Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0465142	05/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hardtner Medical Center	1102 North Pine Road, Olla, 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 Hardtner Medical Center, CLIA ID # 19D0465142, on May 21, 2021 through May 27, 2021. Hardtner Medical Center 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 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing, Laboratory Director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's package insert, test menu, and interview with personnel, the laboratory failed to establish their own means and ranges for quality control (QC) material utilized for Erythrocyte Sedimentation Rate (ESR) testing per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Wintrobe tubes manual method for ESR testing. 2. In interview on May 26, 2021 at 1:28 pm, the Laboratory Manager stated ESR controls are not established. The Laboratory Manager further stated according to the insert these should be established. 3. Review of the "ESR-Chex" package insert under "Expected Results" section revealed " Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits." 4. Review of the laboratory's test menu revealed the laboratory performs 698 ESR tests annually.

D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure proficiency testing records were stored under conditions that ensured preservation. Findings: 1. Observation by surveyor on May 26, 2021 at 5:00 pm revealed the laboratory's College of American Pathologists (CAP) proficiency testing documents that included attestation statements and reporting forms were stored in brown cardboard boxes. Surveyor further observed damp proficiency testing documents that included water stains and rust marks from rusty staples. 2. In interview on May 27, 2021 at 9:25 am, the laboratory's manager (General Supervisor) stated the laboratory's proficiency testing records are stored under a cabinet that leaks.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of nursing administration policies, laboratory policies, and interview with personnel, the laboratory failed to define specific criteria for suspected transfusion reactions. Findings: 1. Review of the laboratory's blood bank procedures revealed the laboratory had the following three (3) transfusion reaction documents signed by the Laboratory Director in January 2016: a) "Suspected Blood Transfusion Reaction Report:" The following clinical symptoms were listed: "temp elevation of 2 degrees above the initial temp/chills, tachycardia, chest pain, low back pain, significant variation from baseline B/P (>/= 15 % higher or lower than baseline), urticaria/rash/pruritis, dyspnea, asthmatic episode/wheezing, facial or glottal edema, nausea and vomiting, other" b) "Transfusion Reaction QA/QI Monitoring Tool:" The following "reactions" were listed: "temp elevation of 2 degrees above the initial temp /chills, tachycardia, chest pain, low back pain, significant increase or drop in B/P (30 mm hg systolic or 20 mm hg diastolic), Urticaria/rash/pruritis, dyspnea, ashtmatic episode/wheezing, facial or glottal edema, nausea and vomiting, and other" c) "Investigation of Suspected Transfusion Reaction" policy with the following "Immediate: hemolysis with symptoms, febrile non-hemolytic reaction, anaphylaxis, urticaria, non-cardia pulmonary edema, marked fever and shock, congestive heart failure, hemoloysis without symptoms, red cell incompat. Ab to WBC (HLA) ag, Ab to IgA, Ab to plasma proteins, Ab to Wbc (HLA) ag, bacterial contaminant, volume overload, physical destruction of RBC's. Delayed: hemolysis, graft vs host disease, post transfusion purpura, iron overload, hepatitis or AIDS, protozoal infection, anamnestic response to antigens, engraftment of transfused lymph's, anti-platelet Ab, multiple transfusion (100 + units) , usually NANB:OCC. B, usually malaria." 2. Review of the "Nursing Department Protocol" revealed the following signs/symptoms that would initiate the transfusion reaction procedure: " temp elevation of 2 degrees

	above the initial temp, tachycardia, chest pain, low back pain, significant variation from baseline B/P (>/= 15 % higher or lower than baseline), urticaria/rash/pruritis, asthmatic episode/wheezing, facial or glottal edema, nausea, and vomiting, fluid overload: chest pain, dyspnea, decrease in urinary output, edema." 3. Further review of the "Nursing Department Protocol" revealed the "Transfusion Reaction QA/QI Monitoring Tool," "Blood Administration Plan of Care," and "Suspected Blood Transfusion Reaction Report" forms were included. The clinical symptoms listed in "Suspected Blood Transfusion Reaction Report" provided by the Manager of the Surgery Department did not match the one provided by the laboratory. The following clinical symptoms were listed: "chills, vomiting, chest pains, oozing from wound, hives, facial edema, rash, frothy sputum, rapid temp. increase, headache, hematuria, dyspnea, nausea, itching, back pain, immediate post transfusion jaundice, cyanosis, decreased B/P, coughing, and other." 4. Review of the following four (4) transfusion reaction work-ups from 2019 through 2021 revealed the nursing staff completed a "Suspected Blood Transfusion Reaction Report" whose clinical symptom criteria and form did not match those included with their protocol or the laboratory's protocol: a) May 23, 2019: Patient 17400-0091 b) June 21, 2019: Patient 260025-0145 c) January 21, 2020: Patient 43661-0002 d) January 14, 2021: Patient 150063-0118 5. Surveyor was provided three (3) " Suspected Blood Transfusion Reaction Reports" that had differing clinical symptoms for a suspected transfusion reaction listed. 6. In interview on May 27, 2021 at 12:40 pm, the Manager of the Surgery Department stated the nursing forms for transfusion reactions were implemented in 2016. The Manager of the Surgery Department confirmed the forms and criteria utilized by nursing for suspected transfusion reactions did not match the nursing department's protocol or the laboratory's forms and criteria.
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 the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403. 3. The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407. 4. The laboratory failed to document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411. 5. The laboratory failed to ensure blood bank reagents had not exceeded their expiration dates. Refer to D5417. 6. The laboratory failed to perform reportable range and reference range studies for D-dimer testing. Refer to D5421. 7. The laboratory failed to perform calibration procedures for phosphorus, total bilirubin, triglycerides, creatinine, and uric acid testing at least every six (6) months per manufacturer requirements. Refer to D5439. 8. The laboratory failed to establish their own means and ranges for QC material utilized for Urinalysis testing. Refer to D5469 I. 9. The laboratory failed to establish their own means and ranges for QC material

