Findings include: a. The laboratory failed to follow the established test procedure to enter the correct expiration date for reagents in the hematology analyzer (Ref D5401). b. The laboratory failed to include panic or alert values in the test procedures for hematology and chemistry testing (Ref D5403). c. The laboratory failed to obtain the laboratory director signature on the standard operating procedures (Ref D5407). d. The laboratory failed to ensure the humidity in the laboratory met manufacturer's required operating conditions for the chemistry analyzer (Ref D5413). e. The laboratory failed to properly label the staining reagents on the laboratory bench (Ref D5415). f. The laboratory failed to ensure in-use reagents are not expired (Ref D5417). g. The laboratory failed to validate C-reactive protein (CRP) prior to reporting patients (Ref D5423). h. The laboratory failed to test immunoassay QC materials prior to reporting patients (Ref. D5447). i. The laboratory failed to document the condition of media upon receipt and failed to perform QC testing of the media with each new lot and shipment received (Ref D5477). j. The laboratory failed to follow the manufacturer's instructions and perform all control procedures for the

coagulation analyzer (Ref D5479). k. The laboratory failed to ensure the ambient humidity met the manufacturer's specifications for operating the chemistry analyzer, and failed to take corrective action when laboratory temperatures and humidity were not recorded each day of testing (Ref D5781). l. The laboratory failed to take any corrective action when QC materials were not tested each day patient specimens were tested, when hematology reagents in the analyzer had expired, when calibrations failed, and when calibrations were not performed when required (Ref D5783). m. The laboratory failed to take any corrective action when the temperatures in the refrigerator and freezer were recorded as outside their acceptable ranges (Ref D5785).

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 a review of the laboratory's written policies, the operator's manual, daily reagent check reports, and staff interview, the laboratory failed to follow their written procedure to ensure the correct expiration dates for the reagents were entered in the Beckman Coulter hematology analyzer prior to reporting patients' results for complete blood count (CBC) testing, and approximately 1200 patient results had been reported. Findings Include: a. The laboratory performs complete blood count (CBC) testing using a Beckman Coulter LH750 Hematology Analyzer. b. The laboratory's policy for Reagent Labeling, Storage, Reagent Checks and Correlations (#GEN.0021, effective 6-3-16) states, "All reagents will be used within their indicated expiration date or the date as assigned by the tech preparing the solution." c. The laboratory's procedure (Hematology Defined Protocol) states the operator's manual should be followed for directions. d. The operator's manual for reagent set-up states that the reagent information should be entered by barcode scanner or by manual entry. e. The daily reagent check report showed CBC lyse reagent (lot #101580F) expired on 12/26/2017. f. The CBC lyse reagent (lot #101580F) in the instrument on the date of survey (4/6/2018) expired on 2/28/2018. g. The daily reagent check report showed the Diff Pack reagent (lot #111006K) expired on 2/4/2018. h. The Diff Pack reagent (lot #111006K) in the instrument on the date of survey (4/6/2018) expired on 3/13/2018. i. During the onsite survey on 4/10/2018 at around 11 a.m., the technical consultant confirmed the laboratory failed to follow their written procedure to enter the expiration dates of the reagents into the hematology analyzer and had reported patient results when expired reagents were in use in the analyzer.

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 a review of the test procedures (Critical Values Policy #400) and staff confirmation, the laboratory failed to have complete written procedures in place for chemistry and hematology testing that include imminently life-threatening test results, or panic or alert values for testing personnel to follow in 2017 and 2018.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's written test procedures and staff confirmation, the laboratory director failed to review, sign and date her approval of the procedures after assuming directorship on 2-6-17, to include the new test procedures found in the laboratory during the survey on 4/10/2018.

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:
1. Based on a review of the operator's manual, maintenance records, and staff interview, the laboratory failed in 2017 and 2018 to ensure the humidity in the laboratory met the manufacturer's required operating conditions for the Beckman Coulter AU480 chemistry analyzer. Findings include: a. The operator's manual for the Beckman Coulter AU480 chemistry analyzer stated the testing environment in the laboratory must have 40-80% ambient relative humidity. b. Monthly maintenance log sheets for December 2016 through July 2017 listed the acceptable range for the room humidity as 20-80% and the monthly maintenance log sheets for August 2017 through April 2018 listed the acceptable range for the room humidity as less than 50%. c. On

4-10-18 at around 2 p.m., staff stated they were unaware the acceptable humidity range listed on their maintenance log sheets was incorrect. d. On 4-10-18 at around 2 p.m., staff confirmed the laboratory had the incorrect range for humidity listed on their log sheets and had not ensured a testing environment of at least 40% relative humidity as required by the operator's manual for the Beckman Coulter AU480 chemistry analyzer. 2. Based on a review of maintenance records and staff interview, the laboratory failed in 2017 and 2018 to document the temperature of the True Class refrigerator #1, the Maytag freezer, the ambient room temperature, and the room humidity each day of use. Findings include: a. The laboratory's policy for Reagent Labeling, Storage, Reagent Checks and Correlations (#GEN.0021, effective 6-3-16) states, "All reagents media and solutions must be stored as recommended by the manufacturer" and, "Temperature of reagent storage is monitored through the temperature log system." b. The laboratory's policy for Coagulation General Quality (#COAG.0019, effective 5-6-16) states, "Daily temperatures are recorded for the appropriate instruments and logged on the appropriate charts" and, "Refrigerators and freezers are continually monitored by thermometers." c. The laboratory's QA plan (Policy/Procedure #530) states, "Specimens are collected, handled, stored and preserved as appropriate." d. Maintenance records for the first three months of 2018 showed the temperature of the True Class refrigerator #1 was outside of the acceptable range of 2-8C on 7 of 75 days. Moreover, the temperature of the Maytag freezer was outside of the acceptable range of -20 to -30C listed on the log sheet on 52 of 75 days. e. Maintenance records for 2017 showed the temperature of the True Class refrigerator #1 was outside of the acceptable range on 9 of 275 days. Moreover, the temperature of the Maytag freezer was outside of the acceptable range listed on the log sheet on 78 of 275 days. f. Maintenance records for the True Class refrigerator #1, the Maytag freezer, the room temperature and the humidity showed the environmental conditions were not recorded for 30 days in 2017: August (9 days), September (9 days), October (7 days), November (1 day), and December (4 days). g. Maintenance log sheets listed an incorrect range of -20C to -20C for the Maytag freezer for 7 months (Oct. 2017 through Apr. 2018) rather than the range of -20C to -30C. h. Maintenance records showed testing personnel documented the temperature within the True Class refrigerator #1 as a negative number on 4 days in February 2018 and on 14 days in March 2018. i. Staff confirmed the temperatures and humidity were not documented each day, the temperature range on the log sheets for the Maytag freezer was incorrect, and the refrigerator temperature should not have been documented as a negative number.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

