

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0052243	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Tyler County Hospital Laboratory	Street Address, City, State 1100 West Bluff Street, Woodville, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records from 2020 and 2021, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analytes: Total Bilirubin for 2 of 5 testing events and CKMB for 1 of 5 testing events reviewed. Findings were: 1. Review of the 2020 and 2021 API proficiency testing records revealed the laboratory failed to attain an 80% for the the following analytes: Total Bilirubin and CKMB. 2020 Chemistry Core 3rd event Total Bilirubin 20% CKMB 60% 2021 Chemistry Core 3rd event Total Bilirubin 40% 2. Review of the laboratory corrective actions for the above PT failures revealed no documentation of the patient remedial action. 3. An interview with the technical consultant on 11/9/21 at 1035 hours in the laboratory confirmed the above findings.</p>

D3007

FACILITIES

CFR(s): 493.1101(b)

The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

This STANDARD is not met as evidenced by:

Base on direct observation, review of laboratory procedure, the CMS116, urinalysis reference manual, and confirmed in interview, the laboratory failed to have an appropriate centrifuge for one of one test: urine sediment analysis. 1. Direct observation in the laboratory at 15:30 hours on 11/09/2021 revealed a model 614V Lab Centrifuge near the urinalysis station with a taped RPM dial fixed at approximately 3,000. 2. Review of the laboratory policy 'Routine Urinalysis Practice 1064', signed by the laboratory director on 1/31/2021, section Microscopic step 2 stated: "The sample is centrifuged for approximately five to seven minutes at 3000 rpm." 3. Review of 'Preanalytical requirements of uinalysis' by Joris Delanghe and Marijn Speeckaert (published in Biochemia Medica 2014;24(1)89-104) Section 'Manual Methods' states: "A 5-minute centrifugation time at 400 g [RCF, relative centrifugal force (g) = 1.118 x 10^(^-5) x radius (cm) x RPM (revolutions per minutes)] preferably at 4(degrees) C is necessary for optimal sediment concentration." 4. Review of the CMS116, Section VII 'PPM Testing' lists their estimated annual volume for PPM tests performed at 1,774. 5. Interview with the laboratory supervisor at 15:35 hours on 11/09/2021 in the lab confirmed that the centrifuge near the urinalysis station with the taped RPM dial was the one utilized for urine centrifugation for microscopic urine sediment analysis, and was set at the incorrect RPM.

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 the facility and laboratory blood/blood product transfusion policies, patient transfusion records, and confirmed in interview, the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products for 4 of 12 transfusion records reviewed. Findings included: 1. Review of the laboratory policy Blood Administration (effective 03/86) under Implementation "watch for [signs and symptoms] of transfusion reactions which may include: elevation of temperature more than 2 degree above baseline; flank pain (pain in the lumbar area); nausea/vomiting; unexplained oozing of blood at operative site; unexplained blood in urine; tachycardia; unexplained fall in blood pressure; chills; itching of skin; hives; edematous skin vesicles; edema of larynx; shortness of breath, wheezing; cyanosis; symptoms of shock." 2. Review of the laboratory policy Suspected Transfusion Reaction#1106 revealed "any of the following symptoms may indicate a possible reaction and should be investigated. Transfusion reactions are not always immediate and may take days to become evident. back pain dark urine chills fainting or dizziness fever flank pain skin flushing shortness of breath itching 3. Random review of blood product administration patient

records from 2020 to 2021 revealed the following 4 of 12 patients in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. Patient ID #10087366 Date 5/15/21 blood pressure - 4AM: 93/57; 8AM: 66/39; 12N: 105/62 b. Patient ID #10074419 Date 4/10/20 after transfusion - Pulse: 1510 hours, 102; 1514 hours, 159; 1517 hours, 131; 1519 hours, 111 c. Patient ID #10073145 Date 3/3/20 after transfusion - blood pressure - 12M: 133/84; 4AM: 103/60; 8AM: 104/67 d. Patient ID#10092353 date 9/22/21 Unit W03652194273 at 60 mins - blood pressure 112/71 at 90 mins - blood pressure 158/96 4. An interview with the nurse administrator on 11/10/21 at 1020 hours in the laboratory supervisor's office confirmed the above findings. She acknowledged that the facility should revisit their transfusion reaction policies. Word Key: P = pulse BP=Blood Pressure

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on review of laboratory and patient test records from 2020 and 2021 and confirmed in interview, the laboratory failed to have written instructions available to the laboratory's clients that included information on conditions for transportation for blood lab specimens for CBC (complete blood count); Protime; and chemistry patient testing. Findings were: 1. Review of laboratory records revealed no documentation of written instructions for clients that used the laboratory as a referral laboratory for specimen testing that included: collection, preservation, storage, transport requirements. 2. An interview with the laboratory supervisor on 11/9/21 at 1130 hours in the office confirmed the above findings. She acknowledged that there were home health facilities that collect and bring their testing to the lab but no specific instructions are provided to them.

