Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656773	11/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mccurtain Memorial Hospital	1301 Lincoln Road, Idabel, OK	

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	The recertification survey was performed on 11/03,04,05,06/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, laboratory manager/technical consultant #2, assistant laboratory manager, chief nursing officer, and the med-surg director during an exit conference performed at the conclusion of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to review and evaluate proficiency testing results for 2 of 26 events. Findings include: (1) On 11/03/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following biases (the biases was identified using the SDI (Standard Deviation Index) values assigned by the proficiency program: (a) First 2019 Chemistry Core Event (i) Alkaline Phosphatase- 3 of 5 results exhibited a positive bias (aa) CH-06 - SDI of 2.2 (bb) CH-08 - SDI of 2.0 (cc) CH-10 - SDI of 2.0 (b) Second 2020 Chemistry Core Event (i) Alkaline Phosphatase- 5 of 5 results exhibited a positive bias (aa) CH-06 - SDI of 3.3 (bb) CH-07 - SDI of 2.4 (cc) CH-08 - SDI of 2.6 (dd) CH-09 - SDI of 2.1 (ee) CH-10 - SDI of 2.4 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) Surveyor #2 then reviewed the records with the laboratory manager/technical consultant #2, and asked if the biases had been addressed. The laboratory manager/technical consultant #2 stated on 11/03/2020 at 10:40 am the biases had not been addressed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 3 of 26 events. Findings include: (1) On 11/03/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 first event (aa) Blood Cell ID-ECI-01 (ii) 2020 second event (aa) Blood Cell ID - ECI-06 (b) Microbiology Event (i) 2019 second event (aa) MIC Microscan/Tetrcycline -ES-02 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) Surveyor #2 asked the laboratory manager/technical consultant #2 if the results had been documented as evaluated. The laboratory manager/technical consultant #2 reviewed the records and stated on 11/03/2020 at 10:30 am the non-graded results had not been documented as reviewed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the assistant laboratory manager and laboratory manager/technical consultant #2, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory for H. pylori and Shigatoxin testing; and failed to have written Urinalysis and Blood Culture procedures. Findings include: H.PYLORI (1) On 11/04/2020 at 1:50 pm, the assistant laboratory manager stated to surveyor #1 that Helicobacter pylori (H. pylor) testing was performed using Cardinal Health H. pylori Rapid test and whole blood specimens (as a waived procedure); (2) Surveyor #1 reviewed the procedure titled, "Helicobacter pylori testing (moderate complexity) serum or plasma" which did not reflect the laboratory's current method of performing H. pylori testing; (3) Surveyor #1 reviewed the findings with the assistant laboratory manager, who stated on 11/04/2020 at 02:00 pm, the laboratory did not use serum or plasma samples and the procedure was not reflective of the current method of H. pylori testing. SHIGATOXIN (1) On 11/05/2020 surveyor #1 reviewed the procedure manual titled, "Microbiology Standard Operating Procedures" and identified a procedure titled, "Shigatoxin"; (2) Surveyor #1 asked the laboratory manager /technical consultant #2 if Shigatoxin testing was performed in the laboratory. The laboratory manager/technical consultant #2 stated on 11/05/2020 at 10:50 am the

procedure had been written becuase the laboratory had planned on performing the testing, but never put the test into use and did not remove the procedure from the manual; (3) Surveyor #1 determined the procedure was not reflective of the current practices in the laboratory. URINALYSIS (1) On 11/05/2020 at 10:35 am, the assistant laboratory manager stated to surveyor #1 the laboratory began using the Cobas u411 analyzer to perform Urinalysis testing (for the analysis of Leukocytes, Nitrites, Protein, Blood, Glucose, Ketones, Bilirubin, Urobilinogen, pH, Specific Gravity, and Creatinine in patient urine specimens) on 07/21/2020; (2) Surveyor #1 reviewed the procedure manual titled, "Laboratory Urine Analysis Section Procedure Manual". A Urinalysis procedure using the Cobas u411 analyzer could not be located; (3) Surveyor #1 asked the laboratory manager/technical consultant #2 if a written Urinalysis procedure, using the Cobas u411 analyzer existed. The laboratory manager /technical consultant #2 stated on 11/05/2020 at 12:45 pm, a procedure had not been written. BLOOD CULTURE (1) On 11/06/2020 at 12:00 pm, the laboratory manager /technical consultant #2 stated to surveyor #1 the laboratory began using two BD Bactec FX40 analyzers to perform patient Blood Culture testing on 09/08/2020; (2) Surveyor #1 reviewed the procedure manual titled, "Microbiology Standard Operating Procedures". A procedure for blood culture testing using the BD Bactec FX40 analyzers could not be located; (3) Surveyor #1 asked the laboratory manager /technical consultant #2 if a written Blood Culture procedure, using the BD Bactec FX40 analyzers existed. The laboratory manager/technical consultant #2 stated on 11 /06/2020 at 12:15 pm, a procedure had not been written. 