1. Based on a review of the laboratory's policies, direct observation of four glass coplin staining jars in the laboratory and interview of testing personnel, the laboratory failed to properly label the staining reagents stored on the laboratory bench. Findings include: a. The laboratory's policy for reagent labeling (GEN.0021, effective 6-3-16) states, "Upon receipt or reconstitution, it will be verified that all reagents are properly

labeled with: content and quantity, storage requirements, date prepared or reconstituted, and expiration date." b. The laboratory's QA plan (effective 4-8-18) states, "Reagents are monitored for acceptable labeling (identity of substance, open or preparation dates, expiration dates) and storage." c. One staining jar with red liquid in it was labeled as "Soln 1." d. One staining jar with blue liquid in it had no identification or information on it of any kind. e. One staining jar with purple liquid in it was labeled as "Soln 2." f. One empty staining jar was labeled as "fixative." g. Staff stated these jars were used to stain peripheral smears to check for platelet clumping in the patients' blood specimens. h. Staff stated they were unaware of the regulatory requirements for labeling solutions and confirmed the labels did not include all required components according to their laboratory policy and the federal CLIA regulations.

2. Based on a review of the laboratory's policies, the manufacturer's quality control (QC) assay sheet, the direct observation of three bottles of in-use Beckman Coulter 5C Cell hematology controls, and staff interview, the laboratory failed to label the bottles of control material with the date the vials were opened and the corresponding expiration date of the control materials to ensure they were not used past their date of expiration. Findings include: a. The laboratory's Hematology policy for general quality (#HEM.0071, effective 5-9-16) states, "Reagents are labeled with the date received, date put in use, storage requirements, and expiration date, and initialed when received" and, "All outdated reagents are discarded." b. The laboratory's policy for reagent labeling (#GEN.0021, effective 6-3-16) states, "If, by opening a container, the expiration date changes, the new expiration date will be noted on the container." c. The manufacturer's assay sheet for the 5C Cell control material stated that vials that have been opened expire in 13 days. d. No date of opening or the corresponding expiration date was written on any of the three in-use vials of hematology control material: Normal QC (lot #880800), Abnormal 1 QC (lot #870200), and Abnormal 2 QC (lot # 869100). e. On 4-6-18 at about 12 p.m., the surveyor instructed the laboratory not to perform any further patient testing using expired control materials and recommended the laboratory dispose of anything that has expired to prevent any further patient testing using expired laboratory supplies. f. Staff confirmed they had not documented the date the vials were opened and therefore could not determine the expiration date of the in-use hematology control materials as required by their laboratory policy, the manufacturer's requirements, and federal CLIA regulation.

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:

1. Based on the direct observation of supplies stored in Refrigerator #2 in the microbiology department, and staff interview, the laboratory failed in 2017, and 2018 to replace laboratory supplies when they had exceeded their expiration date. Findings include: a. Expired microbiology media: chocolate agar (lot #7173617) expired 10-16-17, one full box plus 2 sleeves of 10 agar plates each, chocolate agar (lot #7138817) expired 9-8-17, one full box plus 2 sleeves of 10 agar plates each, MacConkey agar (lot #7173634) expired 9-19-17, one box of 9 sleeves with 10 agar plates each, MacConkey agar (lot #7299877) expired 1-23-18, one full box of 10 sleeves of 10 agar plates each, Trypticase Soy agar (TSA) with 5% sheep blood (log #7159916)