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:
I. Based on review of laboratory policy, a urinalysis reference manual, the CMS116, and confirmed in interview, the laboratory failed to have an appropriate policy in place for one of six urinalysis policies reviewed; Microscopic Urine Sediment Analysis. 1. Review of 'Preanalytical requirements of uinalysis' by Joris Delanghe and Marijn Speeckaert (published in Biochimica Medica 2014;24(1)89-104) Section 'Manual Methods' states: "A 5-minute centrifugation time at 400 g [RCF, relative centrifugal force ($g = 1.118 \times 10^{-5} \times \text{radius (cm)} \times \text{RPM (revolutions per minutes)}$)] preferably at 4(degrees) C is necessary for optimal sediment concentration." 2. Review of the laboratory policy 'Routine Urinalysis Practice 1064', signed by the

laboratory director on 1/31/2021, section Microscopic step 2 stated: "The sample is centrifuged for approximately five to seven minutes at 3000 rpm." 3. Review of the CMS116, Section VII 'PPM Testing' lists their estimated annual volume for PPM tests performed at 1,774. 4. Interview with the laboratory supervisor at 15:35 hours on 11/09/2021 in the lab confirmed that the laboratory policy had an incorrect RPM, per the reference manual, to centrifuge urine for approximately five to seven minutes at 3000 rpm.. II. Based on review of policy, laboratory worksheets, and confirmed in interview, the laboratory failed to follow its procedure for the acceptability of patient criteria for their normal patient mean value study two of two new lot Innovin coagulation reagents reviewed for PT. 1. Review of the 'Normal Patient Mean Value for Coagulation Lot Change of Reagents', signed by the laboratory director 10/21/2019, section 'procedure', step 2 stated: "20 normal patients must be obtained, using the patient questionnaire to verify the patients are on nothing that will affect the values obtained." 2. Review of the patient questionnaire instructions titled 'Coagulation Patient: Normal Mean values Worksheet' stated: " ... Answers to the below questions must be no to be eligible to give a blood sample to the lab." Questions listed as follows: 1. Alcohol in the past 24 hours? Yes No 2. Aspirin in the past 24 hours? Yes No 3. Taking antibiotics, oral contraceptive or Vitamin K? Yes No 3. a. Review of the New Lot PT Reagent worksheet for Innovin reagent lot 549736, expiration 11/1/2021, with a date of initial use of 6/22/2020 includes the following three of twenty patients answered 'yes' to one or more of the questions on the 'Coagulation Patient: Normal Means Value Worksheet'. Patient 44825 - answered 'yes' to Aspirin in the past 24 hours. Patient 47971 - answered 'yes' to Aspirin in the past 24 hours. Patient 5436 - answered 'yes' to Aspirin in the past 24 hours. b. Review of the New Lot PT Reagent worksheet for Innovin reagent lot 549779A, expiration 5/28/2023, with a date of initial use of 6/27/2021 includes the following one of twenty patients answered 'yes' to one or more of the questions on the 'Coagulation Patient: Normal Means Value Worksheet'. Patient 15 - answered 'yes' to Alcohol in the past 24 hours. 4. Interview with the laboratory supervisor at 11:35 hours on 11/9/2021 in the office confirmed the above findings. Key: PT - Prothrombin Time PPM - Provider Performed Microscopy RCF - relative centrifugal force RPM - revolutions per minutes C - Celcius

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:

I. Based on review of the manufacturer's instructions, laboratory policy, laboratory quality control (QC) records from 2021, and confirmed in interview, the laboratory failed to establish acceptance criteria for control procedures for two of five control materials for the Beckman Coulter DxC chemistry analyzer: MAS CardioImmune and MAS Chemtrak. Findings were: 1. Based on review of the package inserts under control ranges revealed "instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges. All values have been assigned with instruments and reagents available at the time of assay and expected values may vary with different reagents and/or methodologies. Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modification may invalidate assigned values. MAS CardioImmune (CXL21121, exp 12/31/21) MAS Chemtrak (CHA22101A CHA22102A CHA22103A, exp 10/31/22) 2. Review of the laboratory policy for chemistry controls revealed no documentation of the acceptance criteria used to establish the acceptable ranges for the above control materials. 3. Review of the CMS116 revealed the laboratory performed 85974 chemistry tests annually. 4. An interview with the laboratory supervisor and technical consultant on 11/9/21 at 1500 hours in the lab office confirmed the above findings. 45469 II. Based on review of policy, instructions for use, laboratory worksheets, and confirmed in interview, the laboratory failed to have the appropriate calculation needed for the verification of normal patient means for 2 of 2 Establishments of Normal Patient Mean with New Reagent Lot change for the PT coagulation reagent Innovin. 1. Review of the 'Normal Patient Mean Value for Coagulation Lot Change of Reagents', signed by the laboratory director 10/21/2019, Procedure section step 1 stated: "When the lot changes in Prothrombin reagent, a normal patient mean value must be established." 2. Review of the 'Siemens Healthcare Diagnostics Sysmex CA-600 Series System Installation Package Rev 1.2', Section XVI. Reagent Lot Roll-Over Studies', subsection I, step D states: "MNPT for INR calculation must be the geometric mean. 3. a. Review of the New Lot PT Reagent worksheet for Innovin reagent lot 549736, expiration 11/1/2021, with a date of initial use of 6/22/2020 has the following Normal Patient PT Results, with an excel calculated average, that was put in use, of 9.77. 10.1, 10.2, 9.5, 9.8, 9.3, 9.4, 11.3, 9.6, 10.3, 9.3, 9.4, 9.3, 9.9, 10.0, 9.9, 9.8, 9.9, 9.5, 9.4, 9.5. The geometric mean for the data set indicated is 9.759, as calculated by the surveyor. b. Review of the New Lot PT Reagent worksheet for Innovin reagent lot 549779A, expiration 5/28/2023, with a date of initial use of 6/27/2021 has the following Normal Patient PT Results with an excel calculated average that, was put in use, of 10.39: 10.4, 10.4, 10.4, 10.4, 10.2, 10.1, 10.3, 10.5, 11.0, 10.4, 10.4, 10.2, 10.2, 11.0, 10.4, 10.1, 9.9, 10.8, 10.9, 9.8. The geometric mean for the data set indicated is 10.385, as calculated by the surveyor. 4. When asked to show the calculation used for the normal patient mean the laboratory supervisor stated that 'the average was calculated by the excel spreadsheet', at 14:23 hours on 11/9/2021. Further review of the lab policy revealed no documentation of the calculation for the geometric mean. 5. Interview with the laboratory supervisor at 14:25 hours on 11/9/2021 in the office confirmed the above. Key: MNPT - Mean Normal Prothrombin Time INR - International normalized ratio PT - Prothrombin Time

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 review of the Sysmex CA-600 Series System installation Package (rev 1.2), laboratory policy, review of the CMS116, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions in place for the verification of reagent lot roll over for two of three coagulation test; PT (prothrombin time) and aPTT (activated partial thromboplastin time). 1. a. Review of the Sysmex CA-600 Series System Installation Package (rev 1.2) Section XIV states: "These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system. All recommendation are based on CLSI to meet CLIA/CAP requirements for Hemostasis." b. Section II 'Method Correlation' lists the steps: A. 40 samples: 20 normal, 20 abnormal. Normal samples (section I.) may be used for Method Correlation and Verification of Reference Range. Abnormal samples should span the Reportable Range of assay. B. Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other. C. Calculate Linear Regression statistics. 2. Review of the laboratory coagulation worksheets for new lot PT reagent Innovin showed the use of 20 normal patients used for the verification of new lot PT reagent Innovin. 3. Review of laboratory Coagulation policy revealed that the laboratory did not have a policy in place for the assessment of new lot reagent Dade Actin FSL Activated PTT Reagent, for the aPTT coagulation test. 4. Review of the CMS166 Section VII lists a total annual volume of 61,102 for the Hematology specialty. 5. Interview at 14:30 hour on 11/9/2021 in the office with the laboratory supervisor confirmed the above with a statement that they use 20 normal patient samples for a lot to lot verification for new lot of PT reagent, and that there is no formal policy in place for new lot aPTT reagent. Key: CLSI- Clinical Laboratory Standards Institute CLIA - Clinical Laboratory Improvement Amendments CAP - College of American Pathologist PT - Prothrombin Time aPTT - Activated Partial Thromboplastin Time

