Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0498840	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cuero Regional Hospital	2550 N Esplanade, Cuero, 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	A recertification survey was conducted July 18 -19, 2018. The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493. 1250 analytic systems 493.1403 laboratories performing moderate 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: A. Based on direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions for monitoring revised expiration dates for quality control reagents and test strips for the NOVA STAT strip whole blood glucose monitoring system. The findings included: 1. Direct observation made by the surveyor on July 18, 2018 at 1330 hours in the Emergency Department revealed the following in use items: a. NOVA STAT glucometer test strips (quantity of 14 remaining in vial) Lot 0318025249 Manufacturer Expiration Date: 01-25-2020 b. NOVA STAT quality control reagent (level 1) Lot 0417060301 Manufacturer Expiration Date: 09-01-2019 c. NOVA STAT quality control reagent (level 3) Lot 0477027303 Manufacturer Expiration Date: 07-27-2019 d. NOVA STAT quality control reagent (level 3) Lot 0417230303 Manufacturer Expiration Date: 02-18-2020 2. Further observation of the items revealed each of the 4 of 4 items were not labeled with a revised expiration date or an open date. 3. Review of the manufacturer's instructions revealed NOVA STAT strips have a revised expiration date once they are opened of 180 days or 6 months. 4.

	Review of the manufacturer's instructions revealed NOVA STAT quality control reagents have a revised expiration date once they are opened of 90 days or 3 months. 5. An interview with the phlebotomy supervisor on July 18, 2018 at 1330 hours confirmed the findings. She agreed the items were not labeled with open dates or revised expiration dates. B. Based on direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions to monitor the room temperature where glucometer supplies were stored. The findings included: 1. Direct observation made in the Emergency Department Supply Room on July 18, 2018 at 13:30 hours revealed NOVA STAT glucometer test strips were stored in a bin. 2. Further observations made in the supply room revealed no means to monitor the room temperature. 3. Review of the manufacturer's instructions on the outside of the supply packing revealed the strips are to be stored at 15-30 degrees Celsius. 4. The above findings were confirmed in interview of the phlebotomy supervisor on July 18, 2018 at 13:30 hours in the Emergency Department.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2016, 2017, and 2018, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing proficiency testing using routine patient procedures. The findings were: 1. Review of laboratory policy "Proficiency Testing" approved by the laboratory director stated, under "Procedure: F. Process proficiency specimens following guidelines established for patient specimen testing ..." 2. Review of the laboratory's AAB proficiency testing records for 2016 (event 3), 2017 (events 1, 2, and 3) and 2018 (event 1) revealed 2 of 5 the events were tested by multiple testing persons. Quarter 1 Nonchemistry 2018 Tested by 6 testing persons Quarter 1 Nonchemistry 2017 Tested by 6 testing persons 3. An interview with the laboratory manager on July 18, 2018 in the private dining room at 14:00 hours confirmed the findings. She revealed she thought the additional testing was done after the proficiency testing event had been submitted.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical

	assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2016, 2017 and 2018, it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of hematology for the analyte Prothrombin Time (PT). (refer to D2130)
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2016, 2017, and 2018, and confirmed in interview, it was determined the laboratory failed to attain a score of at least 80% acceptable responses for each analyte in the subspecialty of hematology. The findings included: 1. A review of the laboratory's AAB proficiency testing records for 2016 (event 3), 2017 (events 1, 2, and 3) and 2018 (event 1) revealed the following unsatisfactory scores: AAB 2017 - event 3 Prothrombin Time Score = 40% AAB 2018 - event 1 Prothrombin Time Score = 60% 2. An interview with the laboratory manager on July 19, 2018 at 14:20 hours in the Huddle Room confirmed the findings. She revealed the failures were due to a clerical error. 3. On July 18, 2018, the surveyor conducted a telephone interview with a representative from AAB who revealed the proficiency testing agency was unable to retrieve documentation of the laboratory notifying the agency of a method code change for Prothrombin Time (PT) and would not be issuing a corrected report.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2016, 2017, and 2018, and confirmed in interview, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in the specialty of hematology in two consecutive testing events or two out of three consecutive testing