expired 9-26-17, 14 sleeves of 10 agar plates each. b. Expired Culti-Loops quality control (QC) organisms (lot #9004474) expired 1-24-18, 1 pack of 5 individually packaged swabs. c. Expired Gibson Bioscience Trivalent Swabs, Negative Control (lot #6050532) expired 2-18-17, 6 packs of 5 individually packaged swabs. d. Expired Gibson Bioscience Trivalent Swabs, Positive Control (lot #6057526) expired 2-25-17, 6 packs of 5 individually packaged swabs. e. Expired Gibson Bioscience Trivalent Swabs, Validation Swab Set #5 through 22 (lot #6036534) expired 2-4-17. f. Urine culture on blood agar (lot #7270921) expired 1-16-18, and a urine culture on MacConkey agar (lot #7173634) expired on 9-19-17. Both culture plates had a preprinted label showing the patient's specimen (#32158) had been inoculated on 4-3-18. g. Urine culture on blood agar (lot #7270921) expired 1-16-18, and a urine culture on MacConkey agar (lot #7173634) expired on 9-19-17. Both culture plates had a preprinted label showing the patient's specimen (#32130) had been inoculated on 4-3-18. h. Urine culture on MacConkey agar (lot #7173634) expired on 9-19-17. The culture plate had a preprinted label showing the patient's specimen (#32127) had been inoculated on 4-3-18. i. On 4-6-18 at around 12 p.m., staff stated the microbiology media and patient urine cultures are used to grow cultures for the validation of their new Biomerieux Vitek 2 microbiology analyzer, and the Trivalent Swabs might also be used to validate the Vitek 2 analyzer or to validate the BD Affirm microbial identification analyzer. j. On 4/6/2018 at around 12 p.m., the State surveyor instructed testing personnel the expired reagents can no longer be used for testing and recommended to the laboratory to dispose of anything that is expired to prevent any further testing using expired laboratory supplies. k. On 4-6-18 at around 12 p.m., staff confirmed these supplies were expired and began throwing them away as required by their laboratory policy and the federal CLIA regulations. 2. Based on a review of the laboratory's policies, the direct observation of supplies stored in Maytag freezer (serial #U54701591), and staff interview, the laboratory failed in 2016, 2017, and 2018 to replace laboratory supplies when they had exceeded their expiration date. Findings include: a. The laboratory's policy for Reagent Labeling, Storage, Reagent Checks and Correlations (#GEN.0021, effective 6-3-16) states, "All reagents will be used within their indicated expiration date or the date as assigned by the tech preparing the solution." b. Expired VeriChem Chemistry 3 Install Verifier Kit (lot #K350701) expired 6-30-16. c. Expired BioRad Liquichek Cardiac Markers Plus Control: Level 1 (lot # 23611) expired 9-30-17, 6 bottles; Level 2 (lot # 23612) expired 9-30-17, 8 bottles; Level 3 (lot # 23613) expired 9-30-17, 10 bottles. d. Expired BioRad Liquichek Specialty Immunoassay (lot #29827) expired 5-31-16, 2 bottles. e. Expired Hemoglobin A1C Calibrator, Levels 2, 3, 4, 5, and 6 (lot #0031) expired 3-1-18. f. Expired thermometer (serial #150455571), the last calibration was 6-15-17. f. On 4-6-18 at around 12 p.m., staff confirmed the reagents and supplies were expired and stated she does not remove anything that has expired because she does not want to step on the owner's toes. g. On 4/6/2018 at around 12 p.m., the surveyor instructed testing personnel the expired reagents can no longer be used for testing and recommended to the laboratory to dispose of anything that is expired to prevent any further testing using expired laboratory supplies. h. On 4-6-18 at around 12 p.m., staff acknowledged the reagents were expired and began throwing the expired reagents away as required by their laboratory policy and the federal CLIA regulations. 3. Based on a review of the laboratory's policies, the direct observation of supplies stored in True Class refrigerator (serial #8101962), and staff interview, the laboratory failed in 2016, 2017, and 2018 to replace laboratory supplies when they had exceeded their expiration date. Findings include: a. The laboratory's policy for Reagent Labeling, Storage, Reagent Checks and Correlations (#GEN.0021, effective 6-3-16) states, "All reagents will be used within their indicated expiration date or the date as assigned by the tech preparing the solution." b. Expired urinary/cerebral spinal fluid (CSF)

reagents (2 boxes): Ref. OSR6170, R1 calibrator (lot #8346), expired 11-1-16, and Ref. OSR6170, R1 calibrator (lot #9378), expired 7-1-17. c. Expired APTT reagent, SynthASil, 5x10 mL, 2 and 1/2 boxes (lot #N0261011), SEQ 05608, expired 2/2018. d. Expired Syphilis RPR Dry Control Cards, Impact RPR 61C2 (lot #1678) expired 2/2018. e. Expired Alere Afinion Hemoglobin A1C controls, 1 box, ref. #1115178 (lot #10180989) expired 1/2016. f. Expired BD Affirm VPIII kits: (lot #6092806) expired 10-18-16, 2 boxes; and (lot #6012524) expired 11-9-16, 1 box. g. Expired thermometer (serial #1507365), calibration expired 10-2-17. h. Expired erythrocyte sedimentation rate (ESR) controls for the Vital Accu-Sed Plus test system: Normal ESR control (lot #15219000-3) expired 1-25-17, 1 bottle; and Abnormal ESR control (lot #15219100-3) expired 1-25-17, 1 bottle. i. On 4/6/2018 at around 1 p.m., the surveyor instructed testing personnel the expired reagents can no longer be used for testing and recommended to the laboratory to dispose of anything that is expired to prevent any further testing using expired laboratory supplies. j. On 4-6-18 at around 1 p.m., staff acknowledged the reagents were expired and began throwing the expired reagents away as required by their laboratory policy and the federal CLIA regulations.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
 Based on the lack of verification records, Equipment Validation policy, and staff interview, the laboratory failed to verify the accuracy, precision, reportable range, analytical sensitivity and specificity, and verify the manufacturer's reference intervals for the use of off-label Sekisui reagents for C-reactive protein (CRP) using the Beckman Coulter AU480 Chemistry Analyzer before testing patient specimens in February 2018. Findings include: a. The QA Plan for equipment validation (Policy /Procedure #470) states, "Each laboratory that modifies an FDA-cleared or approved test system must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range and reference intervals, any other performance characteristics required for test performance, determine calibration and control procedures and document all of the above." b. On 4/6/2018, a Sekisui CRP reagent was found on the chemistry analyzer labeled as 'CRP' without any manufacturer's label or barcode. c. On 4/6/2018, Sekisui supplies were found in the laboratory refrigerator: a CRP reagent kit (lot #51376, expiration date: 02/28/19) and Sekisui CRP Calibrators (lot #50434, expiration date: 01/31/19). d. On 4/6/2018, no records were found to show that the manufacturer's performance specifications had been established for the accuracy, precision, reportable range, analytical sensitivity and specificity, and reference intervals using the off-label Sekisui CRP reagents. e. A

patient report was found showing CRP testing was performed by testing personnel in the laboratory on 2/5/2018 at 3:02 p.m. (#1480-7434). f. On 4/6/18 at around 10 a.m., testing personnel stated CRP was not being performed in the laboratory, and the patient specimens had been sent to a reference laboratory for testing. g. No CRP patient report from a reference laboratory was found for the patient reported by this laboratory on 2/5/2018. h. On 4/10/2018 at around 3 p.m., the technical consultant stated he thought a Beckman Coulter Technical Representative validated the AU480 chemistry analyzer to perform CRP testing using the Sekisui reagents. i. On 4/10/2018 at around 3 p.m., the technical consultant confirmed there was no documentation of validation studies performed for using the Sekisui CRP reagents on the Beckman Coulter AU480 chemistry analyzer before reporting patient CRP results in February 2018.

