

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0048403	(X3) Date Survey Completed 07/18/2024
Name of Provider or Supplier Hood Memorial Hospital	Street Address, City, State 301 West Walnut Street, Amite, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed at Hood Memorial Hospital, CLIA ID 19D0048403, on July 15, 2024 through July 18, 2024. Hood Memorial Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES : 42 CFR 493.1250 CONDITION : Analytic systems 42 CFR 493.1403 CONDITION : Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409: CONDITION : Laboratories performing moderate complexity testing; Technical Consultant
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: ***Repeat deficiency from previous survey performed on November 14, 2022 through November 17, 2022 *** Based on observation by surveyor, review of coagulation quality control (QC) records, and interview with personnel, the laboratory failed to maintain instrument printouts in a manner to ensure visibility of data for at least two (2) years. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the Siemens CA 600 for coagulation testing (Prothrombin time (PT) and Partial thromboplastin time (PTT)). 2. Observation by surveyor on July 17, 2024 at 11:19 am revealed the laboratory taped the thermal paper printout of coagulation QC results to copier paper and photocopied each. 3. Review of the laboratory's coagulation QC records revealed the QC results for the following dates were not visible on the thermal paper printouts or photocopies: June 1, 2024 at 19:36 QC 03 for PT and PTT June 8, 2024 time not visible QC 03 for PT 4. In interview on July 17, 2024 at 1:24 pm, the Lab Manager stated the non-visible coagulation QC was not able to be retrieved. The Lab Manager confirmed the</p>

laboratory did not ensure visibility of coagulation QC results for the identified two dates in June 2024.

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:

Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to document the open expiration date of the saline utilized for blood bank testing as required. Refer to D5415. 2. The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417. 3. The laboratory failed to perform reportable range studies for erythrocyte sedimentation rate (ESR) testing. Refer to D5421 I. 4. The laboratory failed to perform performance specification verification studies for the OSOM serum human chorionic gonadotropin (hCG) test. Refer to D5421 II. 5. The laboratory failed to perform external quality controls (QC) each day of patient testing for qualitative serum human chorionic gonadotropin (hCG) testing for three (3) of thirteen (13) days in 2024 reviewed. Refer to D5449. 6. The laboratory failed to establish their own means and ranges for QC material utilized for microscopic Urinalysis testing. Refer to D5469. 7. The laboratory failed to document quality control for blood bank testing prior to patient testing for two (2) of 194 days in 2024 reviewed. Refer to D5559. 8. The laboratory failed to have documentation of complete corrective actions performed that included review and approval of findings for patient testing on recalled Total T4 reagent. Refer to D5781. 9. The laboratory failed to take corrective actions when QC values were unacceptable for Chemistry testing for two (2) of twenty seven (27) days reviewed. Refer D5783 I. 10. The laboratory failed to take corrective actions when QC values for coagulation testing were unacceptable for one (1) of thirty (30) days reviewed in June 2024. Refer to D5783 II. 11. The laboratory failed to ensure their monitors identified issues within the analytic system. Refer to D5793.

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:

Based on observation by surveyor, review of the laboratory's blood bank records, and interview with personnel, the laboratory failed to document the open and expiration date of the saline utilized for blood bank testing as required. Findings: 1. Observation

by surveyor during the laboratory tour of the blood bank area on July 15, 2024 at 11: 13 am revealed the manufacturer's instructions on the in-use saline box stated "use within one month of open date." 2. Review of the following random selection of 2024 blood bank records revealed the laboratory did not document the open or expiration date of the saline: May 3, 2024: Saline lot 587487 expiration date documented as "9/30 /24" June 14, 2024: Saline lot 587482 expiration date documented as "9-30-24" June 19, 2024: Saline lot 587482 expiration date documented as "9/30/24" July 1, 2024: Saline lot 587482 expiration date documented as "9-30-24" July 5, 2024: Saline lot 587482 expiration date documented as "09-30-24" 3. In interview on July 18, 2024 at 10:00 am, the Lab Manager stated the laboratory staff writes the open expiration date on the saline box, not on the blood bank QC logs. The Lab Manger confirmed the laboratory documents the unopened saline's expiration date on their QC logs, not the open expiration date.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2024 at 10: 28 am revealed the following expired items: a) Phlebotomy room: Vacuette serum tubes, lot B23033NK, Expiration date: 2024-06-13, Quantity: twelve (12) of fifty (50) tubes were expired b) Main lab area in the silver storage closet: Beckman Coulter ISE Reference Solution, lot M301629, Expiration date: 2024-06-30, Quantity: one (1) bottle 2. In interview on July 15, 2024 at 10:28 am, the Diagnostic Services Director confirmed the identified Vacuette serum tubes were expired. 3. In interview on July 15, 2024 at 11:13 am, the Regulatory Quality Coordinator confirmed the ISE reference solution was expired.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
***Repeat deficiency from previous survey performed on November 14, 2022 through November 17, 2022 *** I. Based on observation by surveyor, review of the laboratory's policies, performance specification verification records, and interview with personnel, the laboratory failed to perform reportable range studies for erythrocyte sedimentation rate (ESR) testing. Findings: 1. Observation by surveyor

during laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the Excyte Mini analyzer for ESR testing. 2. In interview on July 15, 2024 at 12:15 pm, the Lab Manager stated the laboratory validated a new Excyte Mini analyzer in June 2023. 3. Review of the laboratory's "Method Validation" policy revealed under the "Quantitative Test Methods" section "The laboratory will verify the following manufacturer's stated performance specifications provided in the package insert before reporting patient results: a) Accuracy/Method comparison(s) b) Precision c) Reportable range/Analytical Measurement Range (AMR) d) Reference range(s). 4. Review of the laboratory's performance specification verification records for the Excyte Mini revealed the laboratory did not include reportable range studies (raw data and acceptability criteria). 5. In interview on July 15, 2024 at 12:45 pm, the Diagnostic Services Director stated the laboratory utilized the manufacturer's reportable range. The Diagnostic Services Director confirmed the laboratory did not perform their own reportable range studies to verify the manufacturer's reportable range. II. Based on observation by surveyor, review of the laboratory's policies, U.S. Food and Drug Administration's (FDA) CLIA database, manufacturer's package insert, and interview with personnel, the laboratory failed to perform performance specification verification studies for the OSOM serum human chorionic gonadotropin (hCG) test. Findings: 1. Observation by surveyor during laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the OSOM hCG combo test for serum hCG testing. 2. Review of the OSOM hCG Combo Test package insert and the FDA CLIA test complexity database revealed serum is classified as non-waived, moderate complexity. 3. Review of the laboratory's "Method Validation" policy revealed under the "Qualitative Test Methods" section "To confirm accuracy, the Laboratory must verify the presence or absence of the analyte. Select 10 known positive and 10 known negative samples. These may be patient samples, controls or previous proficiency testing samples. Test the samples in duplicate on two different days using two different testing personnel, if possible." 4. In interview on July 15, 2024 at 3:58 pm, the Lab Manager stated the laboratory changed from the Clarity hCG test kits to OSOM on April 12, 2023. The Lab Manager stated the laboratory did not perform performance specification verification studies on the OSOM hCG test kits for serum sample testing. 5. Review of the laboratory's test menu revealed the laboratory performs twenty three (23) serum hCG tests annually utilizing the OSOM test kits.

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 observation by surveyor, review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to perform external quality controls (QC) each day of patient testing for qualitative serum human chorionic gonadotropin (hCG) testing for three (3) of thirteen (13) days in 2024 reviewed. Findings: 1. Observation by surveyor during laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the OSOM hCG combo test for serum hCG testing. 2. Review of the laboratory's "QC Program" policy revealed "All

quantitative and qualitative assays will be performed using a normal and at least one abnormal control. Quality controls will be performed each 24 hours of patient testing unless otherwise stated in IFU." 3. Review of the laboratory's 2024 QC records for the OSOM serum hCG test and patient test logs revealed the laboratory did not perform external controls for the following dates and patients: a) February 19, 2024: Patient 834178 b) February 20, 2024: Patient 1022765 c) May 23, 2024: Patient 836384 4. In interview on July 16, 2024 at 3:55 pm, the Lab Manager confirmed the laboratory did not have documentation of performance of external controls for the identified dates.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's package insert, quality control (QC) records, test menu, and interview with personnel, the laboratory failed to establish their own means and ranges for QC material utilized for microscopic Urinalysis testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs microscopic urinalysis utilizing KOVA-Trol human urinalysis controls. 2. Review of the "KOVA-Trol" QC package insert revealed "establish their own ranges for good quality control." 3. Review of the laboratory's quality control records revealed the laboratory did not have documentation of establishing their own QC means and ranges for the current in-use controls, KOVA-Trol Control I lot 605927 and KOVA-Trol Control III lot 306724. 4. In interview on July 18, 2024 at 1:15 pm, the Diagnostic Services Director stated the laboratory did not establish their own QC means and ranges for the current in-use urinalysis controls. 5. Further review of the laboratory's test menu revealed the laboratory performs 3,992 microscopic urinalysis tests annually.

