Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660286	02/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Liberty Dayton Regional Medical Center	1353 North Travis Street, Liberty, 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	An announced survey of the laboratory was conducted from 01/30/2024 through 02/01/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document required attestation signatures for 2 of 19 PT events reviewed from June 2022 to December 2023. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as its PT provider. 2. Review of API instructions revealed: "For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 3. Further review of the PT records from June 2022 to December 2023 revealed the following 2 of 19 reviewed events where results did not have the attestation statements signed by the Laboratory Director or designee: API 2023 Immunology/Immunohematology 1st Event API 2023 Chemistry Misc. Verification 1st Event 4. In an interview on 01/30/2024 at 1545 hours in the office, the laboratory's General Supervisor (as listed on submitted form CMS 209) confirmed the findings.
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 the review of the laboratory's policies and confirmed in an interview, the laboratory failed to have a written procedure for one of eight moderate complexity tests: serum acetest or serun ketone. The findings were: 1. Review of the laboratory's policies revealed the laboratory failed to have a written procedure for one of eight moderate complexity tests for serum acetest or serum ketone. 2. An interview with the testing personnel #14 on 02/01/2024 at 11:09 am in a conference room confirmed the above findings.
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 surveyor's observations in the laboratory, review of manufacturer instructions/package inserts and staff interview, the laboratory failed to document open, reconstitution or amended expiration dates for two of two coagulation controls in use observed. Findings included: 1. Surveyor's observations on 01/31/2023 at 1140 hours in the laboratory revealed two reconstituted Hemosil controls loaded on the ACL TOP 350 coagulation analyzer, the Hemosil Abnormal Control 3 (Lot N0431121), and the Hemosil Normal Control 1 (Lot N0531900). There was no open /reconstitution date or amended expiration date documented on either of the two control vials. 2. Review of the Hemosil Abnormal Control 3 - 0020014100 manufacturer instructions (document 303981 R2 04/2018) revealed: "Reagent storage and stability ...Stability after reconstitution: - at 2-8C (Degrees Celsius) in the original vial: 24 hours - at 15-25C in the original vial: 24 hours" 3. Review of the Hemosil Normal Control 1 - 0020013900 manufacturer instructions (document 303975 R2 04 /2018) revealed: "Reagent storage and stability ...Stability after reconstitution: - at 2-8C in the original vial: 24 hours - at 15-25C in the original vial: 24 hours" 4. In an interview on 01/31/2024 at 1209 hours in the laboratory, Testing Person number 14 (as listed on submitted form CMS 209) confirmed the findings.
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 the manufacturer's instructions, review of the laboratory's maintenance logs from 7/13/23 to 12/31/23, and confirmed in interview, the