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 a review of the quality assessment (QA) plan, test procedures, a lack of quality control (QC) records, and staff interview, the laboratory failed in 2018 to analyze control materials each day of patient testing on the Beckman Coulter Access 2 immunoassay analyzer before reporting patient test results. Findings include: a. The Quality Control Policy for chemistry (#CHM.0014, effective 5-8-16) states, "No patient result can be released without acceptable QC results, therefore all QC results must be documented as they are run" and "The results of the control specimens are analyzed before patient data is released." b. The Quality Control Policy (Policy /Procedure #540) states, "Perform a minimum of two levels of control per assay, each day of patient testing, or per manufacturer's recommendations." c. No testing of folate QC material was performed on 12 days of patient testing in 2018 and 16 patient results were reported (3/5: 2 patients, 3/7: 1 patient, 3/12: 1 patient, 3/15: 1 patient, 3/19: 1 patient, 3/20: 1 patient, 3/21: 1 patient, 3/27: 1 patient, 3/30: 1 patient, 4/2: 2 patients, 4/3: 3 patients, 4/5: 1 patient). d. No testing of parathyroid hormone (PTH) QC material was performed on 3 days of patient testing in 2018, and 4 patient results were reported (3/12: 1 patient, 3/21: 1 patient, 3/27: 2 patients). e. No testing of prostate-specific antigen (PSA) QC material was performed on 8 days of patient testing in 2018 and 8 patient results were reported (1/10: 1 patient, 3/6: 1 patient, 3/9: 1 patient, 3/14: 1 patient, 3/19: 1 patient, 3/19: 1 patient, 3/21: 1 patient, 3/22: 1 patient, 4/4: 1 patient). f. No testing of testosterone QC material was performed on 3 days of patient testing in 2018, and 3 patient results were reported (3/14: 1 patient, 3/22: 1 patient, 3/27: 1 patient). g. On 4/10/18 at about 3 p.m., the technical consultant confirmed the laboratory failed to analyze QC materials for folate, PTH, and PSA on the Access 2 analyzer before reporting patient test results in 2018.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)

(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a lack of quality control (QC) records and staff interview, the laboratory failed in 2017 and 2018 to document the condition of each lot and shipment of media received in the laboratory, and failed to test each lot and shipment of media with appropriate control organisms before or concurrent with initial use. Findings include: a. The State surveyor found microbiology media stored in Refrigerator #2: Trypticase Soy agar (TSA) with 5% sheep blood, MacConkey agar, and biplates of MacConkey and TSA/blood agar. a. No records existed to show the microbiology media received in the laboratory was inspected for defects or deterioration. b. No records existed to show the laboratory had tested each new lot and shipment of media with appropriate control organisms. c. On 4-6-18 at around 11 a.m., staff stated the laboratory uses these agars to grow control organisms to validate the new Biomerieux Vitek 2 microbiology analyzer. d. On 4-6-18 at around 11 a.m., staff stated they were unaware of these regulatory requirements, and confirmed the laboratory had not documented the condition of the media upon receipt and had not tested any media with control organisms in 2017 and 2018.

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of test procedures, operator's manual, reagent package inserts, and staff interview, the laboratory failed to follow in 2018 the manufacturer's instructions for the entering the correct international sensitivity index (ISI) value into the ACL Elite coagulation analyzer with each new lot number of reagent for the prothrombin time test (PT). Findings include: a. The coagulation test procedure (Coagulation Protocol) states that the international sensitivity index (ISI) value from each new package insert must be entered into the analyzer to obtain the correct calculation for the international normalized ratio (INR). b. In the section for PT calibration, the coagulation procedure states, "If the INR calculation is not properly set up, then erroneous patient results may be reported. If the reagent lot number changes, then the new ISI value from the package insert must be entered and mean normal range verified /changed." c. The ACL Elite operator's manual states new lot numbers of RecombinPlasTin 2G reagent must have the expiration date, ISI number, and calibration target entered into the analyzer before use. d. The package insert for RecombinPlasTin 2G reagent (lot #N1072885), stated the ISI value is 1.02. e. On 4/6 /2018, the State surveyor observed that the ISI value entered on ACL Elite coagulation analyzer was 1.00. f. On 4/10/2018, the State surveyor observed that the ISI value entered on ACL Elite coagulation analyzer was 1.02. g. On 4/10/18, the

technical consultant stated the ISI in the ACL Elite coagulation analyzer was changed to the correct ISI value of 1.02 on 4/9/2018. h. On 4/10/18 at around noon, the technical consultant confirmed the correct ISI in the ACL Elite coagulation analyzer was not used before 4/9/2018. i. On 4/10/18 at around noon, the technical consultant stated he was unaware of how many lot numbers of reagent were used before 4-9-18 since he had not retained the package inserts with their corresponding ISI values from the previous lots of reagent that had been used in the laboratory. j. On 4/10/2018 at around noon, the technical consultant confirmed the laboratory did not follow the manufacturer's instructions to enter into the ACL Elite coagulation analyzer the correct ISI value for the RecombinPlasTin 2G reagent in 2018.