	utilized for D-dimer testing. Refer to D5469 II. 10. The laboratory failed to ensure quality control was performed prior to patient samples for four (4) dates for serum human chorionic gonadotropin (HCG) and Rheumatoid Factor (RF) tests. Refer to D5481. 11. The laboratory failed to document quality control for blood bank testing prior to patient testing. Refer to D5559. 12. The laboratory failed to have complete documentation of corrective action for the blood bank refrigerator that did not maintain there required temperature for one (1) of thirty days in April 2021. Refer to D5781. 13. The laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for thirty eight (38) of eighty eight (88) days reviewed. Refer to D5783. 14. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 review of the laboratory's policies and procedures, and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written policies and procedures that included the following: a) Reporting of SARS COV-2 test results to state public health agency b) Platelet Poor Plasma to include frequency and acceptability criteria c) Complete Blood Counts (CBC) flags for the Sysmex 2. In interview on May 26, 2021 at 2:37 pm, the Laboratory Manager confirmed the laboratory did not include the identified policies /procedures in their manual.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written policies and procedures that included the following: a) Quality control to include, but not limited to: identity, establishment of means and ranges, verification procedures, acceptability criteria, who is to monitor b) Calibration and calibration verification procedures including frequency c) Reportable range for D-dimer 2. In interview on May 26, 2021 at 2:37 pm, the Laboratory Manager confirmed the laboratory did not include the identified policies/procedures in their manual.
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 review of the laboratory's procedures and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current practices. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have current policies for the following: a) Urinalysis, including microscopic: was not updated to include the laboratory's current procedure b) Complete Blood Counts (CBC) to include the laboratory's current instrumentation (Sysmex) c) "Quality Control" procedure to include the laboratory's current Coagulation instrumentation 2. In interview on May 25, 2021 at 9:23 am, the Laboratory Manager confirmed the laboratory did not include the laboratory's current coagulation instrument in the laboratory's quality control policy. The Laboratory Manager stated the instrument listed in the policy was the laboratory's previous analyzer. 3. In further interview on May 26, 2021 at 11:58 am, the Laboratory Manager confirmed the laboratory's CBC policy was not for the laboratory's current instrument, the Sysmex. 4. In further interview on May 27, 2021 at 4:49 pm, the Laboratory Manager stated the laboratory's urinalysis procedure was antiquated. The Laboratory Manager stated the laboratory no longer uses a refractometer as listed in the laboratory's procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to document visual inspections on blood culture bottles before use per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2021 revealed the laboratory utilizes Aero Med Blood Culture Pediatric and Adult Kits that contained BacT/ALERT blood culture bottles. 2. Review

	of the laboratory's "Blood Cultures" policy "Blood culture bottles are checked for contamination cracks and or other signs of deterioration each time a blood culture is drawn and logged into our computer system." 3. Review of the BacT/ALERT package insert revealed "Prior to use, visually inspect all BacT/ALERT bottles for evidence of damage or contamination. A bottle should not be used if any evidence of leakage is notes. Do not use a bottle which contains media exhibiting turbidity, excess gas pressure, or a yellow sensor; these are signs of possible contamination." 4. In interview on May 25, 2021 at 9:54 am, Testing Personnel 3 stated once the laboratory collects the blood culture samples it (patient information) is logged into the the computer system. Testing Personnel 3 confirned the laboratory does not document the visual inspections of blood culture bottles prior to use. Testing Personnel 3 stated the lab would not log the blood culture sample into the system if the bottle was unacceptable.
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, record review, and interview with personnel, the laboratory failed to ensure blood bank reagents had not exceeded their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2021 at 2:12 pm revealed the following expired reagent: a) Anti-B, Anti-ABO2, Lot BBB811A, Expiration date: 2021-05-07, Quantity: two (2) bottles 2. Review of the laboratory's "Reagent Storage and Preparation" policy revealed "Any expired reagents will be discarded. Reagent lot numbers and expiration dates are kept on file in the laboratory." 3. In interview on May 24, 2021 at 2:19 pm, the Laboratory Manager confirmed the identified reagents were expired.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the validation studies, policies and procedures, and interview with personnel, the laboratory failed to perform reportable range and reference range studies for D-dimer testing. Findings: 1. Observation by surveyor on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Sysmex CA-600 series for coagulation testing. 2. Review of the laboratory's validation records for the Sysmex CA-600 series revealed the laboratory did not include the following for D-dimer: a) Reportable range b) Reference range 3. Review of the manufacturer's