	events. Two out of three unsatisfactory scores results in unsuccessful PT (proficiency testing) performance. The findings included: 1. A review of the laboratory's AAB proficiency testing records for 2016 (event 3), 2017 (events 1, 2, and 3) and 2018 (event 1) revealed the following unsatisfactory scores: AAB 2017 - event 3 Prothrombin Time Score = 40% AAB 2018 - event 1 Prothrombin Time Score = 60% 2. An interview with the laboratory manager on July 19, 2018 at 14:20 hours in the Huddle Room confirmed the findings. She revealed the failures were due to a clerical error. 3. On July 18, 2018, the surveyor conducted a telephone interview with a representative from AAB who revealed the proficiency testing agency was unable to retrieve documentation of the laboratory notifying the agency of a method code change for PT and would not be issuing a corrected report.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing results from 2016, 2017, and 2018, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of evaluating proficiency testing results returned as 'not graded' by the proficiency testing agency. The findings included: 1. This is a repeat deficiency 2. A review of the laboratory's API proficiency testing results from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed the proficiency agency returned the following results as "Not Graded": 2018 Hematology / Coagulation - event 1 Analyte / Method: PMN (CSF/body fluid) (%) Sample ID: BFL-02 Grade: "Not Graded" (with a superscript of 2) 3. The proficiency testing agency defined code "2" as: No Consensus. 4. An interview with the laboratory manager on July 18, 2018 at 14:00 hours in the private dining room confirmed the findings.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's proficiency testing records, and interview of facility personnel, the laboratory's quality assurance program failed to identify and correct that the laboratory failed to ensure proficiency test results that are returned to the laboratory as ungraded are self-graded. (refer to D5213)
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 direct observations, review of manufacturer's instructions, review of quality control records, review of maintenance records, review of instrument verification records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for acceptability of instrument temperatures on the Beckman Coulter Microscan WalkAway. (refer to D5411-A) 2. The laboratory failed to follow the manufacturer's instructions for documenting the final dispense weight when performing RENOK maintenance. (refer to D5411-B) 3. The laboratory failed to monitor the room temperature where supplies were stored in the Emergency Department. (refer to D413) 4. The laboratory failed to ensure expired items were not available for use in patient testing. (refer to D5417) 5. The laboratory failed to ensure maintenance was performed on the BACTEC blood culture analyzer. (refer to D5429-A) 6. The laboratory failed to ensure semi-annual maintenance was performed on the Helmer cell washer in 2017. (refer to D5429-B) 7. The laboratory failed to ensure calibration verification was performed and complete every 6 months. (refer to D5439) 8. The laboratory failed to perform two levels of quality control according to its IQCP for serum hCG testing. (refer to D5445-A) 9. The laboratory failed to perform quality control testing every 30 days according to its IQCP for D-Dimer testing. (refer to D5445-B) 10. The laboratory failed to perform quality control each day of patient testing for identification and sensitivities in bacteriology. (refer to D5507) 11. The laboratory failed to ensure only normal donors were used to establish normal patient ranges for coagulation studies. (refer to D5545)
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: A. Based on review of the manufacturer's instructions for the Dade Behring WalkAway instrument, random review of the laboratory's WalkAway QC Diagnostics Reports from January 1, 2018 to July 18, 2018 (the day of the survey), and confirmed in interview of facility personnel, revealed the laboratory failed to have documentation of following the manufacturer's instructions for the acceptability of instrument temperatures. The findings were: 1. This is a repeat deficiency from the survey conducted on July 28, 2016. 2. A review of the manufacturer's instructions for the Beckman Coulter WalkAway instrument (9020-7223, Rev. A) under the section titled "Monitor the Temperature" revealed, "The WalkAway instrument displays the internal temperature on the control panel; however, you must also check the

	temperature on the thermometer located on the top left corner of the instrument. The temperature must be 35C +/- 1C. The temperatures displayed on the control panel and the external thermometer must agree within +/- 0.5C. 3. A random review of the laboratory's WalkAway QC Diagnostics Reports from January 1, 2017 to July 18, 2018 (the day of the survey), identified the following days when the documented display temperature was not within +/- 0.5 Celsius of the external thermometer reading: Date Display Temp External Temp Difference 07/08/2018 35.0 not documented could not be determined 07/07/2018 34.8 not documented could not be determined 07/01/2018 34.7 not documented could not be determined 06/30/2018 34.9 not documented could not be determined 06/22/2018 34.9 not documented could not be determined 05/28/2018 34.9 not documented could not be determined 05/27 /2018 34.9 not documented could not be determined 05/26/2018 34.9 not documented could not be determined 04/22/2018 34.9 not documented could not be determined 04 /21/2018 34.8 not documented could not be determined 01/31/2018 34.9 not documented could not be determined 01/30/2018 34.8 not documented could not be determined 01/29/2018 34.8 not documented could not be determined 01/28/2018 35.0 not documented could not be determined 01/27/2018 34.9 not documented could not be determined 4. An interview with the laboratory manager on July 19, 2018 at 164:45 hours in the Huddle Room confirmed the findings. B. Based on review of manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions to record final dispense weight when performing RENOK monthly maintenance. The findings were: 1. Review of the manufacturer's instructions for the RENOK Rehydrator/Inoculator System Operation (9020-7328A) stated under, "Maintenance: These maintenance procedures describe checking the dispense volume of the RENOK unit (should there be evidence of consistent low fills), replacing the rubber seal (should there by evidence of low fills or if cleaning is required), and cleaning the RENOK unit (should contamination occur)." 