D5779

CORRECTIVE ACTIONS
CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

1. Based on a review of the laboratory's quality assessment (QA) plan, result log sheets for the prothrombin time and international normalized ratio (PT/INR) test, and staff interview, the laboratory failed in 2017 and 2018 to establish policies and procedures to follow for taking corrective actions when panic or alert values are obtained for the PT/INR test. Findings include: a. The laboratory performs quantitative PT/INR testing in the specialty of hematology using the ACL Elite coagulation analyzer. b. The PT/INR procedure (Policy/Procedure: Testing Personnel) states, "The PT-INR assay reports PT results as International Normalized Ratio (INR) values that are used to monitor patients on stable oral anticoagulant therapy" and, "Many commonly administered drugs may affect PT-INR results, and further studies should be made to determine the source of unexpected abnormal results." c. The policy for Coagulation General Quality (#COAG.0019, effective 5-6-16) states, "The supervisor will ensure that the appropriate policies and procedures are followed, adequate records maintained and training of personnel conducted." d. The policy for Review and Reporting Results (#GEN.0022, effective 6-3-16) states, "If erroneous results are suspected, the specimen will be rechecked for correct labeling, rerun if possible, and troubleshooting steps taken" and, "Results requiring corrections or additional comments by the supervisor/pathologist will be identified clearly in the report as corrective or addendum." e. The QA Plan for patient testing (Policy /Procedure #530) states, "Corrective actions will be documented for any out-of-range results." f. The PT/INR procedure (Policy/Procedure: Testing Personnel) states that the normal range for INR is 0.9-1.1, the therapeutic range is 2.0-3.0, the mechanical heart valve range is 2.5-3.5, and the critical call is an INR result greater than 5.0. g. A review of PT/INR testing log sheets dated 2-5-18 through 4-5-18 showed 47 patients with an INR result higher than 3.5 and no repeat testing was documented to confirm the abnormal result, and no comment was found to indicate the patient had mechanical heart valves (patient ID #29673, 30285, 29944, 29879, 29781, 29824, 29810, 30120, 30225, 30308, 30336, 30475, 30644, 30812, 30949, 30952, 31963, 32179, 32174, 32201, 30962, 30961, 30966, 30971, 30975, 30684, 30702, 30633, 31052, 31258, 31261, 31283, 31347, 31426, 31445, 31583, 31664, 31840, 31851, 32151, 31011, 31016, 32267, 32318, 32321, 32330, 32335). h. A review of PT/INR testing log sheets dated 2-5-18 through 4-5-18 showed 11 patients with an INR result higher than 5.0 and no repeat testing was documented to confirm the critical result

(patient ID #29859, 29838, 30311, 30360, 32189, 32235, 30735, 31192, 31262, 317880, 31806). i. On 4-10-18 at around 4 p.m., the technical consultant stated that most of their patient specimens come from nursing homes, that 95% of those patients are on anticoagulant medication, and the laboratory does not document in the electronic patient testing record or on the patient's test report whether the patient is currently taking anticoagulation medication or if the abnormal result was confirmed by repeat analysis. j. On 4-10-18 at around 4 p.m., the technical consultant confirmed the laboratory did not follow their corrective action policies, they typically do not take corrective action to repeat a PT/INR test with an abnormal or a critical result or document the results of a patient's PT/INR test that was repeated. 2. Based on a review of the laboratory's policies, quality control (QC) records, and staff interview, the laboratory failed in 2018 to follow their policy to ensure QC materials were tested each day of patient testing for the Access 2 immunoassay analyzer. Findings include: a. The laboratory's written policy (Policy/Procedure #540) states, "Perform a minimum of 2 levels of control per assay, each day of patient testing, or per manufacturer's recommendations." b. The laboratory's written policy (Policy /Procedure #540) states, "Review all QC on a weekly basis in addition to monthly to ensure all QC is within an acceptable range." c. QC records from the Access 2 immunoassay analyzer showed no QC was performed each day of patient testing for folate (10 days in March and 2 days in April), parathyroid hormone (PTH) (3 days in March), prostate-specific antigen (PSA) (1 day in January, 6 days in March, and 1 day in April) and testosterone (3 days in March). d. No documentation of corrective action existed for the QC materials that were not tested in 2018 on days of patient testing on the Access 2 immunoassay analyzer. e. Staff confirmed that QC materials were not tested each day in 2018 that patient specimens were tested for folate, PTH, PSA, and testosterone, and that there was no evidence of any corrective actions taken for the missed QC for the Access 2 immunoassay analyzer. 3. Based on a review of the laboratory's procedure manual, daily analyzer reagent printouts, and staff interview, the laboratory failed in 2017 and 2018 to follow their procedure to dispose of expired reagents when they were still in use on the Beckman Coulter LH750 hematology analyzer and past their expiration dates. Findings include: a. The laboratory's written procedure for reagents (Hematology Defined Protocol) states, "Dispose of expired reagents, do not use reagents for patient testing beyond their expiration date" and, "Be mindful of marking new expiration date on opened reagents." b. On the date of survey (4/6/2018), the daily reagent check report showed no corrective action had been taken to replace the CBC lyse reagent (lot #101580F) that had expired on 12/26/2017. c. On the date of survey (4/6/2018), the daily reagent check report showed no corrective action had been taken to replace the Diff Pack reagent (lot #111006K) that had expired on 2/4/2018. d. On the date of survey (4/6/2018), the daily reagent check report showed no corrective action had been taken to replace the Cleaner pack reagent (lot #33253F) that had expired on 3/6/2018. e. Staff stated the testing personnel did not routinely update the reagent information in the analyzer promptly, and the reagent information entered in the analyzer consistently did not match the reagents placed into the analyzer. f. On the date of survey (4/10/2018) at around 11 a.m., the technical consultant confirmed the laboratory follow established policies and did not routinely replace expired reagents that were still in use in the hematology analyzer in 2017 and 2018.