39088 Based on a review of records, policy and procedure manual and interview with the laboratory manager /technical consultant #2, the laboratory failed to follow the WBC (white blood cell) slide review procedure for 5 of 8 patient reports and failed to follow the Sorvall CellWasher weekly maintenance procedure for 2 of 6 months. Findings include: SLIDE REVIEW PROCEDURE (1) On 11/03/2020 at 09:50 am, the laboratory manager/technical consultant #2 stated to surveyor #2 CBC (Complete Blood Count) testing was performed on two analyzers: (a) Sysmex XN 1000 - primary analyzer; (b) Sysmex XP 300 - back-up analyzer. (2) Surveyor #2 reviewed the laboratory's written procedure manual for slide reviews which stated, "Slide Review for WBC, RBC, or PLT Flags": (a) "1. A manual slide review by a technologist must be performed when any of the following criteria is evident on the automated CBC report." (i) "e. PLATELETS" (aa) "flag for PLT clumps" (bb) "flag for PLT ABN scattergram" (cc) "flag for PLT ABN distribution" (b) "2. WBC flags that require smear review" (i) "WBC abnormal scattergram" (WBC Abn Scattergram) (3) Surveyor #2 reviewed 8 patient instrument printouts from testing performed on 09/14/2020. Each printout contained at least one data flag. There was no evidence the laboratory followed their written procedure for CBC automated flags for 5 of the 8 patient printouts. The flags were: (a) Report #1 - A "PLT Abn Distribution" flag was obtained at 12:38 pm; (b) Report #2 - A "PLT Abn Distribution" and "PLT Clumps?" flag were obtained at 03: 15 pm; (c) Report #3 - A "PLT Abn Distribution" flag was obtained at 03:25 pm; (d) Report #4 - A "PLT Clumps?" flag was obtained at 03:40 pm; (e) Report #5 - A "WBC Abn Scattergram" flag was obtained at 07:30 pm. (4) Surveyor #2 reviewed the patient records with the laboratory manager/technical consultant #2. The laboratory manager/technical consultant #2 stated on 11/06/2020 at 10:30 am, the laboratory failed to follow written procedures for slide reviews. SORVALL CELLWASHER WEEKLY MAINTENANCE (1) On 11/03/2020 at 09:45 am, the laboratory manager/technical consultant #2 stated to surveyor #2 the Sorvall CellWasher was used in the laboratory to wash blood cells for antiglobulin reagent tests for procedures such as ABO/Rh compatibility testing and Crossmatch testing; (2) On 11/05/2020, surveyor #2 reviewed the laboratory's written procedure for the Sorvall CellWasher weekly maintenance which stated: (a) "Check rotator and bowl

	for cracks and corrosion" (b) "Check rotator for stability (it should not wobble)" (c) "Check gaps in tube holder bands (gaps should be 2 mm or less)" (d) "Clean and decontaminate" (e) "Clean fill volume" (3) On 11/05/2020, surveyor #2 reviewed Sorvall CellWasher weekly maintenance records between June 2019 through November 2019 and identified the following for 2 of 6 months: (a) The weekly maintenance had not been performed between 08/25/2019 and 09/14/2019; (b) The weekly maintenance had not been performed between 10/30/2019 and 11/18/2019. (4) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2. The laboratory manager/technical consultant #2 stated on 11/05/2020 at 03:35 pm, the laboratory did not perform the weekly maintenance as indicated above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures and interview with the laboratory manager/technical consultant #2 and assistant laboratory manager, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the current laboratory director. Findings include: URINALYSIS (1) On 11/03 /2020 at 11:00 am, the assistant laboratory manager stated to surveyor #2 the laboratory performed urinalysis testing using the Cobas u411 analyzer; (2) Surveyor #1 reviewed the procedure manual titled, "Laboratory Urine Analysis Section Procedure Manual". It had not been approved, signed and dated by the current laboratory director; (3) Surveyor #1 reviewed the procedure manual with the laboratory manager/technical consultant #2, who stated on 11/03/2020 at 11:15 am, the procedure manual had not been signed and dated as approved by the laboratory director. MICROBIOLOGY (1) On 11/03/2020 at 11:30 am, the assistant laboratory manager stated to surveyor #2 the laboratory performed the following testing in the microbiology department: (a) Microbiological cultures from urine, throat, ocular, sputum, wound, genital, body fluids, and stool specimens; (b) Clostridium difficile testing using the Meridian Premier C. Diff Tox A/B test kit; (c) Gram Stain testing (2) On 11/06/2020, surveyor #1 reviewed the procedure manual titled, "Microbiology Standard Operating Procedures". The following procedures had not been approved, signed and dated by the current laboratory director: (a) "Premier Toxins A&B" (b) "Inoculation of Culture Media" (c) "Gram Stain Procedure" (3) Surveyor #1 reviewed the procedure manual with the laboratory manager/technical consultant #2, who stated on 11/06/2020 at 11:20 am, the procedures had not been signed and dated as approved by the laboratory director.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the laboratory manager /technical consultant #2, the laboratory failed to ensure that a written procedure no

	longer in use had been discontinued. Findings include: (1) On 11/05/2020 surveyor #1 reviewed the procedure manual titled, "Microbiology Standard Operating Procedures" and identified a procedure titled, "India Ink Procedure"; (2) Surveyor #1 reviewed the procedure with the laboratory manager/technical consultant #2, who stated on 11/05 /2020 at 12:30 pm, the procedure should have been indicated as discontinued when India Ink had been discontinued.