2. Further review of the manufacturer's instructions for the RENOK Rehydrator/Inoculator System Operation System, under "Checking the Dispense Volume" stated, "Step 3: Record the final weight. If the weight of the inoculated cover tray is not between 10.1 and 12.0 grams, retest the RENOK using another transfer lid and trough, preferably from another box. If the volume is still not within the above limits, try replacing the rubber seal (see section on Replacing the Rubber Seal). Finally, if the volume is still not within the above limits contact MicroScan for a replacement." 3. Review of the laboratory's MicroScan WalkAway /Computer Maintenance Checklist from January 2017 to June 2018 revealed the laboratory documented performing the RENOK maintenance procedures monthly but failed to document the final dispense volume as required by the manufacturer. 4. An interview with general supervisor two (as listed on Form CMS-209) on July 18, 2018 at 16:00 hours in the microbiology section confirmed the findings.
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 direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the room temperature where supplies were stored. The findings included: 1. Direct observation made by the surveyor on July 18, 2018 at 1330 hours revealed the following items were located in the area of the nurse's station in the Emergency Department: a. BBL Transport swabs for aerobic and anaerobic microorganisms Lot 172106416 Expiration Date: 08-31-2019 Quantity of 3 swabs b. BACTEC blood culture bottles (aerobic) Lot 7361855 Expiration Date: 10-31-2018 Quantity of 2 bottles c. BACTEC blood culture bottles (anaerobic) Lot 7361871 Expiration Date: 10-31-2018 Quantity of 2 bottles 2. Further observations revealed no means to monitor the room temperature in the area of the nurse's station. 3. Review of the manufacturer's instructions for the BBL Transport swabs on the outside of the packaging revealed the storage requirement for the swabs is 5 to 25 degrees Celsius. 4. Review of the manufacturer's instructions for the BACTEC blood culture bottles on the bottle label revealed the storage requirements for the bottles is 2 to 25 degrees Celsius. 5. The above findings were confirmed in interview of the phlebotomy supervisor on July 18, 2018 at 13:30 hours in the Emergency Department.
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 direct observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not available for use in patient testing. The findings were: 1. Based on direct observation made in the Emergency Department on July 18, 2018 at 13:30 hours revealed the following expired items: a. Gray top pediatric tubes Lot 7089902 Expiration Date: 06-30-2018 Quantity of 2 b. Red top pediatric tubes Lot UE2131 Expiration Date: 03-31-2018 Quantity of 2 2. Review of the laboratory's policy titled, "Phlebotomy Tray" approved by the laboratory director on January 10, 2018 stated, "C. All items in the tray should be checked daily to remove anything that has expired." 3. The above findings were confirmed in interview of the phlebotomy supervisor on July 18, 2018 at 13:30 hours in the Emergency Department.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on review of manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of instrument maintenance for the BACTEC blood

	culture analyzer. The findings included: 1. Review of the manufacturer's instructions for the BACTEC blood culture system (9000 bc2, Revision B) revealed under, "Instrument Maintenance, "The following procedures should be performed at the start of each day's testing and recorded on the maintenance log." The manufacturer's instructions went on to list daily and weekly maintenance requirements. 2. Review of the laboratory's BACTEC maintenance logs from January 2017 to June 2018 revealed the maintenance log sheet for December 2016 was missing. 3. The laboratory was asked to provide documentation of performing BACTEC instrument maintenance in December 2016 or for the missing records. No documentation was provided. 4. The above findings were confirmed in interview of the technical supervisor on July 18, 2018 at 16:00 hours in the microbiology section. She tried to locate the missing records but was unable to recover them. B. Based on review of manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of semi-annual instrument maintenance on the Helmer Cell Washer. The findings included: 1. Review of the manufacturer's instructions for the maintenance on the Helmer Scientific Automatic Cell Washing System Operation Manual UltraCW (360084-1/O) stated, under "Frequency," "Semi-Annually: Check the rotor speed and calibrate it if necessary." 2. Review of the laboratory's maintenance records for the Helmer Cell Washer from January 1, 2017 to December 31, 2017 revealed semi-annual maintenance was performed on January 27, 2017. 3. The laboratory was asked to provide documentation of performing the required semi-annual maintenance an additional time in 2017. No documentation was provided. 4. An interview with the technical supervisor on July 19, 2018 at 16:00 hours in the Blood Bank Room confirmed the findings.