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 a review of the operator's manual, quality assessment (QA) plan, maintenance records, and staff interview, the laboratory failed in 2017 and 2018 to take corrective action when the humidity in the laboratory did not meet the manufacturer's required operating conditions for the Beckman Coulter AU480 chemistry analyzer. Findings include: a. The operator's manual for the Beckman Coulter AU480 chemistry analyzer stated the testing environment in the laboratory must have 40-80% ambient relative humidity. b. The QA plan (Policy/Procedure #530) states that corrective actions must be documented for any out-of-range results. c. Monthly maintenance records for 2018 showed no corrective action was taken when the room humidity in the laboratory was below 40% on 75 of 75 days of testing in the first three months of 2018. d. Maintenance records for 2017 showed no corrective action was taken when the room humidity in the laboratory was recorded as below 40% on 207 of 253 days of testing. e. Maintenance records for 2017 showed no corrective action was taken when humidity was not recorded on 30 days of testing (9 days in August, 9 days in September, 7 days in October, 1 day in November, and 4 days in December). f. On 4-6-18 at around 3 p.m., staff confirmed the laboratory had not taken corrective action when the room humidity fell below the acceptable range, and when the room humidity was not documented on days of patient testing as required by federal CLIA regulation.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's procedure manual, calibration records, and staff interview, the laboratory failed in 2017 and 2018 to take any corrective action when the calibration failed and when calibration was not performed when required for the Beckman Coulter LH750 hematology analyzer. Findings include: a. The laboratory's written procedure (Hematology Defined Protocol) states that calibration of the Beckman Coulter LH750 hematology analyzer should be performed at least every six months, and any calibration issues should be documented on the Corrective Action Form. b. The quality assessment (QA) plan for calibration and calibration verification (Policy/Procedure #480) states, "This facility shall calibrate at a minimum of every six months as required by COLA, or as the manufacturer requires, or more frequent as the

need arises." c. The quality assessment (QA) plan for recalibration (Policy/Procedure #480) states, "When calibration verification fails to meet the established criteria of the laboratory, recalibrate with each new lot of reagent, patient testing will immediately cease until corrective action can be taken, check reagents for adequate volume and expiration date, check the calibrator material for sufficient volume and expiration date, and document all steps taken to correct the problem." d. No calibration records existed for 2017 before 12/22/2017 for the Beckman Coulter LH750 analyzer. e. Calibration records showed no corrective action was taken when the calibration failed on 12/22/2017 for the Beckman Coulter LH750 analyzer. f. No calibration records existed for 2018 for the Beckman Coulter LH750 analyzer up to the date of the survey on 4-10-18. g. On 4/10/18 at around 11 a.m., the technical consultant confirmed the laboratory had not taken any corrective action when the calibration of the hematology analyzer had failed in 2017 and had not taken any corrective action when calibration was not performed in the first half of 2017 and 2018.

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 a review of the manufacturer instructions, the laboratory's quality assessment (QA) plan, temperature logs, and staff interview, the laboratory failed in 2017 and 2018 to take any corrective action when the temperature of the refrigerator and freezer were not documented each day of use, and when the temperatures were outside the acceptable range for the storage of laboratory reagents and supplies. Findings include: a. The laboratory's written policy (Hematology Defined Protocol) states quality control (QC) material should be stored at 2 to 8Centigrade. b. The laboratory's written chemistry policy (AU 480 Protocol) states reagents are stored at 2to 8C. No freezer temperature range was provided for freezing and storing the chemistry supplies. c. The QA Plan (effective 4/8/18) states reagents will be monitored for acceptable labeling and storage. d. The QA plan (Policy/Procedure #530) states that corrective actions must be documented for any out-of-range results. e. Maintenance records for the first three months of 2018 showed no corrective actions were taken on 7 of 75 days when the temperature of the True Class refrigerator #1 (serial #8101962) was outside of the acceptable range. Moreover, no corrective actions were taken on 52 of 75 days when the temperature of the Maytag freezer was outside of the acceptable range listed on the temperature log sheet. f. Maintenance records for 2017 showed no corrective actions were taken on 9 of 275 days when the temperature of the True Class refrigerator #1was outside of the acceptable range, and on 78 of 275 days when the temperature of the Maytag freezer was outside of the acceptable range. g. Maintenance records for the True Class refrigerator #1 and the Maytag freezer showed no corrective actions were taken when temperatures were not recorded on 30 days of testing in 2017: August (9 days), September (9 days), October (7 days), November (1 day), and December (4 days). h. Maintenance records showed no corrective action was taken when the log sheets listed an incorrect range of -20C to -20C for the Maytag freezer for 7 months (Oct. 2017 through Apr. 2018) rather than the appropriate range of -20C to -30C. i. Maintenance records showed no corrective action was taken when the testing personnel incorrectly documented the temperature within the True Class refrigerator #1 as a negative

number on 4 days in February 2018 and on 14 days in March 2018. j. On 4-6-18 at around 3 p.m., staff confirmed no corrective actions were taken when the temperatures were outside of the acceptable range, when no temperatures were documented at all, when the temperature range listed on the log sheets for the Maytag freezer was incorrect, and when the refrigerator temperature was incorrectly documented as a negative number.

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:
1. Based on a review of the quality assessment (QA) plan, testing records and staff interview, the laboratory failed in 2017 and 2018 to establish written policies and procedures for staff to follow as an ongoing mechanism to monitor, assess, and correct problems in the analytic systems. Findings include: a. No QA activities were performed to ensure calibrations were acceptable and ensure calibrations were performed at the required frequency for the hematology analyzer (Ref D5783). b. No QA activities were performed to ensure calibrations were performed for the coagulation analyzer (Ref D5783). c. No QA activities were performed to ensure quality control (QC) materials were tested each day tht patient specimens were tested using the immunoassay analyzer (Ref D5783). d. No QA activities were performed to ensure corrective actions were taken upon receipt of unsatisfactory or unsuccessful (PT) scores (Ref D5783). e. No QA activities were performed to ensure the correct international sensitivity index (ISI) value from each new lot of reagent was entered into the coagulation analyzer (Ref D5783). f. No QA activities were performed to ensure reagents in the hematology analyzer had not expired (Ref D5783). g. No QA activities were performed to ensure stored reagents or laboratory supplies had not expired (Ref D5417). h. No QA activities were performed to ensure abnormal results obtained from the prothrombin time and international normalized ratio (PT/INR) test were related to anticoagulant medication taken by the patient. h. On 4/10/18 at around 3p.m., the technical consultant confirmed that the laboratory did not establish QA policies, procedures, or checklists to follow to monitor the ongoing activities in the analytic laboratory systems and correct problems in a timely manner.