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 a review of records, manufacturer's instructions, and interview with the assistant laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 11/05 /2020 at 1:00 pm, the assistant laboratory manager stated the following to surveyor #1: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (b) The following reagents had been put into use on 10/27/2020, and were currently in use: (i) PT - Innovin reagent lot #549747A (ii) PTT - Actin FSL reagent lot #562622A (iii) Ci-Trol 1 control - lot #564818 (iv) Ci-Trol 3 control - lot #556536 (2) Surveyor #1 reviewed the manufacturer's instructions for implementing new reagents in Section XIV of the Installation Package section titled, "Lot Roll-Over Procedure" which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (iv) "Calculate Linear Regression statistics". (b) Section titled, "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTT protocols"; (ii) "Collect a minimum of 30 data points over multiple days and stability limits of control"; (iii) "Calculate the mean, 2 SD and 2 SD range". (3) Surveyor #1 reviewed the records for the lot changes with the following identified: (a) PT-Innovin reagent lot #549747A (i) Method Correlation - The records showed the laboratory had not spanned the reportable range for the assay. The laboratory values ranged from 9.7-47.6 and the laboratory's reportable range for the assay was 8.9-170.9. (b) PTT-Actin FSL reagent lot #562622A (i) Method Correlation - The records showed the laboratory had not spanned the reportable range for the assay. The laboratory values ranged from 26.4-113.3 and the laboratory's reportable range for the assay was 19.9-192.4. (c) Quality Control (QC) (i) Ci-Trol 1 lot #564818 - The records showed the laboratory had used 15 data points to establish QC ranges for PT and PTT instead of 30 data points as required by the manufacturer; (ii) Ci-Trol 3 lot #556536 - The records showed the laboratory had used 15 data points to establish QC ranges for PT and PTT instead of 30 data points as required by the manufacturer. (4) Surveyor #1

	reviewed the records with the assistant laboratory manager who stated on 11/06/2020 at 09:25 am, the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
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 records and interview with the laboratory manager/technical consultant #2, the laboratory failed to ensure units of packed red blood cells and fresh frozen plasma were stored as required for 9 of 13 months. Findings include: (1) On 11 /03/2020 at 09:20 am, the laboratory manager/technical consultant #2 stated the following to surveyor #2: (a) Units of packed red blood cells (PRBC), stored in the blood bank refrigerator, were used for patient transfusions; (b) Units of fresh frozen plasma (FFP), stored in the blood bank freezer, were used for patient transfusions. (2) Surveyor #2 reviewed refrigerator and freezer temperature records from March 2019 through November 2019 and records between May 2020 through August 2020 for the refrigerator and freezer. (Note: units of PRBC must be stored at 1-6 degrees Centigrade (C) and units of FFP must be stored at -18 degrees C or colder). The following was identified: (a) Refrigerator - temperatures not documented (i) March 2019 - day 1 (ii) June 2019 - day 15 (iii) September 2019 - day 25 (iv) October 2019 - days 24,29 (v) November 2019 - day 3 (vi) May 2020 - day 7 (vii) June 2020 - day 30 (viii) July 2020 - day 5 (ix) August 2020 - day 8 (b) Freezer (i) March 2019 - day 1 (ii) June 2019 - day 15 (iii) August 2019 - day 13 (iv) September 2019 - day 26 (v) October 2019 - days 24,29 (vi) November 2019 - day 3 (vii) July 2020 - days 5,12 (3) Surveyor #2 reviewed the temperature records for the blood bank refrigerator and freezer with the laboratory manager/technical consultant #2. The laboratory manager /technical consultant #2 stated on 11/06/2020 at 11:25 am the temperatures were not documented as indicated above.
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 and interview with the laboratory manager/technical consultant #2, the laboratory failed to ensure expired blood collection tubes were not available for use; and failed to ensure expired blood bank quality controls were not available for use for 7 of 11 days. Findings include: BLOOD COLLECTION TUBES (1) On 11/03/2020 at 09:50 am, surveyor #2 observed blood collection tubes located

	in the laboratory: (a) Four BD (Becton Dickinson) Tiger Top SST blood collection tubes (lot #9263404) were observed that had a manufacturer's expiration date of 09/30 /2020; (b) One BD (Becton Dickinson) Tiger Top SST blood collection tube (lot #8345979) was observed that had a manufacturer's expiration date of 11/30/2019. (2) Surveyor #2 showed the expired tubes to the laboratory manager/technical consultant #2, who stated on 11/03/2020 at 10:00 am the expired tubes were available for patient use. BLOOD BANK REAGENTS (1) On 11/03/2020 at 09:35 am, the laboratory manager/technical consultant #2 stated to surveyor #2 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 11/06/2020, surveyor #2 reviewed quality control and patient testing records for testing performed from 01/01/2020 through 01/17/2020 and 05/11/2020 through 05/16 /2020 and identified expired reagents had been used 7 of 16 days of testing reviewed as follows: (a) Immucor Anti-A, lot #301540, expiration date 12/31/2019 had been used for patient testing on 01/09/2020 and 01/10/2020; (b) Immucor A1 Cells, lot #111293, expiration date 05/15/2020 had been used for patient testing on 05/16/2020; (c) Immucor A2 Cells, lot #112884, expiration date 05/15/2020 had been used for patient testing on 05/16/2020; (d) Immucor B Cells, lot #113293, expiration date 05/15 /2020 had been used for patient testing on 05/16/2020; (e) Immucor O Cells, lot #114384, expiration date 05/15/2020 had been used for patient testing on 05/16/2020; (f) Immucor Screen Cells, lot #10178, expiration date 05/15/2020 had been used for patient testing on 05/16/2020. (3) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2 who stated on 11:06 at 11:42 am expired reagents had been used as indicated above.