	Installation Guide revealed: a) "Reportable Range determination is addressed both in CLIA requirements and CLSI Guidelines. While CLIA requires the laboratory to verify the Reportable Range, the method used is not explicit and leaves this up to the individual laboratories." b) "Reference Verification: A reference interval must be established for Fibrinogen, Prothrombin Times, APTT's, D-Dimer, and Thrombin Times by each institution. Some tests, such as factor assays, do not require that each individual laboratory perform a reference interval, as clinical investigations have established reference values that are widely accepted by the medical community." 4. Further review of the laboratory's validation studies revealed the Laboratory Director approved the studies on June 20, 2018 5. In the interview on May 26, 2021 at 4:24 pm, the Technical Consultant confirmed the laboratory did not include documentation of a reference range study for D-dimer. The Technical Consultant stated the laboratory is utilizing the manufacturer's range. The Technical Consultant stated she did not find a statement from the Laboratory Director approving use of the manufacturer's range. 6. In interview on May 27, 2021 at 11:41 am, the Technical Consultant confirmed the laboratory did not include the laboratory's reportable range for D-dimer in their validation studies. 7. Review of the laboratory's test menu revealed the laboratory performs 351 D-dimer tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, manufacturer's instrument manual, calibration records, and interview with personnel, the laboratory failed to perform calibration procedures for phosphorus, total bilirubin, triglycerides, creatinine, and uric acid testing at least every six (6) months per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Ortho Vitros 350 for the following Chemistry analytes: albumin, alkaline phosphatase, alanine aminotransferase (ALTV), amylase, aspartate aminotransferase, unconjugated bilirubin, conjugated bilirubin, BUN, calcium, cholesterol, creatine kinase, chloride,

	creatinine, dHDL, ECO2, GGT, glucose, potassium, LDH, lithium, lipase, magnesium, sodium, phosphate, total protein, total bilirubin, triglycerides, uric acid, lactate, CRP, and EtOH. 2. Review of the Vitros instrument manual under "Calibrating" section revealed "You should calibrate when: Reagent lot numbers are changed due to a new slide generation or lot, when there are changes in reference fluid lots for potentiometric tests, or when there are changes in immuno-wash fluid lots for immuno-rate tests. Required by government regulations. In the United States, the Vitros 250/350 Chemistry System must have calibration verified or be recalibrated at least every six months." 3. Review of the laboratory's calibration records for 2019, 2020, and 2021 revealed the laboratory did not have documentation of performance of calibration every six (6) months for the following analytes: a) Phosphorus: February 2020 missed b) Total bilirubin: February 2019 missed c) Triglycerides: May 2020 missed (lab performed once in 2020: August 12, 2020) d) Creatinine: February 2019 missed e) Uric Acid: April 202 missed 4. In interview on May 26, 2021 at 9:49 am, the Laboratory Manager stated the laboratory calibrates the Vitros when new lot number of reagent received or every six (6) months. 5. In further interview on May 26, 2021 at 10:20 am, the Laboratory Manager confirmed the laboratory did not perform calibrations for the identified analytes at least every six (6) months.
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: I. Based on observation by surveyor, review of manufacturer 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 Urinalysis testing. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Clinitek 100 with Bio Rad Liquichek Urinalysis controls for urinalysis testing. 2. Review of the "Bio-Rad Liquichek Urinalysis Control" package insert under "Assignment of Values" section revealed " Each laboratory should use the results provided only as a reference and establish its own parameters of precision." 3. Review of the laboratory's quality control records for urinalysis revealed the laboratory did not have documentation of establishing their own QC means and ranges for Bio-Rad Liquichek Urinalysis Control lot number 87710. 4. In interview on May 26, 2021 at 11:38 am, the Laboratory Manager stated the laboratory verifies the QC values falls within the manufacturer's ranges. The Laboratory Manager confirmed the laboratory does not establish their own means and ranges for the Bio-Rad urinalysis controls. 5. Review of the laboratory's test menu revealed the laboratory performs 2,959 urinalysis test annually. II. Based on