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 laboratory policy, review of the laboratory's calibration verification records for Potassium, Sodium, and Chloride performed on the Dade Dimension EXL

	chemistry analyzer in 2017 and 2018, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of performing the calibration verification every 6 months. The findings were: 1. This is a repeat deficiency. 2. Review of the laboratory's policy titled, "Calibration Verification" approved by the laboratory director on January 10, 2018 under, "Limitations /Frequency" stated, "B. Successful calibration verification certifies that the calibration is still valid." 3. A review of the laboratory's calibration verification records for Potassium, Sodium, and Chloride performed on the Dade Dimension EXL chemistry analyzer in 2017 and 2018 revealed the laboratory had documentation of performing the verification at the following times: March 2017 September 2017 March 2018 4. The calibration verification performed in March 2018 was incomplete. The documentation provided for review was raw data and had not been evaluated to ensure the continued accuracy of the analytes throughout the instrument's reportable range. 5. An interview with the laboratory manager on July 19, 2018 at 10:30 hours in the Huddle Room confirmed the findings. She revealed the laboratory was trying to regain access to the statistical analysis program EP Evaluator.
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: A. Based on review of the laboratory's IQCP (Individualized Quality Control Plan) for serum hCG (human chorionic gonadotropin), review of manufacturer's instructions, review of patient result log sheets, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following its own IQCP plan to run two levels of quality control with each new lot or shipment, every 30 days, with each new operator, or new test system requirement. The findings included: 1. Review of the laboratory's IQCP for serum hCG approved by the laboratory director on January 10, 2018 under "Quality Assessment" stated, "d. External QC: QC Sample-2 levels (New Lot/Shipment, every 30 days, each new operator, or test system requirement). 2. Review of the manufacturer's instructions for Sure-Vue Serum/Urine hCG (DN: 1155810904, Effective Date: 2010-01-15) under "Quality Control" stated, " ...For serum testing, federal, state, and local guidelines should be followed." 3. Review of patient result logs sheets from May and June 2018 and July and August 2017 revealed the following patients were tested were tested when only level of serum hCG control was performed: May 2018 Accession Number: 0509:S14 Accession Number: 0510:S2 Accession Number: 0511:S1 Accession Number: 0512:S2 Accession Number: 0517: S4 Accession Number: 0518:S2 Accession Number: 0518:S5 Accession Number: 0525:S4 Accession Number: 0525:S5 Accession Number: 0528:S1 Accession Number: 0528:S2 Accession Number: 0529:S6 Accession Number: 0529:S17 Accession Number: 0529:S22 Accession Number: 0529:S23 Accession Number: 0531:S2 June 2018 Accession Number: 0602:S1 Accession Number: 0604:S1 Accession Number: 0606:S1 Accession Number: 0606:S3 Accession Number: 0607:

S7 Accession Number: 0608:S1 Accession Number: 0615:S5 Accession Number: 0615:S7 Accession Number: 0618:S1 Accession Number: 0618:S5 Accession Number: 0618:S10 Accession Number: 0619:S4 Accession Number: 0622:S6 Accession Number: 0623:S1 Accession Number: 0629:S15 Accession Number: 0630: S1 July 2017 Accession Number: 0702:S1 Accession Number: 0703:S3 Accession Number: 0705:S6 Accession Number: 0708:S1 Accession Number: 0709:S1 Accession Number: 0710:S7 Accession Number: 0713:S7 Accession Number: 0714: S3 Accession Number: 0714:S4 Accession Number: 0714:S6 Accession Number: 0714:S9 Accession Number: 0716:S1 Accession Number: 0716:S2 Accession Number: 0717:S4 Accession Number: 0718:S2 Accession Number: 0718:S6 Accession Number: 0718:S8 Accession Number: 0719:S1 Accession Number: 0720: S2 Accession Number: 0721:S6 Accession Number: 0722:S1 Accession Number: 0725:S10 Accession Number: 0725:S11 Accession Number: 0726:S2 Accession Number: 0727:S4 Accession Number: 0728:S5 Accession Number: 0730:S1 Accession Number: 0731:S1 Accession Number: 0731:S2 August 2017 Accession Number: 0801:S3 Accession Number: 0808:S3 