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 a review of records, and interview with the assistant laboratory manager and the laboratory manager/technical consultant #2, the laboratory failed to demonstrate the performance specifications for a new urinalysis analyzer; and failed to provide evidence the verification data had been evaluated prior to implementing the new blood culture analyzers. Findings include: URINALYSIS ANALYZER (1) On 11/05/2020 at 10:35 am, the assistant laboratory manager stated to surveyor #1 the laboratory began using the Cobas u411 analyzer to perform Urinalysis testing (for the analysis of Leukocytes, Nitrites, Protein, Blood, Glucose, Ketones, Bilirubin, Urobilinogen, pH, Specific Gravity, and Creatinine in patient urine specimens) on 07/21/2020; (2) The surveyor requested records from the laboratory manager/technical consultant #2 to substantiate the performance specifications (i.e., accuracy, precision, reportable range, and reference range, as applicable) had been demonstrated for the new test system before it had been put into use; (3) The laboratory manager/technical consultant #2 stated to surveyor #1 on 11/05/2020 at 12:45 pm, the performance specifications had not been demonstrated for the test system. BLOOD CULTURE ANALYZERS (1) On 11/06/2020at 12:00 pm, the laboratory manager/technical consultant #2 stated to

	surveyor #1 the laboratory began using two BD Bactec FX40 analyzer to perform patient blood culture testing on 09/08/2020; (2) Surveyor #1 reviewed the performance specification records for the analyzers. There was no evidence the data had been reviewed and evaluated by the laboratory until 11/06/2020; (3) Surveyor #1 reviewed the records with the laboratory manager/technical consultant #2, who stated on 11/06/2020 at 12:30 pm, the data had not been signed and dated as approved until 11/13/2018. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")
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: Based on a review of records, manufacturer's instructions, and interview with the assistant laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: SIEMENS DIMENSION EXL WITH LM ANALYZERS (1) On 11/03/2020 at 11:00 am, the assistant laboratory manager stated the following to surveyor #2: (a) *CMP, Ammonia, Amylase, CK (Creatine Kinase), CKMB, HDL (High Density Lipoprotein), Triglycerides, Direct Bilirubin, Ethyl Alcohol, Iron, Total Iron Binding Capacity, Lactic Acid, Lipase, Lithium, Magnesium, Uric Acid, CRP (C-Reactive Protein), Myoglobin, Troponin I, Acetaminophen, Carbamazepine, Digoxin, Gentamicin, HCG (Human Chorionic Gonadotropin), Phenobarbital, Dilantin, T-Uptake, Thyroxine, TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), Salicylate, Theophylline, Tobramycin, Vancomycin and Valproic Acid testing were performed on the Siemens Dimension EXL with LM analyzer, denoted by the laboratory as "B" as the primary method; (b) *CMP, Ammonia, Ethyl Alcohol, Amylase, CK, CKMB, Direct Bilirubin, Lipase, Magnesium, Troponin I, Acetaminophen, HCG, Digoxin, Dilantin, Thyroxine, TSH, CRP, Myoglobin, CSF (Cerebral Spinal Fluid) Glucose, CSF Protein, and Urine Creatinine testing were performed on the Siemens Dimension EXL with LM analyzer, denoted by the laboratory as "D" as the back-up method. (2) On 11/05/2020, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's weekly and monthly maintenance logs for both analyzers titled, "Dimension EXL with LM and Dimension EXL 200 integrated chemistry system Weekly/Monthly Maintenance". The requirements were as follows: (a) Weekly (i) Clean Outside of R2 Probe (ii) Clean Outside of HM Wash Probes (c) Monthly (i) Replace IMT Pump Tubing (ii) Clean IMT System (iii) Replace/Clean Air Filters (iv) Replace HM Pump Heads (v) Stylette HM Wash Probes (vi) Clean R2 Drain (vii) Clean R3 Drain (3) Surveyor #1 then reviewed maintenance records for both analyzers from January through October 2020. The following was identified: (a) "B" Analyzer (i) Weekly - Not documented as performed between (aa) 02/22/2020 and 03/03/2020 (bb) 04/01/2020 and 04/12/2020 (cc) 07/15/2020 and 07/28/2020 (ii) Monthly (aa) Replace IMT Pump Tubing, Clean IMT System, Replace/Clean Air Filters, Stylette HM Wash Probes, Replace HM

	Pump Heads, Clean R2 Drain, and Clean R3 Drain not documented as performed between 06/21/2020 and 08/12/2020. (b) "D" Analyzer (i) Weekly - Not documented as performed between: (aa) 08/30/2020 and 09/07/2020 (bb) 09/22/2020 and 10/05 /2020 (ii) Monthly (aa) Replace IMT Pump Tubing, Clean IMT System, Replace /Clean Air Filters, Stylette HM Wash Probes, Replace HM Pump Heads, Clean R2 Drain, and Clean R3 Drain not documented as performed between 02/12/2020 and 04 /06/2020; (bb) Clean IMT System, Replace/Clean Air Filters, Stylette HM Wash Probes, Replace HM Pump Heads, Clean R2 Drain, and Clean R3 Drain not documented as performed between 08/18/2020 and 10/15/2020; (cc) Replace IMT Pump Tubing not documented as performed after 08/18/2020. (4) Surveyor #1 reviewed the records with the assistant laboratory manager who stated on 11/06/2020 at 09:06 am, the above maintenance procedures had not been performed as required. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein SYSMEX CA-660 ANALYZER (1) On 11/03/2020 at 11:00 am, the assistant laboratory manager stated to surveyor #2 PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing was performed using the System CA-660 analyzer; (2) On 11/05/2020 surveyor #1 reviewed reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer titled, "Sysmex CA-600 Maintenance Checklist". The quarterly requirements were as follows: (a) Perform LED Calibration (b) Clean Filters Under Front of Analyzer (3) Surveyor #1 then reviewed maintenance records from January 2019 through the October 2020. Quarterly maintenance had not been documented as performed between 08/24/2019 and 01/03/2020; (4) Surveyor #1 reviewed the records with the assistant laboratory manager, who stated on 10/05/2020 at 2:45 pm, the quarterly maintenance procedures had not been performed as identified above.