	observation by surveyor, review of manufacturer 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 D-dimer testing. Findings: 1. Observation by surveyor during laboratory tour on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Sysmex CA-600 series analyzer with Siemens Innovance D-dimer controls for D-dimer testing. 2. Review of the Siemens Innovance D-dimer controls under the "Assigned Constituent Values" section revealed "If used as a precision control, the user should establish the target concentration and confidence limits during a preliminary phase. The ranges provided are intended only as guidelines. Each laboratory should determine its own individual ranges." 3. Review of the laboratory's QC records revealed the laboratory did not have documentation of establishing their own QC means and ranges for Innovance D-dimer controls, Lot 562273 (Control 1) and Lot 562173 (Control 2). 4. In interview on May 27, 2021 at 10:44 am, the Technical Consultant stated the laboratory utilizes the manufacturer's ranges for the D-dimer QC. 5. Review of the laboratory's test menu revealed the laboratory performs 351 D-dimer tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records for 2019, 2020, and January through April 2021, patient test logs, test menu, and interview with personnel, the laboratory failed to ensure quality control was performed prior to patient samples for four (4) dates for serum human chorionic gonadotropin (HCG) and Rheumatoid Factor (RF) tests. Findings: 1. Review of the laboratory's quality control records and patient test logs for 2019, 2020, and 2021 revealed quality control was documented after the patient samples for the following four (4) dates and patients: a) Rheumatoid Factor: December 18, 2019; Patient 1912180161 b) Rheumatoid Factor: February 27, 2020; Patient 202270101 c) Serum HCG: February 13, 2019; Patient 1902130181 d) Serum HCG: November 9, 2020; Patient 2011090262 2. In interview on May 27, 2021 at 3: 08 pm, the Laboratory Manager stated the quality control was run after the patients for the identified dates. 3. Review of the laboratory's test menu revealed the laboratory performs twenty three (23) McKesson serum HCG, forty (40) Stanbio serum HCG, and 173 Rheumatoid Factor 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 records, patient transfusion logs, and interview with personnel, the laboratory failed to document quality control for blood bank testing prior to patient testing. Findings: 1. Review of the laboratory's "Quality Control Using Orthos Confidence System Qualitative Controls" policy revealed: a) "Perform ABO red cell grouping and Rh typing using Confidence Reagent cells and record results in the daily control log." b) " Perform Rh typing using Affirmagen A1 or B and record results in daily control log." c) " Perform reverse grouping and an antibody screen using Confidence Antiserum Reagent and record results in daily QC log." 2. Review of the laboratory's blood bank quality control (QC) records and patient transfusion logs from January 2020 through May 21, 2021 revealed the laboratory did not perform QC for the following one (1) patient: a) Patient 2103180144 reported March 18, 2021; Last documented QC March 16, 2021 3. In interview on May 27, 2021 at 3:55 pm, the Laboratory Manager confirmed the laboratory did not have documentation of QC for the identified patient.
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 circular blood bank refrigerator temperature charts and interview with personnel, the laboratory failed to have complete documentation of corrective action for the blood bank refrigerator that did not maintain 1-6 degrees Celsius temperature for one (1) of thirty days in April 2021. Findings: 1. Review of the laboratory's circular blood bank refrigerator charts for the week of April 12, 2021 through April 19, 2021 revealed on April 19, 2021 from 12:00 am to 8:00 am the temperature raised above 6 degrees Celsius. The laboratory documented the following: "Time out 4/19/21 0030 temp 5.3 to coag reagent fridge in BB. Time in 4 /19/21 0900 temp 3.7" The laboratory documented the "coag" refrigerator temperatures every hour from 1:00 am to 9:00 am; however, the laboratory did not document the corrective actions performed on the blood bank refrigerator. 2. In interview on May 27, 2021at 2:20 pm, the Laboratory Manager confirmed the laboratory did not have documentation of corrective actions performed on the blood bank refrigerator for the identified date.
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 observation during laboratory tour, review of manufacturer package inserts, policies, quality control (QC) records, patient test reports, and interview with personnel, the laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for thirty eight (38) of eighty eight (88) days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on May 24, 2021 at 2:12 pm revealed the laboratory utilizes the Ortho Vitros 350 and Architect i1000SR for Chemistry testing for the following analytes: Vitros: Performance Verifier I and II: albumin, alkaline phosphatase, alanine aminotransferase (ALTV), amylase, aspartate aminotransferase, unconjugated bilirubin, conjugated bilirubin, BUN, calcium, cholesterol, creatine kinase, chloride, creatinine, dHDL, ECO2, GGT, glucose, potassium, LDH, lithium, lipase, magnesium, sodium, phosphate, total protein, total bilirubin, triglycerides, uric acid, lactate, CRP, and EtOH; Architect: Architect: troponin, CKMB, Covid Ig G, and BNP; Architect: Technopath Multichem IA Plus: Digoxin, Phenytoin, Gentamicin, Vancomycin, Valproic Acid 2. Review of the manufacturer package inserts for controls revealed the following: a) Vitros Performance Verifier I and II: Each laboratory should establish its own analyte-specific mean. Each laboratory should evaluate and if, necessary update the mean after each reagent lot change." b) Architect: "Each laboratory should establish its own concentration ranges for new control lots at each control level." c) Multichem IA Plus: " Values are provided only as guidelines, each laboratory should establish its own statistical limits." 3. Review of the laboratory's "Troubleshooting Steps" revealed the following: a) "Repeat control using a fresh sample" b) "Repeat with a new reconstituted control" c)"For any steps taken past 1 and 2 a patient impact study must be done" d) " Check reagent, is it expired? does it look contaminated? is the reagent volume low? Recent calibration? New Lot? 'blow a new well' " e)"Perform and indicate maintenance and cleaning as last resort. If problem still exists, call technical service. Document on corrective action form. If supervisor is available, call PRIOR TO TECHNICAL SERVICE." 4. Review of Chemistry QC records from February 2019, September 2020 and April 2021 revealed the laboratory did not perform corrective action for the following thirty eight (38) dates with unacceptable QC: a) February 4, 2019: Troponin low reported 0.115 "Flag: 1-2s" (acceptable range: 0.115-0.143); Troponin medium reported 0.519 "Flag 1-2s" (acceptable range: 0.532-0.610); Troponin high reported 13.670 "Flag 1-2s" (acceptable range 13.734-15.673) b) February 5, 2019: Troponin high reported 13.393" Flag: 1-2s; " (acceptable range: 13.734-15.673) c) February 6, 2019: Troponin high reported 13.366 " Flag: 1-2s; " (acceptable range: 13.734-15.673) d) February 7, 2019: Troponin high reported 13.461 "Flag: 1-2s; " (acceptable range: 13.734-15.673) e) February 8, 2019: Troponin high reported 13.477 "Flag: 1-2s; " (acceptable range: 13.734-15.673) f) February 11, 2019: Troponin high reported 13.590 "Flag 1-2s; " (acceptable range: 13.734-15.673) g) February 19, 2019: Creatinine level 2 reported 4.94, flag "F2" h) February 20, 2019: Creatinine level 2 reported 4.90, flag "F2" i) February 21, 2019: Creatinine level 2 reported 4.95, flag "F2" February 21, 2019: Cholesterol level 2 reported 224, flag "F2" j) February 22, 2019: Creatinine level 2 reported 4.91, flag "F2" k) February 23, 2019: Creatinine level 2 reported 4.93, flag "F2" l) February 24,