D5559

IMMUNOHEMATOLOGY
CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being

transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of policies, quality control (QC) records, patient transfusion logs, and interview with personnel, the laboratory failed to document quality control for blood bank testing prior to patient testing for two (2) of 194 days in 2024 reviewed. Findings: 1. Review of the laboratory's "QC Program" policy revealed "QC data will be documented in the LIS and or manual log." 2. Review of the laboratory's blood bank QC records and patient transfusion logs revealed the laboratory did not perform QC for the following dates: May 5, 2024: Patient 1025370; last documented QC May 3, 2024 July 2, 2024: Patient 8327291; last documented QC July 1, 2024 3. In interview on July 17, 2024 at 3:43 pm, the Lab Manager confirmed the laboratory did not have documented QC for the identified dates.

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 review of the laboratory's Chemistry records and interview with personnel, the laboratory failed to have documentation of complete corrective actions performed that included review and approval of findings for patient testing on recalled Total T4 reagent. Findings: 1. Review of the laboratory's Chemistry records revealed Beckman Coulter issued a reagent recall for the Access Total T4 reagent, which included the following recommended actions: a) Discontinue using the Access Total T4 reagent lots listed above. Discard all remaining reagent packs from these lots. b) Beckman Coulter recommends performing a retrospective review on patient results generated with the affected reagent lots and assess the need for retesting. c) Contact your local Beckman Coulter representative for replacement product requests. 2. Further review of the laboratory's Chemistry records revealed the laboratory performed a review of 10 % of patients who were tested on a recalled lot of Total T4 reagents. 3. Further review of the laboratory's Chemistry records revealed "QC was pulled and reviewed form 11/20/2023-02/14/2024 all QC was within range. It is believed that all patient results were valid;" however, there was no documentation of who performed the review and the Laboratory Director's review/approval. 4. In interview on July 16, 2024 at 3:52 pm, the Lab Manager confirmed the laboratory did not have documentation of the review/approval of the corrective actions performed.

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:

I. Based on observation by surveyor, review of the laboratory's policies, quality control (QC) records, patient test logs, and interview with personnel, the laboratory failed to take corrective actions when QC values were unacceptable for Chemistry testing for two (2) of twenty seven (27) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the following instruments for Chemistry testing: a) Beckman Coulter Access 2 for testing of the following analytes: Ferritin, Total T3, Free T3, Free T3, Total T4, Free T4, Testosterone, TSH, Folate, PSA, Vitamin B12, Ck-MB, BNP, Troponin, and Vitamin D. b) Beckman Coulter AU 700: Albumin, Alkaline Phosphatase, Alanine Transaminase, Amylase, Aspartate Transferase, Total Bilirubin, Calcium, CO2, Chloride, Cholesterol, Ethanol, Glucose, HDL, Iron, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Total Protein, Sodium, Triglycerides, Uric Acid, Blood Urea Nitrogen (BUN), Creatine Kinase, Acetaminophen, Salicylate, Digoxin, Phenobarbital, Phenytoin, Valproic Acid, Vancomycin, Gentamycin Transferrin, Prealbumin, Hgb A1C, Ammonia, D-dimer, urine Creatinine, urine Protein, urine Microalbumin, urine Chloride, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methadone, Opiate, THC, C-reactive Protein, Lactate Dehydrogenase, and serum Creatinine. 2. Review of the laboratory's "QC Program" policy revealed the following actions for unacceptable QC: a) Review the function of equipment and correct any problems if noted. Then repeat with a fresh control (mix a new control if applicable). b) Verify that all controls and reagents have been prepared properly and are being used within stated stability ranges. If there is a question, use fresh reagents and/or controls and repeat controls. c) Check calibration and recalibrate assay if necessary and reset the controls. d) Evaluate any environmental conditions that may have an affect on control material (temperature changes, humidity, etc.) e) If corrective measures are attempted but the results are still out. report the problem to the Lab Manager. 3. Review of a random selection of quality control records and patient test logs revealed the laboratory did not perform corrective actions for the following dates with unacceptable QC: a) July 12, 2023: Free T3 level 3; result reported 9.57 pg/mL flag QCF (QCF= QC out): Patient 1014750 b) April 8, 2024: urine Potassium level 2; result reported 76.60 flagged ACC; Patient 1024605 4. In interview on July 16, 2024 at 4:46 pm, the Lab Manager stated she thinks the QC mean/range were adjusted for the Free T3; however, she did not have documentation of the adjusted range. 5. In further interview on July 17, 2024 at 9:05 am, the Lab Manager stated she thinks the urine potassium QC mean/range were adjusted; however, she did not have documentation of the adjusted range. The Lab Manager confirmed the laboratory did not have documentation of corrective actions for the identified unacceptable Chemistry QC. II. Based on observation by surveyor, review of the laboratory's policies, quality control (QC) records, patient test logs, and interview with personnel, the laboratory failed to take corrective actions when QC values for coagulation testing were unacceptable for one (1) of thirty (30) days in June 2024. Findings: 1. Observation by surveyor during the laboratory tour on July 15, 2024 at 10:28 am revealed the laboratory utilizes the Siemens CA 600 for coagulation testing