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the assistant laboratory manager, the laboratory failed to ensure function checks were within the manufacturer's acceptable limits before patient testing was conducted for 4 of 9 months. Findings include: (1) On 11/03/2020 at 11:00 am, the assistant laboratory manager stated the following to surveyor #2: (a) *CMP, Ammonia, Amylase, CK (Creatine Kinase), CKMB, HDL (High Density Lipoprotein), Triglycerides, Direct Bilirubin, Ethyl Alcohol, Iron, Total Iron Binding Capacity, Lactic Acid, Lipase, Lithium, Magnesium, Uric Acid, CRP (C-Reactive Protein), Myoglobin, Troponin I, Acetaminophen, Carbamazepine, Digoxin, Gentamicin, HCG (Human Chorionic Gonadotropin), Phenobarbital, Dilantin, T-Uptake, Thyroxine, TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), Salicylate, Theophylline, Tobramycin, Vancomycin and Valproic Acid testing were performed on the Siemens Dimension EXL with LM analyzer, denoted by the laboratory as "B" as the primary method. (2) On 11/05/2020, surveyor #1 reviewed the manufacturer's instructions for

	performing function checks on the analyzer. The manufacturer's maintenance log titled, "Log 1-Daily Maintenance Log" required daily recording of the cuvette temperature. In addition, the manufacturer's acceptable cuvette temperature range was 36.8 to 37.2 degrees Centigrade (C) (3) Surveyor #1 then reviewed the cuvette temperature records from January through October 2020. The records showed the temperature was beyond the manufacturer's range during 4 of 10 months reviewed for analyzer "B" as follows: (a) June - 4 of 30 temperatures were below 36.8 degrees C; (b) July - 2 of 31 temperatures were below 36.8 degrees C; (c) August - 6 of 31 temperatures were below 36.8 degrees C; (d) September - 4 of 30 temperatures were below 36.8 degrees C. (4) Surveyor #1 reviewed the records with the assistant laboratory manager who stated on 11/06/2020 at 09:06 am, the temperatures had not been maintained as defined by the manufacturer. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the assistant laboratory manager, the laboratory failed to ensure the urine centrifuge was functioning properly. Findings include: (1) On 11/05/2020 at 09:55 am, the laboratory manager/technical consultant #2 stated the following to surveyor #1: (a) The laboratory performed microscopic urine sediment examinations; (b) The laboratory had used the Model 614V Drucker centrifuge to process urines at a speed of 1500 rpm (revolutions per minute) for 5 minutes until 06/16/2020, when the centrifuge was taken out of service. (2) Surveyor #1 reviewed the function check policy titled, "Urinalysis Centrifuge Calibration Verification" which stated, "In accordance with the manufacturer's guidelines, the RPM calibration and timer calibration must be verified semi-annually"; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2018 and to date in 2020. There was no documentation speed and timer checks had been performed between 11/19/2018 and 12/17/2019. In addition, for 3 of 3 checks performed, the following was identified: (a) 05/14/2018 - The speed had been checked at 3315 rpm, which was not the speed urine specimens were processed. In addition, the timer had not been checked; (b) 11/19/2018 - The speed had been checked at 3324 rpm, which was not the speed urine specimens were processed. In addition, the timer had not been checked; (c) 12/17/19 - The timer had been checked at 10 minutes, which was not the time urine specimens were processed. (4) Surveyor #1 reviewed the findings with the assistant laboratory manager, who stated on 11/05/2020 at 10:15 am, the laboratory did not ensure the urine centrifuge was functioning properly as indicated above.

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 a review of records and interview with the laboratory manager/technical consultant #2 and assistant laboratory manager, the laboratory failed to perform calibration verification every six months. Findings include: ALERE TRIAGE METER PRO (1) On 11/05/2020 at the laboratory manager/technical consultant #2 stated to surveyor #1 D-dimer testing was performed using the Alere Triage Meter Pro analyzer; (2) Surveyor #1 reviewed records for testing performed in 2019 and to date in 2020, and could not locate documentation to prove calibration verification procedures had been performed (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months); (3) Surveyor #1 reviewed the records with the laboratory manager/technical consultant #2 and asked if calibration verification procedures had been performed every six months for D-dimer. The laboratory manager/technical consultant stated on 11/05/2020 at 1:00 pm, calibration verification had not been performed every six months for D-dimer. DIMENSION ANALYZERS (1) On 11/03/2020 at 11:00 am, the assistant laboratory manager stated to surveyor #2 Chloride, Potassium, and Sodium testing were performed as follows: (a) Using the Dimension EXL with LM analyzer denoted by the laboratory as "B" as the primary method; (b) Using the Dimension EXL with LM analyzer denoted by the laboratory as "D" as the back-up method. (2) Surveyor #1 reviewed calibration verification records for Chloride, Potassium, and Sodium (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed between 06/19/2019 and 02/03/2020 for analyzer "B" and analyzer "D" (due 12/2019); (3) Surveyor #1 reviewed the records with the assistant laboratory manager who stated on 11/05/2020 at 09:15 am calibration verification had not been performed every 6 months as shown above.