Accession Number: 0808:S5 Accession Number: 0809:S8 Accession Number: 0811:S2 Accession Number: 0812: S1 Accession Number: 0813:S2 Accession Number: 0814:S1 Accession Number: 0816:S1 Accession Number: 0817:S1 Accession Number: 0818:S2 Accession Number: 0818:S7 Accession Number: 0819:S2 Accession Number: 0820:S1 Accession Number: 0820:S2 Accession Number: 0821:S1 Accession Number: 0821: S5 Accession Number: 0822:S2 Accession Number: 0823:S4 Accession Number: 0824:S5 Accession Number: 0825:S1 Accession Number: 0828:S1 Accession Number: 0830:S4 Accession Number: 0831:S2 4. The laboratory was asked to provide documentation of performing two levels of quality control at the designated times according to its quality control plan. No documentation was provided, 5. The above findings were confirmed in interview of the technical supervisor on July 18, 2018 at 15:30 hours in the microbiology section. B. Based on review of review of the CLIA FDA database, review of the laboratory's IQCP for D-Dimer performed on the Alere Triage meter from January 1, 2017 to May 31, 2017, review of manufacturer's instructions, review of patient results, and confirmed in interview of facility the laboratory's IQCP for D-Dimer, personnel, the laboratory failed to perform quality control every 30 days of patient testing according to its IQCP. The findings included: 1. As of June 18, 2018, the day of the survey, the laboratory is currently using the Alere Triage meter for D-Dimer testing as its back-up method. However, from January 1, 2017 to May 31, 2017, the Alere Triage meter was the laboratory's primary testing methodology for D-Dimer. 2. Review of the CLIA FDA database confirmed the D-Dimer test performed on the Alere Triage meter is a moderately complex test. The laboratory developed an IQCP to decrease the frequency of quality control. 3. Review of the laboratory's IQCP approved by the laboratory director on January 10, 2018 under, "Quality Assessment" stated "d. External QC:QC Sample-2 levels (New lot, every 30 days, or test system requirement) Note: Patient results are not available if out of range." 4. Review of the manufacturer's instructions (PN: 26164 en Rev. E, 2017/10) under "Quality Control" stated, "Good laboratory practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as other otherwise required by your laboratory's standard quality control procedures." The manufacturer's instructions went on to state, "Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 5. Review of quality control records for D-Dimer from December 21, 2017 to May 31, 2017 revealed external quality control testing was performed on the following dates: 12-28-2016 03-16-2017 6. Review of patient results from January 1, 2017 to May 31, 2017, identified the following patients were tested when quality control had not been performed each 30

	days of patient testing according to the laboratory's IQCP: Date Accession Number 01-30-2017 0130:CG22 01-31-2017 0131:CG2 01-31-2017 0131:CG12 02-01-2017 0201: CG8 02-02-2017 0202:CG1 02-04-2017 0204:CG3 02-07-2017 0207:CG8 02-14-2017 0214:CG7 02-16-2017 0216:CG9 02-17-2017 0217:CG10 02-18-2017 0218: CG3 02-24-2017 0224:CG14 03-01-2017 0301:CG12 03-02-2017 0302:CG14 03-04-2017 0304:CG2 03-05-2017 0305:CG2 03-09-2017 0309:CG1 03-09-2017 0309: CG16 03-10-2017 0310:CG1 03-12-2017 0312:CG1 03-12-2017 0312:CG3 04-19-2017 0419:CG1 04-20-2017 0420:CG8 04-20-2017 0420:CG12 04-22-2017 0422: CG2 04-23-2017 0423:CG2 04-23-2017 0423:CG3 04-26-2017 0426:CG9 04-26-2017 0426:CG11 04-27-2017 0427:CG5 04-27-2017 0427:CG12 04-30-2017 0430: CG2 05-01-2017 0501:CG17 05-01-2017 0501:CG18 05-03-2017 0503:CG1 05-06-2017 0506:CG2 05-07-2017 0507:CG3 05-07-2017 0507:CG5 05-09-2017 0509: CG13 05-17-2017 0517:CG5 05-26-2017 0526:CG8 05-27-2017 0527:CG1 05-28-2017 0528:CG1 05-30-2017 0530:CG1 05-30-2017 0530:CG2 7. The above findings were confirmed in interview with general supervisor one on July 19, 2018 at 16:45 hours in the Huddle Room.