(Prothrombin time (PT) and Partial thromboplastin time (PTT)). 2. Review of the laboratory's "QC Program" policy revealed the following actions for unacceptable QC: a) Review the function of equipment and correct any problems if noted. Then repeat with a fresh control (mix a new control if applicable). b) Verify that all controls and reagents have been prepared properly and are being used within stated stability ranges. If there is a question, use fresh reagents and/or controls and repeat controls. c) Check calibration and recalibrate assay if necessary and reset the controls. d) Evaluate any environmental conditions that may have an affect on control material (temperature changes, humidity, etc.) e) If corrective measures are attempted but the results are still out. report the problem to the Lab Manager. 3. Review of the laboratory's June 2024 coagulation QC records and patient test logs revealed the laboratory did not perform corrective actions for the following date of unacceptable QC: a) June 3, 2024 16:56: PTT QC level 1 28.5 sec (acceptable QC value 26.4-28.4); Patient 836683 4. In interview on July 17, 2024 at 11:37 am, the Lab Manager stated she did not have any documentation of corrective actions for the identified unacceptable PTT control.

D5793

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

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality assessment policies, forms, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment and Performance Improvement (QAPI) Plan" revealed "The QAPI program responsibilities include monitoring, evaluating, and improving the quality of services provided. The goal is to identify problems, potential problems, and failures in systems or processes that involve the patients' health and safety to initiate plans of correction." 2. Review the "Laboratory Quality Tracking" form revealed the Laboratory Director performs a quarterly review that included the following monitors: a) Pre-analytical: Sample Quality, Culture Contaminate rate, blood culture tube visual inspection documented. b) Analytical: Undetected Quality Control Failures, Procedure not Followed/Operator error c) Post-Analytical: Critical Values Notification Failure; Transcription Errors/Results Reporting d) Other: Blood Bank Refrigerator maintenance performed, Blood Bank Emergency Release, Downtown Analyzers, Unexepected equipment failures, Incident Reports, and API Failed Events e) Additional Comments Section 3. Further review of the "Laboratory's Quality Tracking" form revealed the laboratory's monitors did not identify the following issue within the analytic system: a) The laboratory failed to document the open expiration date of the saline utilized for blood bank testing as required. Refer to D5415. b) The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417. c) The laboratory failed to perform reportable range studies for erythrocyte sedimentation rate (ESR) testing. Refer to D5421 I. d) The laboratory failed to perform performance specification verification studies for the OSOM serum human chorionic gonadotropin (hCG) test kit. Refer to D5421 II. e) The laboratory failed to perform external quality controls (QC) each day of patient testing