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the assistant laboratory manager, the laboratory failed to perform a negative and positive control material each day of patient testing for 3 of 3 tests. Findings include: CHLAMYDIA (1) On 11/04/2020 at 09:45 am, the assistant laboratory manager stated the following to surveyor #1: (a) Chlamydia testing was performed using the Quidel QuickVue Chlamydia test kit; (b) The laboratory performed negative and positive quality control (QC) materials each day of patient testing. (2) Surveyor #1 reviewed QC and patient testing records from January through October 2020. The review showed that negative and positive QC materials had not been performed 4 of 33 days of patient testing reviewed. The specific days were 01/17/2020, 02/09/2020, 10/06/2020, and 10/15/2020; (4) Surveyor #1 reviewed the records with the assistant laboratory manager, who stated on 11/04 /2020 at 10:05 am, negative and positive QC materials had not been performed each day of patient testing. KETONE TESTING (1) On 11/04/2020 at 09:50 am, the asistant laboratory manager stated the following to surveyor #1: (a) Ketone testing was performed using the K-Check Ketones tablets and serum or plasma samples; (b) The laboratory performed negative and positive QC materials each day of patient testing. (2) Surveyor #1 reviewed QC and patient testing records from January through October 2020. The review showed that negative and positive QC materials had not been performed 8 of 38 days of patient testing reviewed. The specific days were 04/27/2020, 04/28/2020, 05/02/2020, 05/05/2020, 05/25/2020, 06/14/2020, 06/15 /2020, and 06/23/2020; (4) Surveyor #1 reviewed the records with the assistant laboratory manager, who stated on 11/04/2020 at 10:10 am, negative and positive QC materials had not been performed each day of patient testing. CLOSTRIDIUM DIFFICILE (1) On 11/06/2020 at 09:30 am, the assistant laboratory manager stated the following to survyeor #1: (a) Clostridium difficile testing was performed using the Meridian Permier C. diff Tox A/B test kit; (b) The laboratory performed negative and positive QC materials each day of patient testing. (2) Surveyor #1 reviewed QC and patient testing records from January through October 2020. The review showed that negative and positive QC materials had not been performed 8 of 10 days of patient testing reviewed. The specific days were 02/21/2020, 02/25/2020, 06/07/2020, 06/10 /2020, 06/16/2020, 09/08/2020, 09/14/2020, and 09/18/2020; (3) Surveyor #1 reviewed the records with the assistant laboratory manager, who stated on 11/06/2020 at 10:30 am, negative and positive QC materials had not been performed each day of patient testing. 39088 Based on a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to perform a negative and positive control each day of FMH (fetal maternal hemorrhage) RapidScreen testing for 3 of 9 patients; and failed to perform a negative and positive control each day of ABO/Rh and comparability testing for 2 of 17 days of patient testing. Findings include: FETAL MATERNAL HEMORRHAGE SCREENING TEST (1) On 11/03 /2020 at 09:30 am, the laboratory manager/technical consultant #2 stated to surveyor #2 FMH (fetal maternal hemorrhage) RapidScreen testing for the detection of D-positive red cells in D-negative mothers screening kit; (2) On 11/05/2020, the

	laboratory manager/technical consultant stated at 10:43 am to surveyor #2 negative and positive QC (quality control) testing was performed with each patient; (3) Surveyor #2 reviewed QC and patient testing records between 01/09/2019 through 02 /09/2020. The review indicated negative and positive QC testing had not been performed for 3 of 9 patient testing; (5) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2, who stated on 11/05/2020 at 10:55 am that a negative and positive QC materials had been performed with each patient but had not been documented; (6) The following were examples of FMH RapidScreen patient testing when QC testing had not been documented as performed: (a) Testing performed on 02/23/2019 (b) Testing performed on 01/09/2020 (c) Testing performed on 01/17/2020 BLOOD BANK TESTING Findings include: (1) On 11/03/2020 at 09: 28 am, the laboratory manager/technical consultant #2 stated to surveyor #2 the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) Surveyor #2 reviewed records for blood bank testing performed between 01/24/2019 through 06/24/2019 and identified quality control had not been performed for 2 of 17 days when patient Type and Screen or Crossmatch testing had been performed as follows: (a) Patient #1 - A Type and Screen and Crossmatch was performed on 06/20/2019; (b) Patient #2 - A Type and Screen and Crossmatch was performed on 06/23/2019. (3) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2. On 11/06/2020 at 11:35 am, the laboratory manager/technical consultant #2 stated quality control had not been performed as indicated above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 a review of records and interview with the laboratory manager/technical consultant #2, the laboratory failed to ensure that blood products were stored under appropriate conditions for 2 of 4 alarm checks. Findings include: (1) On 11/04/2020 at 09:55 am, the laboratory manager/technical consultant #2 stated the following to surveyor #2: (a) Units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (b) Alarm checks for the refrigerator were performed quarterly by the laboratory. (2) Surveyor #2 reviewed alarm checks records from January 2019 through December 2019 and identified the refrigerator alarm checks had not been performed on a quarter basis as follows: (i) The checks had not been performed between 03/14/2019 and 09/23/2019. (3) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2, who stated on 11/05 /2020 at 02:35 pm the alarm checks had not been performed quarterly as required.