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of the manufacturer's instructions, lab policy, review of the laboratory's freezer temperature logs from 2021, and confirmed in interview, the laboratory failed to establish correct acceptable freezer temperature range for storage of the Triage Total 5 control used for DDimer testing for 3 of 3 months reviewed. Findings include: 1. Review of the package insert for for the Triage Total 5 Controls (ENSRC26601A, PN: 26601) revealed the following storage requirements: "Store frozen at -20C or colder in a non-defrosting freezer." 2. Review of the laboratory

policy Storage Temperatures (Practice #1134) revealed "Storage Temperatures are defined as Freezer - a cold place in which temperature is maintained between -15 and -20 degrees Celsius." 3. Surveyor observations on 11/10/21 at 0930 hours in the laboratory revealed the following Triage Total 5 Controls stored in the laboratory freezer. Lot C3771, exp 4/30/22 Lot C3790, exp 2/8/22 4. Random review of the freezer logs from February 2021, March 2021, and September 2021 revealed the following 9 days with temperature outside of the required storage requirements: -20 C or colder. 2/06/21: -15 C 2/12/21: -17 C 2/23/21: -16 C 3/01/21: -18 C 3/15/21: -18 C 3/28/21: -17 C 9/10/21: -18 C 9/13/21: -16 C 9/29/21: -18 C 5. Review of the CMS116 revealed the laboratory performed 61,102 hematology tests annually. 6. An interview with the laboratory supervisor on 11/10/21 at 1050 hours in her office confirmed the above findings. She acknowledged that the lab should store the control material in another freezer.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on review of laboratory QC documents, the CMS116, and confirmed in interview, the laboratory failed to monitor QC over time for three of three months reviewed, for one of three coagulation tests, D-Dimer, on the Triage Alere. 1. Base on review of laboratory QC documents for July 2021, August 2021, and October 2021 for the D-Dimer coagulation test on the Triage Alere the laboratory failed to monitor QC over time for three of three months reviewed. 2. Review of the CMS116 section VII: 'Non-Waived Testing' lists an estimated annual volume for the specialty Hematology as 61,102. 3. Interview with the laboratory supervisor at 09:10 hours on 11/10/2021 in the office confirmed that the laboratory had not been monitoring QC over time for the coagulation test D-dimer, ran on the Triage Alere.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of laboratory documents, patient records, and confirmed in interview, the laboratory failed to have documentation of the lab assessing the effectiveness of the IQCP (Individualized Quality Control Plan) for one of three coagulation tests performed; D-Dimer. 1. Review of the laboratories IQCP for the Triage Alere D-Dimer coagulation testing system revealed that the laboratory did not have documentation of the assessment for the effectiveness of the IQCP in place for D-Dimer. 2. Review of patient records in July 2021, August 2021, and October 2021 lists the following 130 patients tested for D-Dimer on the Triage Alere; July 24 - 31 2021: Total patient D-Dimers ran 20 7/24/21: Patients: 92172, 92169, 92203, 92209, 92344 7/25/21: Patients: 92331, 92500, 92315, 92318. 7/26/21: Patients: 92475, 92517, 92651, 92706, 92720 7/27/21: Patient: 92763 7/29/21: Patients: 93354, 93382, 93398 7/30/21: Patient: 93466 7/31/21: Patient: 93713 August 1-31 2021: Total patient D-Dimers ran 75 8/1/21: Patients: 93784, 93796 8/2/21: Patients: 93899, 93896, 93969 8/4/21: Patients: 94356, 94400, 94451 8/5/21: Patients: 94571, 94631 8/6/21: Patients: 94731, 94820, 94836, 94860, 94871, 94883 8/7/21: Patients: 95084, 94883 8/8/21: Patients: 95109, 95200, 95230, 95280 8/9/21: Patients: 95245, 95343, 95349 8/10/21: Patients: 95599, 95621, 95682, 95708 8/11/21: Patients: 95742, 95849, 95882, 95898, 95946 8/12/21: Patients: 96032, 96031, 96040, 96086 8/13/21: Patients: 96233, 96330, 96354, 96375 8/15/21: Patient: 96724 8/17/21: Patients: 97099, 97144 8/19/21: Patients: 97713, 97770 8/20/21: Patients: 97755, 97992 8/22/21: Patients: 98291, 98301, 98344 8/23/21: Patients: 98434, 98553 8/24/21: Patients: 98679, 98719 8/25/21: Patients: 98822, 98966, 98974, 99093 8/26/21: Patients: 98981, 98956, 99301 8/27/21: Patients: 99581, 99662, 99685, 99714, 99773 8/28/21: Patients: 99898, 99974 8/29/21: Patients: 81, 130 8/30/21: Patients: 218, 327 8/31/21: Patient: 444 October 1 - 31 2021: Total patient D-Dimers ran 35 10/1/21: Patient: 6132 10/2/21: Patient: 6224 10/4/21: Patients: 6477, 6533, 6626 10/6/21: Patient: 6878 10/7/21: Patients: 7107, 7122 10/8/21: Patient: 7407 10/9/21: Patient: 7705 10/10/21: Patient: 7822 10/11/21: Patients: 7880, 7933, 7985, 7978 10/14/21: Patients: 8598, 8639 10/15/21: Patient: 8732 10/18/21: Patient: 9106 10/19/21: Patient: 9277, 10/20/21: Patients: 9576, 9676 10/21/21: Patient: 9889 10/23/21: Patients: 10203, 10224 10/24/21: Patient: 10256 10/26/21: Patients: 10700, 10713, 10812 10/27/21: Patient: 10980 10/28/21: Patient: 11198 10/29/21: Patient: 11263 10/30/21: Patients: 11378, 11475, 11499 3. Interview on 11/10/2021 at 0900 hours with the laboratory supervisor in the office confirmed that the laboratory did not have a system in place to monitor the effectiveness of the IQCP for the D-Dimer coagulation test ran on the Triage Alere.