D5813

TEST REPORT
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's written polices, patient reports, and direct observation, the laboratory failed to follow their written policies in 2018 to ensure critical values for the complete blood count (CBC) test were reported to the practitioner for 1 of 10 patient reports reviewed. Findings include: a. The laboratory's

policy for Hematology General Quality (#HEM.0071, effective 5-9-16) states, "Critical values are called to the clinician. This call is documented appropriately in the computer." b. The laboratory's procedure for reporting test results (Hematology Defined Protocol) states, "Notify the practitioner immediately and document in the critical values log." c. The reference (normal) range listed on the patient report is 11.1 to 15.9 for hemoglobin and 34.0 to 46.6 for hematocrit. d. A CBC test report for one patient (#32314), performed on 4/5/18 at 5:36 p.m., reported a hemoglobin result of 5.7 and a hematocrit result of 17.2, both of which were flagged on the report as critical low values. e. The patient report documented a comment for the critical results of "left voice mail @07:27 p.m. 04/05/18." f. During the onsite survey on 4/10/18, staff confirmed they could find no documentation to show that the laboratory had notified the practitioner immediately after the critical CBC value was reported.

D5817

TEST REPORT
CFR(s): 493.1291(i)

If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies, patient test reports, a lack of patient reports from reference laboratories, and staff interview, the laboratory failed in 2017 and 2018 to indicate on their cumulative report the name and address of the reference laboratory where testing was performed, and failed to retain all patient reports of supplemental testing performed at reference laboratories. Findings include: a. The laboratory's policy for Review and Reporting of Results (#GEN.0022, effective 6-3-16) states, "Originals from outsourced testing will be retained as per PCL record retention schedule." b. The laboratory's policy for Reporting Results (Policy /Procedure #390) states, "The laboratory will not integrate reference laboratory reports into their LIS to be printed with this laboratory's patient results" and states the laboratory's paper or electronic report must include the name and address of testing laboratory. c. Four patient reports (Acc.#13926 on 5-6-17, #22584 on 10-11-17, #26015 on 12-8-17, and #30884 on 3-13-18) showed urine culture results obtained from a reference laboratory that had been incorporated into the final patient report from this laboratory. The laboratory's reports did not indicate the reference laboratory's name and address that performed the urine culture testing. d. Staff could not provide a copy of any of the original urine culture test reports from the reference laboratory. e. One patient report (Acc. #28964 on 2-5-18) showed a C-reactive protein (CRP) result obtained from a reference laboratory that had been incorporated into the final patient report from this laboratory. The laboratory's report did not indicate the reference laboratory's name and address that performed the CRP testing. f. Staff could not provide a copy of the original CRP test report from the reference laboratory. g. One patient report (accession label #2000-7906) reported on 4/4/2018, contained a result of a valproic acid test performed at a reference laboratory and the report did not contain the reference laboratory's name and address that performed the valproic acid test. h. On 4-10-18 around 4 p.m., the technical consultant stated these patients'

	<p>specimens were sent to a reference laboratory for testing, and that their test report is usually faxed to the ordering physician along with the report from reference laboratory. i. The technical consultant could not locate a copy of the patient reports from the reference laboratory, and confirmed the laboratory report did not indicate the name and address of the testing laboratory and the laboratory did not retain all patient reports from reference laboratories in 2017 and 2018.</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: The laboratory failed in 2017 and 2018 to follow written policies and procedures to monitor, assess, and correct problems in the postanalytic laboratory systems. Findings include: a. No QA activities were performed to ensure critical test values were immediately reported to the ordering physician (Ref D5813). b. No QA activities were performed to ensure the laboratory indicated on their cumulative report the name and address of the reference laboratory where testing was performed, and retained copies of all patient reports obtained from reference laboratories (Ref D5817).</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the quality assessment (QA) plan, manufacturer operator's manuals, accuracy verification records, proficiency testing (PT) records, quality control (QC) records, test procedures, patient test logs, corrective action documentation, and staff confirmation, the laboratory director failed in 2017 and 2018 to provide overall management and direction of the laboratory to ensure quality systems are established and maintained in proficiency testing (D6004), in the general laboratory systems (D5291), in the analytic laboratory systems (D5400), and in the postanalytic laboratory systems (D5891).</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or</p>

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of the quality assessment (QA) plan, proficiency testing (PT) records, accuracy verification records, corrective action documentation, and staff confirmation, the laboratory director failed in 2017 and 2018 to provide for the overall operation and administration of the laboratory for proficiency testing (PT), and failed to ensure compliance with all applicable regulations. Findings include: a. The laboratory failed to enroll and test PT samples in the 1st event of 2017 (Ref D2000). b. Appropriate personnel failed to sign attestation statements for all PT events in 2017 (Ref D2009). c. The laboratory failed to retain a duplicate copy of the PT results sent to the PT provider in 2017 and 2018 (Ref to D2015). d. Appropriate personnel failed to sign the review of PT scores in 2017 and 2018 (Ref to D2016). e. The laboratory failed to assess the accuracy of analytes assigned a score that does not reflect the laboratory's test performance in 2017 (Ref D5215). f. The laboratory failed to investigate unsatisfactory PT results obtained (Ref D5221).