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 a review of written policies and interview with the laboratory manager /technical consultant #2 and the nursing risk manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 9 of 14 units of packed red blood cells. Findings include: (1) On 11/03/2020 at 09:27 am, the laboratory manager/technical consultant #2 stated to surveyor #2 the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) Surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood/Blood Components, Transfusion" under the section, "INTERPRETATION", stated: (a) "Vital signs shall be taken prior to and after procedure. Vital Signs shall be taken prior to the start of infusion, 15 minutes after the start of infusion, 30 minutes after the start of the infusion, 1 hr after start of infusion, at end of transfusion, 1 hr post transfusion and 2 hrs post transfusion." (3) Surveyor #2 then reviewed records for 14 units of PRBCs (Packed Red Blood Cells) that had been transfused between 01/09/2019 through 04/24/2020 for 6 patients, and identified the following: (a) Vitals not taken prior to transfusion (i) Patient #1159875 - Transfused with 1 unit PRBCs (unit #W091018356291) on 01/09 /2019; (ii) Patient #1167029 - Transfused with 1 unit PRBCs (unit #W091019172070) on 04/16/2019. (b) Vitals not taken 30 minutes after the start of infusion (i) Patient #1167029 - Transfused with 1 unit of PRBCs (unit #W091019176700) on 04/16/2019. The unit was started at 11:05 am, vitals taken at 15 minutes 11:20 am, and 11:50 am (45 minutes after start time); (ii) Patient #1189023 - Transfused with 1 unit of PRBCs (unit #W091020103546) on 02/14/2020. The unit was started at 03:45 pm, vitals taken at 15 minutes at 04:00 pm, vitals taken at 06:10 pm (2 hours 10 minutes later). (c) Vitals not taken 1 hour after the start of infusion (i) Patient #1167029- Transfused with 1 unit of PRBCs (unit #W091019172070) on 04/16/2019. The unit was started at 06:55 am, vitals taken at 15 minutes at 07:10 am, vitals taken at 30 minutes (from start time) at 07:25 am, and at the end of the infusion at 09:30 am; (ii) Patient #1167029- Transfused with 1 unit of PRBCs (unit #W091019172070) on 04/16/2019. The unit was started at 08:50 pm, vitals taken at 15 minutes at 09:05 pm, vitals taken at 30 minutes (from start time) at 09:20 pm, and at the end of the infusion at 10:54 pm; (iii) Patient #1167029 - Transfused with 1 unit of PRBCs (unit #W091019126239) on 04/17/2019. The unit was started at 03:25 am, vitals taken at 15 minutes at 03:40 am, vitals taken at 30 minutes (from start time) at 03:55 am, and at 05:26 am (1 hour 31 minutes later); (iv) Patient #1172479 - Transfused with 1 unit of PRBCs (unit #W091019240201) on 07/04/2019. The unit was started at 05:04 pm, vitals taken at 15 minutes at 05:19 pm, vitals taken at 30 minutes (from start time) at 05:34 pm, and at 06:48 pm (1 hour 14 minutes later); (v) Patient #1189023 - Transfused with 1 unit of PRBCs (unit #W091020103546) on 02/14/2020. The unit was started at 03:45 pm, vitals taken at 15 minutes at 04:00 pm, vitals taken at 06:10 pm (2 hours 10 minutes later); (vi) Patient #1193323- Transfused with 1 unit of PRBCs (unit #W091020160252) on 04/26/2020. The unit was started at 07:45 pm,

	vitals taken at 15 minutes at 08:00 pm, vitals taken at 30 minutes (from start time) at 08:15 pm, and at 10:20 pm (2 hours 5 minutes later). (d) Vitals not taken 1 hour post transfusion (i) Patient #1167029 - Transfused with 1 unit of PRBCs (unit #W091019126239) on 04/17/2019. No vitals documented after the infusion ended at 05:26 am; (ii) Patient #1179449 - Transfused with 1 unit of PRBCs (unit #W091019322707) on 10/07/2019. No vitals documented after the infusion ended at 12:30 pm; (iii) Patient #1193323- Transfused with 1 unit of PRBCs (unit #W091020188839) on 04/24/2020. No vitals documented after the infusion ended at 01:42 am. (e) Vitals not taken 2 hour posts transfusion (i)Patient #1167029 - Transfused with 1 unit of PRBCs (unit #W091019126239) on 04/17/2019. No vitals documented after the infusion ended at 05:26 am; (ii) Patient #1179449 - Transfused with 1 unit of PRBCs (unit #W091019322707) on 10/07/2019. Not vitals documented after the infusion ended at 12:30 pm; (iii) Patient #1193323- Transfused with 1 unit of PRBCs (W091020188839) on 04/24/2020. No vitals documented after the infusion ended at 01:42 am. (4) Surveyor #2 reviewed the findings with the nursing risk manager. The nursing risk manager stated on 11/05/2020 at 03:00 pm the written policy and procedure for blood administration had not been followed as indicated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the assistant laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using two different Chemistry analyzers. Findings include: (1) On 11/03/2020 at 11:00 am, the assistant laboratory manager stated to surveyor #2 Acetaminophen, Ammonia, Digoxin, Quantitative HCG (Human Chorionic Gonadotropin), CKMB, Myoglobin, Troponin I, and Alcohol testing were performed as follows: (a) The Siemens Dimension EXL with LM analyzer, denoted by the laboratory as "B" was used as the primary method; (b) The Siemens Dimension EXL with LM analyzer, denoted by the laboratory as "D" was used as the back-up method. (2) On 11/05/2020, surveyor #1 reviewed 2019 and 2020 comparison data for the analyzers. There was no evidence the relationship between the analyzers had been evaluated twice in 2019 and to date in 2020 as follows: (a) There was no documentation the relationship between the analyzers had been evaluated prior to 12 /19/2019; (b) There was no documentation the relationship between the analyzers had been evaluated after 12/19/2019 and to date in 2020. (3) On 11/06/2020, Surveyor #1 reviewed the records with the assistant laboratory manager and asked if the relationship between the analyzers had been evaluated prior to or after 12/19/2019. The assistant laboratory manager stated on 11/06/2020 at 09:30 am, the comparison testing had not been performed prior to 12/19/2019 and to date in 2020.