2019: Creatinine level 2 reported 4.97, flag "F2" m) February 25, 2019: C-Reactive Protein PV2 reported 19.1, flag "F3" February 25, 2019: Creatinine level 2 reported 4.96, flag "F2" n) February 26, 2019: Creatinine level 2 reported 4.92, flag "F2 February 26, 2019: Uric Acid level 2 reported 10.12, flag "F2" o) February 28, 2019: Creatinine level 2 reported 4.91, flag "F2" p) September 1, 2020: Creatinine level 2 reported 5.67, flag "F2" September 1, 2020: Amylase level 2 reported 291 reported, 291, flag "F3" q) September 2, 2020: Creatinine level 2 reported 5.62, flag "F2" September 2, 2020: Amylase level 2 reported 290, flag "F3" September 2, 2020: Triglycerides level 2 reported 247.7, flag "F2" r)September 3, 2020: Creatinine level 2 reported 5.64, flag "F2" s) September 8, 2020: Amylase level 2 reported 292, flag "F3" t) September 9, 2020: Creatinine level 2 reported 5.65, flag "F3" September 9, 2020: Amylase level 2 reported 290, flag "F3" u) September 10, 2020: Amylase level 2 reported 294, flag "F3" v) September 12, 2020: Amylase level 2 reported 287, flag "F3" w) September 14, 2020: Amylase level 2 reported 299, flag "F3" September 14, 2020: Triglycerides level 2 reported 253.6, flag "F2" September 14, 2020:Uric acid level 2 reported 10.01, flag "F2" x) September 15, 2020: Amylase level 2 reported 298, flag "F3" September 15, 2020: Triglycerides level 2 reported 254.7, flag "F2" September 15, 2020: Uric Acid level 2 reported 10.03, flag "F2" y) September 16, 2020: Amylase level 2 reported 299, flag "F3" September 16, 2020: Triglycerides level 2 reported 252, flag "F2" September 16, 2020: Uric Acid level 2 reported 10.07, flag "F2" z) September 17, 2020: Creatinine level 2 reported 5.60, flag "F2" September 17, 2020: Amylase level 2 reported 299, flag "F3" September 17, 2020: Calcium level 2 reported 11.48, flag "F2" aa) September 18, 2020: Amylase level 2 reported 302, flag "F3" bb) September 19, 2020: Total Bilirubin level 2 reported 16.77, flag "F2" cc) September 21, 2020: Amylase level 2 reported 297, flag "F3" dd) September 22, 2020: Amylase level 2 reported 291, flag "F3" ee) September 24, 2020: Amylase level 2 reported 296, flag "F3" ff) September 25, 2020: Amylase level 2 reported 291, flag "F3" gg) September 26, 2020: Amylase level 2 reported 296, flag "F3" hh) September 28, 2020: C-Reactive Protein PV2 reported 24,2, flag "F3" ii) April 14, 2021: Sodium level 1 reported 120.6, flag "F2" jj) April 16, 2021: Carbon Dioxide level 1 reported 27.2 kk) April 28, 2021: Sodium level 2 reported 147.6, flag "F2" April 28, 2021: LDH level 2 reported 1581, flag "F3" ll) April 30, 2021: Sodium level 2 reported 147.9, flag "F2" 5. Review of patient test reports revealed the following patients were reported without corrective action: a) February 4, 2019: Troponin: Patient 1902040108, Patient 190240118, Patient 1902040159, Patient 1902040178, Patient 1902050035 (total 23 patients) b) February 5, 2019: Troponin: Patient 1902050035, Patient 1902050130, Patient 1902050185, Patient 19020050185, Patient 02050202 (total 4 patients) c) February 6, 2019: Troponin: Patient 1902060062, Patient 1902060118, Patient 1902060123, Patient 1902060153, Patient 1902060164 (total 6 patients) d) February 7, 2019: Troponin: Patient 1902070007, Patient 1902070071, Patient 1902070106, Patient 1902070121, Patient 1902070131 (total 5 patients) e) February 8, 2019: Troponin: Patient 1902080103, Patient 1902080108, Patient 19020800126, Patient 1902080151 (total 4 patients) f) February 11, 2019: Troponin: Patient 1902110061, Patient 1902110101, Patient 1902110119, Patient 1902110127, Patient 1902110140 (total 8 patients) g) February 19, 2019: Creatinine: Patient 1902190060, Patient 1902190066, Patient 1902190070, Patient 1902190073 (total 29 patients) h) February 20, 2019: Creatinine: Patient 1902200004, Patient 1902200006, Patient 1902200008, Patient 1902200010, Patient 1902200012 (total 34 patients) i) February 21, 2019: Creatinine: Patient 1902210005, Patient 1902210007, Patient 1902210010, Patient 1902210018, Patient1902210024 (total 39 patients) February 21, 2019: Cholesterol: Patient 1902210062, Patient 1902210024, Patient 1902210028, Patient 1902210032, Patient 19022110038 (total 14 patients) j) February 22, 2019: Creatinine: Patient 1902220002, Patient 1902220019, Patient