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 the WalkAway operator's manual, quality control records, patient test records, and confirmed in staff interview, the laboratory failed to perform quality control for antimicrobial susceptibility on the Gram Positive Breakpoint Combo 20 Panel, the Microstrep Plus Breakpoint Combo, and the Gram Negative Breakpoint Combo 44 Panel each day tests are performed from January 1, 2018 to 2016 through July 18, 2018. The findings included: 1. The laboratory did not provide evidence of performing an IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control testing. The laboratory is required to perform quality control each day of patient testing. 2. Review of the laboratory's policy titled "Bacteriology Quality Control Procedures (Non-Media) approved by thy laboratory director on January 10, 2018 stated, "Microscan Panels: ...QC shall be performed weekly to ensure proper operation of both the panels and the Microscan Walkaway 40 Plus instrument." 3. Review of the operator's manual for the WalkAway (9020-7260, Rev A), under Performing Quality Control, states: "After running the initial quality control tests, you may also need to periodically test antimicrobials on the panels. For additional quality control and testing frequency guidelines, see the CLSI Performance Standards for Antimicrobial Susceptibility Testing and the MicroScan Panel Procedure Manuals." 4. Review of the MicroScan Dried Gram Positive Panel Procedure Manual document (3251-2973B), under Quality Control, states, "The acceptability of the identification media and antimicrobial agents should be checked by testing organism with known reactions and MIC ranges." 5. Review of the MicroScan Dried Gram Negative Panel Procedure Manual document (3251-1019A), under Quality Control, states, "The

	acceptability of the identification media and antimicrobial agents should be checked by testing organism with known reactions and MIC ranges." 6. Review of the MicroScan Dried Microstrep Plus Panel Procedure Manual document (3251-2460B), under Quality Control, states, "The acceptability of the identification media and antimicrobial agents should be checked by testing organism with known reactions and MIC ranges." 7. Random review of quality control records from January 1, 2018 through March 31, 2017 and February 1, 2018 through March 31, 2018 indicate that quality control for each of the 3 of 3 panel types was performed weekly as follows: January 3, 2017 January 11, 2017 January 17, 2017 January 25, 2017 January 31, 2017 February 8, 2017 February 15, 2017 February 22, 2017 February 24, 2017 March 1, 2017 March 8, 2017 March 15, 2017 March 21, 2017 March 29, 2017 February 2, 2018 February 14, 2018 February 21, 2018 February 28, 2018 March 7, 2018 March 14, 2018 March 21, 2018 March 31, 2018 8. According to the Form CMS 116, approved by the laboratory director on July 17, 2018, the laboratory performs 6702 identification and sensitivities annually. 9. In an interview at 15:30 hours on July 18, 2018 in the microbiology section, the technical supervisor and general supervisor two (as listed on Form CMS-209) confirmed an IQCP for identification and sensitivities could not be located and agreed the laboratory was performing quality control testing weekly.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 the laboratory's coagulation quality control records from May 2017 to July 2018, review of patient test records from May 2017, review of the laboratory's patient normal range studies performed during the instrumentation installation, and staff interview, it was revealed the laboratory failed to have documentation of using only normal donor samples for the determination of the patient normal range. The findings were: 1. This is a repeat deficiency. 2. A review of the laboratory's instrument verification records revealed the laboratory implemented a new coagulation analyzer, an Instrumentation Laboratories TOP 350, in June 2017. The laboratory is still on the same lot number of PT reagent (Lot 160407, Expiration Date: 01-2019). 3. Review of the laboratory's Patient Normal Range studies revealed the laboratory had questionnaires completed by study participants to ensure the samples used in the studies were from normal donors who were not taking any medications that may interfere with the assay. The laboratory failed to remove 2 of 20 samples from patients who answered that they were on medications which could interfere with the assay. 4. An interview with the technical supervisor on July 19, 2018 at 14:30 hours in the laboratory after her review of the records confirmed the findings.