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with the laboratory manager/technical consultant #2 and assistant laboratory manager, the laboratory director failed to ensure urine sediment examinations were being performed using a standardized method. Findings include: (1) On 11/05/2020 at 09:55 am, the laboratory manager/technical consultant #2 stated the following to surveyor #1: (a) The laboratory performed microscopic urine sediment examinations; (b) The laboratory began processing urine specimens in the Hamilton Bell Vanguard centrifuge, a fixed speed centrifuge, on 06/16/2020 after the previous urine centrifuge had been taken out of service. (2) Surveyor #1 then reviewed the procedure titled, "Urine Analysis". The procedure stated, "Place a cap on the KOVA tube and centrifuge for 3-5 minutes in the Urinalysis centrifuge". The procedure did not specify the speed urine specimens were to be processed in the centrifuge; (3) Surveyor #1 asked the assistant laboratory manager what speed the laboratory processed urine specimens. The assistant laboratory manager stated on 11/05/2020 at 10:15 am, the laboratory had processed urine specimens in the previous centrifuge at a speed on 1500 rpm for 5 minutes; (4) Surveyor #1 reviewed the function check records for the Hamilton Bell Vanguard centrifuge which showed the centrifuge had been checked on 05/14/2020 at a speed of 3409 rpm and a time of 5 minutes; (5) Surveyor #1 determined the laboratory was not centrifuging urine specimens at a standardized speed to ensure the accurate recovery of all components, since they were processing the specimens at 3409 rpm, and reviewed the records with the assistant laboratory manager. The assistant laboratory manager stated on 11/05/2020 at 10:20 am, urine specimens were not being processed at a standardized speed. NOTE: The following is a reference obtained by the surveyor following the survey which verifies the facility was not centrifuging patient urine specimens at a standardized speed to ensure the accurate recovery of all components: (a) The textbook "A Handbook of Routine Urinalysis" by Sister Laurine Graff (J.B. Lippincott Company), states "In an attempt to standardize the microscopic examination, the laboratory should adopt a regulated speed, time, and amount for the centrifugation of the urine specimens. Mix the specimen and then place approximately 10-15 ml of urine into a centrifuge tube, and centrifuge at 2000 rpm for about 5 minutes".
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of

	testing for 1 of 4 testing persons. Findings include: (1) On 11/03/2020, surveyor #2 reviewed 2019 and 2020 personnel records. The following was identified: (a) Testing Person #7 - The initial training for this person was completed on 11/01/2019. There was no evidence that a semiannual evaluation had been performed (due 05/2020). (2) Surveyor #2 reviewed the records with the laboratory manager/technical consultant #2 who stated on 11/03/2020 at 10:48 am there were no records to prove the above person had been evaluated semiannually.
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 a review of records and interview with the laboratory manager/technical consultant #2, the technical supervisor failed to evaluate testing persons at least semiannually during the first year of performing high complexity testing. Findings include: (1) On 11/03/2020, surveyor #2 reviewed personnel records for 4 persons who performed high complexity testing. For 1 of the persons, a semiannual competency evaluation had not been performed. (a) Testing person #7 - Training had been performed 11/01/2019. The semiannual competency evaluation had not been performed until 10/30/2020 (the evaluation was due 05/2020). (2) Surveyor #2 reviewed the records with the laboratory manager/technical consultant, who stated on 11/03/2020 at 10:48 am that 1 of 4 testing persons performing high complexity testing did not have semiannual evaluation performed as indicated above. High Complexity Testing Includes: 1. Immunohematology - Crossmatches, including ABO/Rh typing, Antibody screens, Compatibility testing using the tube method. 2. Microbiology testing - Blood Cultures, Gram Stain, Direct Acid Fast Bacilli Smears, Ova and Parasite testing, Bacterial Identification and Susceptibility testing.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager/technical consultant #2, the technical supervisor failed to ensure testing persons performing high complexity testing had been evaluated at least annually for 4 of 8 testing persons. Findings include: (1) On 11/03/2020, surveyor #2 reviewed personnel records for 8 persons who performed testing in 2019 and 2020. For 4 of the 8 persons, there was no evidence annual evaluations had been performed as follows: (a) Immunohematology (i) Testing Person #1 - The 2020 annual evaluation not performed (due 05/2020); (ii) Testing Person #8 - The 2019 and 2020 annual evaluation not performed (due 02/2019 and 02/2020); (iii) Testing Person #10 - The 2019 annual evaluation not performed

	(due 02/2019); (iv) Testing Person #11 - The 2020 annual evaluation not performed (due 05/2020); (b) Microbiology (i) Testing Person #8 - The 2019 and 2020 annual evaluation not performed (due 02/2019 and 02/2020); (ii) Testing Person #11 - The 2020 annual evaluation not performed (due 05/2020); (2) Surveyor #2 reviewed the findings with the laboratory manager/technical consultant #2 who stated on 11/03 /2020 at 10:20 am the annual evaluations had not been performed in 2019 and/or 2020 for the 4 testing persons as indicated above. High Complexity Testing Includes: 1. Immunohematology - Crossmatches, including ABO/Rh typing, Antibody screens, Compatibility testing using the tube method. 2. Microbiology testing - Blood Cultures, Gram Stain, Direct Acid Fast Bacilli Smears, Ova and Parasite testing, Bacterial Identification and Susceptibility testing.