1902220025, Patient 1902220033, Patient 1902220036 (total 23 patients) k) February 23, 2019: Creatinine: Patient 1902230003, Patient 190223005, Patient 1902230005 (total 3 patients) l) February 24, 2019: Creatinine: Patient 1902250010, Patient 1902250014, Patient 1902250031 (total 8 patients) m) February 25, 2019: Creatinine: Patient 1902250018, Patient 1902250034, Patient 1902250034 (total 7 patients) February 25, 2019: C-Reactive Protein: Patient 1902250047, Patient 1902250189 (total 23 patients) n) February 26, 2019: Creatinine: Patient 1902260008, Patient 1902260036, Patient 1902260119, Patient 1902260179, Patient 1902260192 (total 41 patients) February 26, 2019: Uric Acid: Patient 1902260142 (total 1 patient) o) February 28, 2019: Creatinine: Patient 190228006, Patient 1902280010, Patient 1902280013, Patient 1902280015, Patient 1902280018 (total 41 patients) p) September 1, 2020: Creatinine: Patient 2009010029, Patient 2009010035, Patient 2009010079, Patient 2009010100, Patient 2009010001 (total 27 patients) q) September 2, 2020: Creatinine: Patient 2009020087, Patient 2009020089, Patient 2009020111, Patient 2009020117, Patient 2009020003 (total 28 patients) September 2, 2020: Amylase: Patient 2009020050, Patient 2009020072 (total 2 patients) September 2, 2020: Triglycerides: Patient 2009020024, Patient 2009020031, Patient 2009020035, Patient 2009020053, Patient 2009020081 (total 7 patients) r) September 3, 2020: Creatinine: Patient 2009030032, Patient 2009030029, Patient 2009030044, Patient 2009030001, Patient 200903003 (total 28 patients) s) September 8, 2020: Creatinine: Patient 2009090105 (total 1 patient) September 8, 2020: Amylase: Patient 2009080001, Patient 2009080086, Patient 2009080122, Patient 2009080129 (total 4 patients) t) September 9, 2020: Creatinine: Patient 2009090017, Patient 2009090020, Patient 2009090029, Patient 2009090032, Patient 2009090095 (total 41 patients) September 9, 2020: Amylase: Patient 200909008, Patient 2009090109, Patient 2009090113, Patient 2009090152 (total 4 patients) u) September 10, 2020: Amylase: Patient 2009199162 (total 1 patient)September 14, 2020: Uric Acid: Patient 2009140130, Patient 2009140136, Patient 2009140143, Patient 2009140156, Patient 2009140162 (total 6 patients) v) September 12, 2020 : Amylase: Patient 2009140030 (total 1 patient) w) September 14, 2020: Amylase: Patient 2009140118, Patient 2009140130, Patient 2009140136, Patient 2009140143, Patient 200140156 (total 7 patients) September 14, 2020: Triglycerides: Patient 2009140002, Patient 2009140050, Patient 2009140070, Patient 2009140070, Patient 2009140078 (total 8 patients) x) September 15, 2020: Amylase: Patient 2009150086 (total 1 patient) September 15, 2020: Triglycerides: Patient 2009150038, Patient 2009150083, Patient 2009150112, Patient 2009150140, Patient 2009150140 (total 7 patients) y) September 16, 2020: Uric Acid: Patient 2009160025 and Patient 2009160169 (total 2 patients) September 16, 2020: Triglycerides: Patient 2009160015, Patient 2009160030, Patient 2009160036, Patient 2009160042, Patient 2009160060 (total 12 patients) z) September 17, 2020: Amylase: Patient 2009170116 (total 1 patient) September 17, 2020: Creatinine: Patient 2009170110, Patient 2009170001, Patient 2009170003, Patient 2009170010, Patient 2009170023(total 31 patients) September 17, 2020: Calcium: Patient 2009170110, Patient 2009170001, Patient 2009170003, Patient 2009170007, Patient 2009170010 (total 31 patients) aa)September 18, 2020: Amylase: Patient 2009180142, (total 1 patient) bb) September 19, 2020: Total bilirubin (unknown number of patients) cc) September 21, 2020: Amylase: Patient 2009210124, Patient 2009210132, Patient 2009210138, Patient 2009210179, Patient 2009210205 (total 9 patients) dd) September 22, 2020: Amylase: Patient 2009220089 (total 1 patient) ee) September 24, 2020: Amylase: Patient 2009240092 (total 1 patient) ff) September 25, 2020: Amylase (unknown total number of patients) gg) September 26, 2020: Amylase (unknown total number of patients) hh) September 28, 2020: C-Reactive Protein: Patient 2009280042, Patient 2009280057, Patient 2009280062, Patient 2009280121, Patient 2009280137 (total 8 patients) ii) April 14,