for qualitative serum human chorionic gonadotropin (hCG) testing for three (3) of thirteen (13) days in 2024 reviewed. Refer to D5449. f) The laboratory failed to establish their own means and ranges for QC material utilized for microscopic Urinalysis testing. Refer to D5469. g) The laboratory failed to document quality control for blood bank testing prior to patient testing for two (2) of 194 days in 2024 reviewed. Refer to D5559. h) The laboratory failed to have documentation of complete corrective actions performed that included review and approval of findings for patient testing on recalled Total T4 reagent. Refer to D5781. i) The laboratory failed to take corrective actions when QC values were unacceptable for Chemistry testing for two (2) of twenty seven (27) days reviewed. Refer D5783 I. j) The laboratory failed to take corrective actions when QC values for coagulation testing were unacceptable for one (1) of thirty (30) days in June 2024. Refer to D5783 II.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's performance verification studies, patient final reports, test menu, and interview with personnel, the laboratory failed to ensure reference ranges on patient final reports for erythrocyte sedimentation rate (ESR) testing matched the laboratory's performance verification studies for two (2) of two (2) randomly selected patient final reports reviewed. Findings: 1. Review of the laboratory's performance verification studies revealed the laboratory's reference ranges were the following: male: 0-15 mm/hr female: 0-20 mm/hr 2. Review of random selection of patient final test reports revealed the following reference ranges for Patient 1026731 and Patient 1015104: male: 0-20 mm/hr femaleL 0-30 mm/hr 3. In interview on July 15, 2024 at 3:58 pm, the Lab Manager confirmed the laboratory's performance verification reference ranges did not match the laboratory's patient final reports. 4. Review of the laboratory's test menu revealed the laboratory performs 495 ESR tests annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance specification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was

maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 5. The Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D6024. 6. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Findings: 1. The laboratory failed to perform reportable range studies for erythrocyte sedimentation rate (ESR) testing. Refer to D5421 I. 2. The laboratory failed to perform performance specification verification studies for the OSOM serum human chorionic gonadotropin (hCG) test. Refer to D5421 II.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to maintain instrument printouts in a manner to ensure visibility of data for at least two (2) years. Refer to D3031. 2. The laboratory failed to document the open expiration date of the saline utilized for blood bank testing as required. Refer to D5415. 3. The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417.

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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform external quality controls (QC) each day of patient testing for qualitative serum human chorionic gonadotropin (hCG) testing for three (3) of thirteen (13) days in 2024 reviewed. Refer to D5449. 2. The laboratory failed to establish their own means and ranges for QC material utilized for microscopic Urinalysis testing. Refer to D5469.

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Findings: 1. The laboratory failed to have documentation of complete corrective actions performed that included review and approval of findings for patient testing on recalled Total T4 reagent. Refer to D5781. 2. The laboratory failed to take corrective actions when QC values were unacceptable for Chemistry testing for two (2) of twenty seven (27) days reviewed. Refer D5783 I. 3. The laboratory failed to take corrective actions when QC values for coagulation testing were unacceptable for one (1) of thirty (30) days reviewed in June 2024. Refer to D5783 II.

<p>D6026</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</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. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5807.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were performed. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultants failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D6043.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to document the open expiration date of the saline utilized for blood bank testing as required. Refer to D5415. 2. The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417.</p>
<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</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.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, review of the laboratory's performance verification studies, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were performed. Findings: 1. The laboratory failed to perform reportable range studies for erythrocyte sedimentation rate (ESR) testing. Refer to D5421 I. 2. The laboratory failed to perform performance specification verification studies for the OSOM serum human chorionic gonadotropin (hCG) test. Refer to D5421 II.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(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;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform external quality controls (QC) each day of patient testing for qualitative serum human chorionic gonadotropin (hCG) testing for three (3) of thirteen (13) days in 2024 reviewed. Refer to D5449. 2. The laboratory failed to establish their own means and ranges for QC material utilized for microscopic Urinalysis testing. Refer to D5469.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to have documentation of complete corrective actions performed that included review and approval of findings for patient testing on recalled Total T4 reagent. Refer to D5781. 2. The laboratory failed to take corrective actions when QC values were unacceptable for Chemistry testing for two (2) of twenty seven (27) days reviewed. Refer D5783 I. 3. The laboratory failed to take corrective actions when QC values for coagulation testing were unacceptable for one (1) of thirty (30) days reviewed in June 2024. Refer to D5783 II.

D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>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. Refer to D5559.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.</p>