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 Accu-Sed Plus controls instructions for use (IFU), quality control (QC) and patient log for random days in December 2020 and August 2021, and confirmed in interview, the laboratory failed establish its own intralaboratory mean and standard deviation for two of two lot of ESR Control for the Excyte 10 Automated ESR Analyzer. 1. Review of the Accu-Sed Plus Normal ESR Control (ref DS-71002) section 'Expected Values' paragraph 2 stated: "Each laboratory should establish its own intralaboratory mean and standard deviation for each lot of ESR Control according to its own established procedures." 2. Review of the QC log showed an QC acceptable range that matched the package insert: August 2021: Normal Control Lot 212010 Exp 2022-06-07 Excyte 10: Mean:7, Range 3-11 Abnormal Control Lot 213110 Exp 2022-06-07 Excyte 10: Mean 67, Range 49-85 December 2020: Normal Control Lot 204010 Exp 9/29/2021 Excyte 10: Mean 7, Range 3-11 Abnormal Control Lot 205110 Exp 9/29/2021 Excyte 10: Mean 63, Range 45-81 3. Review of the patient testing log from random days in December 2020 and August 2021 to lists the following 17 patients tested: 12/15/2020 - Patient 11082313, Patient 10082316, Patient 10082316, Patient 10082341. 12/16/2020 - Patient 10082357 12/21/2020 - Patient 10082479 12/22/2020 - Patient 10082445 12/28/2020 - Patient 10082679 12/29/2020 - Patient 10082696 8/9/2021 - Patient 10090529 8/11/2021 - Patient 10090615, Patient 10090642 8/12/2021 - Patient 96009 8/13/2021 - Patient 10090709 8/18/2021 - Patient 10090955, Patient 10090967 8/19/2021 - Patient 10090984 4. Interview with the laboratory supervisor at 14:35 hours on 11/09/2021 in the laboratory confirmed that they have been using the QC ranges provided on the IFU, and not establishing their own laboratory means and ranges.

D5777

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(b)(c)

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

. Based on review of laboratory policy, review of the CMS 116, and confirmed in interview, the laboratory failed to have a policy in place for the verification of current ABO group with historical records to assess and resolve ABO discrepancies. 1. Based on review of the laboratory records, the laboratory did not have a policy in place for assessing historical patient ABO group. 2. Review of the CMS116 section VII: 'Non-Waived Testing' lists an estimated annual volume for the specialty Immunohematology as 579. 3. Interview with the laboratory supervisor at 09:30 hours, on 11/10/2021 in the blood bank revealed while they do maintain physical patient records for blood bank services, they do not have a formal policy in place for the historical record lookback.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory personnel files, and confirmed in interview, the technical supervisor failed to perform semi-annual competency for 2 of 5 testing person (TP) during the first year of testing patient specimens for high complexity testing in immunohematology. Findings were: 1. A review of the facility's personnel files revealed documentation of the initial and second competency within the first year for 2 of 5 testing personnel (TP#3; TP#4) for blood bank testing by the general supervisor who does not meet the requirements as a technical supervisor for immunohematology. The technical consultant has an associate's degree. 2. An interview with the laboratory supervisor and technical consultant on 11/09/21 at 1105 hours in the office confirmed the above findings.