	2021: Sodium: Patient 21040010, Patient 2104140012, Patient 2104140130, Patient 2104140145, Patient 2104140004, Patient 2104140008 (total 32 patients) jj) April 16, 2021: Carbon Dioxide: Patient 2104160037, Patient 2104160057, Patient 2104160057, Patient 2104160140, Patient 2104160001 (total 31 patients) kk) April 28, 2021: LDH: Patient 2104280116 (total 1 patient) April 28, 2021: Sodium: Patient 2104280005, Patient 2104280085, Patient 2104280091, Patient 2104280148, Patient 2104280135 (total 29 patients) ll) April 30, 2021: Sodium: Patient 2104300009, Patient 2104300011, Patient 2104300011, Patient 2104300107, Patient 2104300115 (total 24 patients) 6. In interview on May 25, 2021 at 10:59 am, the Laboratory Manager stated the identified troponin QC was not repeated since it was within the manufacturer's range. 7. In interview on May 25, 2021 at 1:18 pm, the Laboratory Manager stated for analytes on the Vitros analyzer if the QC is out the laboratory recalibrates the instrument, then uses the manufacturer's quality control ranges and re-establishes the ranges after enough points are collected. The Laboratory Manager further stated the identified flagged QC was accepted as it was within the manufacturer's ranges.
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 observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance" policy revealed "Quality Assurance is carried out in Hardtner Medical Center Laboratory on the audit basis. Periodically defiency [sic] sheets are filled out by the Laboratory Director. These defincies [sic] are turned into our Quality Assurance Director. Action is then taken to correct our problem. Each audit is later repeated to see if our problem has been corrected." 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to establish complete policies and procedures. Refer to D5403. c) The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407. d) The laboratory failed to document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411. e) The laboratory failed to ensure blood bank reagents had not exceeded their expiration dates. Refer to D5417. f) The laboratory failed to perform reportable range and reference range studies for D-dimer testing. Refer to D5421. g) The laboratory failed to perform calibration procedures for phosphorus, total bilirubin, triglycerides, creatinine, and uric acid testing at least every six (6) months per manufacturer requirements. Refer to D5439. h) The laboratory failed to establish their own means and ranges for QC material utilized for Urinalysis testing. Refer to D5469 I. i) The laboratory failed to establish their own means and ranges for QC material utilized for D-dimer testing. Refer to D5469 II. j) The laboratory failed to ensure quality control was performed prior to patient samples for four (4) dates for serum human chorionic gonadotropin (HCG) and Rheumatoid Factor (RF) tests. Refer