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 direct observations, review of manufacturer's instructions, review of quality control records, review of maintenance records, review of instrument verification records, review of patient results, and confirmed in interview of facility personnel, the laboratory's quality assessment program failed to identify and correct errors its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for acceptability of instrument temperatures on the Beckman Coulter Microscan WalkAway. (refer to D5411-A) 2. The laboratory failed to follow the manufacturer's instructions for documenting the final dispense weight when performing RENOK maintenance. (refer to D5411-B) 3. The laboratory failed to monitor the room temperature where supplies were stored in the Emergency Department. (refer to D413) 4. The laboratory failed to ensure expired items were not available for use in patient testing. (refer to D5417) 5. The laboratory failed to ensure maintenance was performed on the BACTEC blood culture analyzer. (refer to D5429-A) 6. The laboratory failed to ensure semi-annual maintenance was performed on the Helmer cell washer in 2017. (refer to D5429-B) 7. The laboratory failed to ensure calibration verification was performed and complete every 6 months. (refer to D5439) 8. The laboratory failed to perform two levels of quality control according to its IQCP for serum hCG testing. (refer to D5445-A) 9. The laboratory failed to perform quality control testing every 30 days according to its IQCP for D-Dimer testing. (refer to D5445-B) 10. The laboratory failed to perform quality control each day of patient testing for identification and sensitivities in bacteriology. (refer to D5507) 11. The laboratory failed to ensure only normal donors were used to establish normal patient ranges for coagulation studies. (refer to D5545)
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 review of the laboratory's American Proficiency Institute (API) proficiency testing records, review of laboratory policy, and confirmed in interview of facility personnel, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. (refer to D6016, D6018, D6020, and 6021)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as

	required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) and American Academy of Bioanalysts (AAB) proficiency testing records, and confirmed in interview of facility personnel, it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. 1. The laboratory director failed to ensure testing persons tested proficiency testing samples using routine patient testing procedures. (refer to D2007) 2. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. (refer to D2130)
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Bioanalysts (AAB) proficiency testing records, and confirmed in interview of facility personnel, it was revealed that the laboratory director failed to ensure review of proficiency testing records identified the wrong method code was entered for Prothrombin Time (PT) testing for 2 of 2 consecutive failed testing events. The findings included: 1. Review of the laboratory's proficiency testing records revealed that the laboratory received the following unsatisfactory scores for Prothrombin Time (PT): AAB 2017 - event 3 Prothrombin Time Score = 40% AAB 2018 - event 1 Prothrombin Time Score = 60% 2. Further review of the records provided during the two day survey process revealed the laboratory had reviewed the proficiency testing results but failed to identify that the method code was not changed by the proficiency testing agency when the laboratory switched testing for Prothrombin Time (PT) from the ACL7000 to Instrument Laboratories (IL) TOP 350 coagulation analyzer in June 2017. 3. On July 18, 2018 the surveyor observed general supervisor one (as listed on Form CMS-209) make a telephone call to AAB and discuss the clerical error. The general supervisor stated the records were submitted to AAB but AAB notified her that they could not recover any records for a change in method code for PT. The surveyor then spoke to the representative at AAB and asked if a corrected report would be provided to the facility, and he stated, "No." 4. It should be noted that the laboratory has tested the 2nd event AAB 2018 for Nonchemistry to included PT testing and the method code still had not been changed. The general supervisor revealed that she had spoken to the AAB representative on July 18, 2018 and because the testing event was closed the method code could not be changed. She revealed that in case of a failure, AAB directed them to document it as a clerical error. Key: CMS - Centers for Medicare and Medicaid Services
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 review of the laboratory's Individualized Quality Control Plans (IQCP), review of manufacturer's instructions, review of quality control results, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to: 1. The laboratory director failed to ensure the laboratory performed quality control testing according to its IQCP studies. (refer to D5445) 2. The laboratory director failed to ensure the laboratory performed quality control testing for identification and sensitivities in bacteriology or to perform an IQCP study to decrease the frequency of quality control testing. (refer to D5507)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on direct observations, review of the laboratory's quality assessment procedures, review of manufacturer's instructions, review of quality control records, review of patient results, review of maintenance records, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory's quality assessment program identified and corrected errors in its analytic systems. (refer to D5793)