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 a review of the laboratory's policies and test procedures, the operator's manuals, the manufacturer instructions, the manufacturer's quality control (QC) assay sheet, quality control (QC) records, calibration records, Equipment Validation policy, the lack of verification records, reagent package inserts, analyzer reagent printouts, direct observation, patient test records, maintenance records, and staff interview, the laboratory director failed in 2017 and 2018 to provide for the overall operation and administration of the analytic laboratory systems and ensure compliance with all applicable regulations. The laboratory director failed to ensure testing personnel do not use expired reagents for testing (D5401), failed to ensure panic values are included in the written test procedures (D5403), failed to sign all written test procedures since assuming the directorship (D5407), failed to ensure the testing personnel document the correct ambient humidity required for reliable test system operation (D5413), document the open-vial date of quality control materials (D5415), dispose of expired reagents and testing supplies (D5417), validate the use of off-label reagents (D5423), analyze QC materials each day of patient testing (D5447), perform QC activities for the microbiology media (D5477), enter the correct international sensitivity index (ISI) for new lots of prothrombin time reagents (D5479), take corrective action for critical international normalized ratio (INR) test results (D5779), take corrective action when no QC materials were analyzed each day of patient testing (D5779), take corrective action when expired reagents are found in the hematology analyzer (D5779), take corrective action when the ambient humidity is recorded as outside of acceptable range for the chemistry analyzer (D5781), take corrective action when calibrations failed or were not performed when required (D5783), and take

corrective action when storage temperatures were recorded outside of the acceptable range (D5785).

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 a review of the laboratory's policies and test procedures, the operator's manuals, the manufacturer instructions, the manufacturer's quality control (QC) assay sheet, quality control (QC) records, calibration records, Equipment Validation policy, the lack of verification records, reagent package inserts, analyzer reagent printouts, direct observation, patient test records, maintenance records, corrective action documentation, competency assessment records, patient test reports, and staff interview, the laboratory director failed in 2017 and 2018 to ensure the quality assessment (QA) programs are established and maintained on an ongoing basis. Findings include: a. The laboratory director failed to ensure monitoring of the general laboratory systems occurred to identify and correct problems promptly (Ref D5291). b. The laboratory director failed to ensure monitoring of the analytic laboratory systems occurred to identify and correct problems promptly (Ref D5791). c. The laboratory director failed to ensure monitoring of the postanalytic laboratory systems occurred to identify and correct problems promptly (Ref D5891). d. During the onsite survey on 4/10/2018 at around 3 p.m., staff stated no documentation of QA activities could be found anywhere in the laboratory.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the quality assessment (QA) plan, laboratory test procedures, proficiency testing (PT) records, competency assessment records, quality control (QC) records, calibration records, maintenance records, patient test records, a lack of corrective action documentation, and staff confirmation, the technical consultant failed in 2017 and 2018 provide technical oversight in all areas of the laboratory. The technical consultant failed to ensure the quality of the general laboratory systems (D5291), failed to ensure the quality of the analytic laboratory systems (D5791), failed to ensure the quality of the postanalytic laboratory systems (D5891), failed to verify new test procedures performed by the laboratory (Ref D6040), failed to enroll and participate in an HHS-approved PT program (Ref D6041), failed to ensure acceptable levels of analytic performance throughout the entire testing process (D6042), failed to resolve technical problems and ensure corrective actions are taken

	<p>(Ref D6044), failed to ensure patient test results are not reported until all corrective action are taken (Ref D6044), failed to evaluate the competency of all testing personal, and failed to ensure the laboratory maintained competency assessment records (Ref D6046).</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality assessment (QA) plan, validation procedures, a lack of validation documentation, and staff confirmation, the technical consultant failed to establish and verify the laboratory's performance of the C-reactive protein (CRP) test using the off-label Sekisui reagents prior to reporting patients (Ref D5423).</p>
D6041	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality assessment (QA) plan, proficiency testing (PT) records, and staff confirmation, the technical consultant failed to enroll in an HHS-approved proficiency testing (PT) program for the 1st event of 2017 (Ref D2000), failed to ensure PT attestation statements were signed by appropriate personnel (Ref D2009), failed to perform a documented review of the PT scores received in 2016, 2017, 2018 (Ref D5211), failed to perform accuracy verification for all enrolled analytes that received a failed PT score (Ref D5215), and failed to document any corrective actions required for PT activities (Ref D5221).</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and test procedures, the operator's manuals, the manufacturer instructions, the manufacturer's quality control (QC) assay sheet, quality control (QC) records, calibration records, Equipment Validation policy, the lack of verification records, reagent package inserts, analyzer reagent printouts, direct observation, patient test records, maintenance records, and staff interview, the</p>

technical consultant failed to ensure acceptable levels of analytic performance throughout the entire testing process in the specialties and subspecialties of hematology, coagulation, and chemistry. The technical consultant failed to ensure the expiration dates of the in-use hematology reagents were updated in the analyzer (D5401), the humidity in the laboratory met the manufacturer's requirements, and the temperatures were recorded as required (D5413), the open-vial date was recorded for quality control (QC) reagents (D5415), expired reagents and supplies were discarded (D5417), the off-label reagents for C-reactive protein were validated before patient use (D5423), that QC materials were tested each day of patient testing (D5447), that corrective actions were taken when the humidity was recorded as below the acceptable range (D5781), that corrective actions were taken when calibrations failed were not performed when required (D5783), and that corrective actions were taken when the storage temperatures were recorded as outside of the acceptable range (D5785).

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:
1. Based on a review of the quality assessment (QA) plan, quality control (QC) records, a lack of corrective action documentation, and staff confirmation, the technical consultant failed to ensure corrective actions were taken when QC was not performed prior to reporting patient test results (Ref D5447), ensure that the correct international sensitivity index (ISI) was entered into the coagulation analyzer for the current lot of reagent (D5479), to ensure corrective actions were taken when critical international normalized ratio (INR) values were obtained from patient specimens (D5779), and corrective actions were taken when no QC was performed on days of patient testing, and when expired reagents were in use in the hematology analyzer (D5779). 2. Based on a review of the quality assessment (QA) plan, the laboratory's test procedures, and staff confirmation, the technical consultant failed to follow the laboratory's policies and procedures for reporting patient tests results obtained from reference laboratories (Ref D5813), and for maintaining patient test reports received from reference laboratories (Ref D5817).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on a review of the quality assessment (QA) plan, competency assessment records, and staff confirmation, the technical consultant failed to assess and document the competency of 3 of 3 testing personnel who performed moderate complexity testing in 2017 and 2018 (Ref D5209).