	to D5481. k) The laboratory failed to document quality control for blood bank testing prior to patient testing. Refer to D5559. l) The laboratory failed to have complete documentation of corrective action for the blood bank refrigerator that did not maintain there required temperature for one (1) of thirty days in April 2021. Refer to D5781. m) The laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for thirty eight (38) of eighty eight (88) days reviewed. Refer to D5783.
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 validation studies, manufacturer's inserts, patient final test reports, test menu, and interview with personnel, the laboratory failed to ensure reference ranges for D-dimer on final reports matched the laboratory's validation studies. Findings: 1. Review of the laboratory's validation studies for the Sysmex CA-600 analyzer for D-dimer revealed the laboratory did not have documentation of the laboratory's reference range studies (Refer to D5421). 2. In interview on May 26, 2021 at 4:24 pm, the Technical Consultant stated the laboratory utilizes the manufacturer's reference range. 3. Review of random selection of D-dimer patient final report from April 2021 revealed the following reference range "0.19-4.40 mg/L." 4. Review of the manufacturer's package insert revealed the following: "Less than 0.59 mg/L FEU for normal health subjects." 5. Further review of the manufacturer's application sheet revealed the reportable range for d-Dimer listed as "0.19 to 4.40 mg/L." 6. In interview on May 26, 2021 at at 5:21 pm, the Technical Consultant stated the laboratory's patient final test reports for D-dimer listed the reportable range, not the reference range. The Technical Consultant confirmed the D-dimer reference range listed on the laboratory's patient final reports was incorrect. 7. Review of the laboratory's test menu revealed the laboratory performs 351 D-dimer 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 provide overall direction and management to the laboratory. Refer to D6004. 2. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 3. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 4. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided.

	Refer to D6020. 5. 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. 6. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 7. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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 she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Refer to D3013.
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 verification studies were complete. Refer to D5421.
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, 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 document visual inspections on blood culture bottles before use per manufacturer's requirements. Refer D5411. 2. The laboratory failed to perform calibration procedures for phosphorus, total bilirubin, triglycerides, creatinine, and uric acid testing at least every six (6) months per manufacturer requirements. Refer to D5439.
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 that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to establish their own means and ranges for QC material utilized for Urinalysis testing. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for QC material utilized for D-dimer testing. Refer to D5469 II. 3. The laboratory failed to ensure quality control was performed prior to patient samples for four (4) dates for serum human chorionic gonadotropin (HCG) and Rheumatoid Factor (RF) tests. Refer to D5481.
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.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)

	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. 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.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403. 3. The laboratory failed to ensure policies and procedures were updated to current practices. Refer to D5407.

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 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 complete. 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 Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6043. 5. The Technical Consultant failed to evaluate competency annually for one (1) of nine (9) main laboratory Testing Personnel reviewed. Refer to D6054.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, 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 visual inspections on blood culture bottles before use per manufacturer's requirements. Refer to D5411. 2. The laboratory failed to perform calibration procedures for phosphorus, total bilirubin, triglycerides, creatinine, and uric acid testing at least every six (6) months per manufacturer requirements. Refer to D5439.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) 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, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
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 observation by surveyor, 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 establish their own means and ranges for QC material utilized for Urinalysis testing. Refer to D5469 I. 2. The laboratory failed to establish their own means and ranges for QC material utilized for D-dimer testing. Refer to D5469 II. 3. The laboratory failed to ensure quality control was performed prior to patient samples for four (4) dates for serum human chorionic gonadotropin (HCG) and Rheumatoid Factor (RF) tests. Refer to D5481.
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 Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: **Repeat deficiency from survey conducted on July 10, 2018 through July 12, 2018. *** Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually for one (1) of nine (9) main laboratory Testing Personnel reviewed. Findings: 1. Review of personnel records revealed the laboratory did not have documentation of an annual competency assessment for 2020 for Testing Personnel 2. 2. In interview on May 24, 2021 at 3:59 pm, the Laboratory Manager stated he did not find the 2020 for Testing Personnel 2.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance

	with 493.1445 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. Findings: 1. The Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6079. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6093. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6094. 5. The Laboratory Director failed to ensure corrective actions were documented when deviations from laboratory's policies occurred. Refer to D6096. 6. The Laboratory Director failed to ensure competency assessments were performed annually for one (1) of nine (9) main laboratory Testing Personnel reviewed. Refer to D6103. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D3013.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 were performing test methods as required. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) 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. 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 established to assure the quality of laboratory testing. Refer to D5559.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. 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.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were documented when deviations from laboratory's policies occurred. Refer to D5781.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, personnel records and interview with personnel, the Laboratory Director failed to ensure competency assessments were performed annually for one (1) of nine (9) main laboratory Testing Personnel

	reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the Laboratory Director also serves as the Technical Supervisor. 2. Review of personnel records revealed the laboratory did not have documentation of an annual competency assessment for 2020 for Testing Personnel 2. 3. In interview on May 24, 2021 at 3:59 pm, the Laboratory Manager stated he did not find the 2020 for Testing Personnel 2.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D3025.