laboratory failed to document the total of 42 of 170 days of daily maintenance, three of six monthly scheduled maintenance reviewed for Cobas pro chemistry analyzer. The findings were: 1. An interview with the technical consultant on 01/30/2024 at 10: 00 am confirmed the cobas pro chemistry analyzer go-live date was 7/13/2023, 2. Review of the manufacturer's instructions titled cobas pro integrated solutions User Guide (Publication version 3.2 Software version 0203. OS-01353-05) under List of Maintenance Intervals revealed the following: " ISE analytical unit Running a daily wash rack-performs Daily c503 analytical unit Performing maintenance of the photometric system-performs Monthly Cleaning the filters-performs Monthly e801 analytical unit Cleaning probes and nozzles-performs Daily" 3. Review of the laboratory's ISE maintenance logs from 7/13/23 to 12/31/23 revealed the laboratory failed to document 18 of 170 days of daily maintenance reviewed. 7/15/2023 7/16 /2023 7/17/2023 7/22/2023 7/23/2023 7/24/2023 7/29/2023 7/30/2023 8/5/2023 8/6 /2023 8/7/2023 8/14/2023 8/21/2023 8/22/2023 8/23/2023 9/26/2023 9/30/2023 3. Review of the laboratory's c503 maintenance logs from 7/13/23 to 12/31/23 revealed the laboratory failed to document three of six months of monthly maintenance reviewed. August, 2023-No documentation of Cleaning the filters October, 2023-No documentation of Cleaning the filters November, 2023-No documentation of Performing maintenance of the photometric system and Cleaning the filters. 4. Review of the laboratory's e801 maintenance logs from 7/13/23 to 12/31/23 revealed the laboratory failed to document 24 of 170 days of daily maintenance reviewed. 7/15 /2023 7/16/2023 7/17/2023 7/22/2023 7/23/2023 7/24/2023 7/29/2023 7/30/2023 8/5 /2023 8/6/2023 8/7/2023 8/12/2023 8/13/2023 8/14/2023 8/19/2023 8/20/2023 8/21 /2023 8/22/2023 9/22/2023 9/23/2023 9/28/2023 9/29/2023 9/30/2023 5. Random review of the daily patient volume for ISE analytical unit for above dates revealed, ISE analytical unit 7/22/2023 Total Patient Volume was 18 7/29/2023 Total Patient Volume was 12 8/6/2023 Total Patient Volume was 18 8/23/2023 Total Patient Volume was 24 9/26/2023 Total Patient Volume was 27 6. Review of the Monthly patient volume for c503 analytical unit for the above months revealed, c503 analytical unit August, 2023 Total patient volume was 2120. October, 2023 Total patient volume was 1736. November, 2023 Total patient volume was 1670. 7. Random review of the daily patient volume for e801 analytical unit for above dates revealed, e801 analytical unit 7/17/2023 Total patient volume was 18 7/24/2023 Total patient volume was 17 8 /14/2023 Total patient volume was 10 8/21/2023 Total patient volume was 11 9/23 /2023 Total patient volume was 4 9/28/2023 Total patient volume was 12 8. An interview with the testing personnel #14 on 01/31/2024 at 12:34 pm in a conference room confirmed the above findings. 44698 B. Based on review of manufacturer instructions and laboratory's maintenance records for the ACL TOP 350 coagulation analyzer, patient test volumes and staff interview, the laboratory failed to document 2 of 16 required weekly maintenance from September to December 2023. Findings included: 1. Review of the "ACL TOP Family and ACL TOP Family 50 Series Hemostasis Testing Systems Basic Operator Training Manual" (IL Training Center Rev 1.1 [2019] and Rev1.2 [2020]) instructions for instrument's maintenance revealed: "Weekly Maintenance Clean Cuvette Waste Drawer (All ACL TOP Family Models) Clean Deep Wash and Clean Cup (All ACL TOP Family Models)" 2. Review of instrument's Maintenance Log Report recorded in the instrument from September to December 2023 revealed the following 2 of 16 reviewed weeks did not have documentation of Clean Deep Wash and Clean Cup, one of the required weekly maintenance components: Week of September 17 to 23, 2023 - no documentation of Clean Deep Wash and Clean Cup Last documented: 09/16/2023 Next documented: 09 /25/2023 Week of October 29 to November 4, 2023 - no documentation of Clean Deep Wash and Clean Cup Last documented: 10/24/2023 Next documented: 11/07 /2023 3. In an interview on 01/31/2024 at 1227 hours in the conference room, the

	laboratory's Testing Person number 14 (as listed on submitted form CMS 209) confirmed the findings.
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 review of laboratory's policies/procedures, platelet poor plasma centrifuge verification studies, test volumes and staff interview, the laboratory failed to document platelet poor plasma verification every 6 months as per its own policy for 3 of 3 six-month intervals reviewed from May 2022 to December 2023. Findings included: 1. Review of laboratory's policy "Platelet Poor Plasma" (policy number 1353.04.15) revealed: "Plasma used for coagulation studies must be platelet poor. Centrifuge speed and duration must be established by the laboratory to ensure platelet counts are less than 10,000/uL (microliter). These parameters should be validated every six months or after repair or preventive maintenance of the centrifuge." 2. Review of laboratory's platelet poor plasma (PPP) centrifuge verification studies revealed the laboratory performed these studies as follows: Centrifuge: Stat Spin Express 3 Model: M502-22 Serial Number (SN): 613M50201073 Studies performed: 05/22/2022 Next PPP verification due November 2022, then May 2023, then November 2023 Studies performed: 12/09/2023 Time elapsed between studies: 19 months Centrifuge: Stat Spin Express 3 Model: M502-22 SN: 1127M50204367 Studies performed: 05/22/2022 Next PPP verification due November 2022, then May 2023, then November 2023 Studies performed: 12/09/2023 Time elapsed between studies: 19 months Centrifuge: Quest Centrifuge Model: Horizon 642E SN: not specified Studies performed: 05/22/2022 Next PPP verification due November 2022, then May 2023, then November 2023 No further studies were performed on this centrifuge to date. 3. Review of laboratory's submitted test volumes revealed the laboratory performed 9662 coagulation tests in 2023. 4. In an interview on 01/31/2024 at 1230 hours in the conference room, the laboratory's General Supervisor (as listed on submitted form CMS 209) confirmed the findings.
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 manufacturer instrument manuals, laboratory's policies

	/procedures, new reagent lot roll-over studies, instrument establishment studies, patient test records and staff interview, the laboratory failed to document verification of INR (international normalized ratio) for each new lot of Recombiplastin (thromboplastin) for one of one reagent lot change in 2023. Findings included: 1. Review of the "ACL TOP Family and ACL TOP Family 50 Series Hemostasis Testing Systems Basic Operator Training Manual" (IL Training Center Rev 1.1 [2019]) revealed: "WARNING: Erroneous patient results may report if the INR calculation is not properly set up." 2. Review of manufacturer's "Hemostasis Performance Verification Manual" revealed: "Enter the ISI VALUE of the PT (prothrombin time) reagent (Recombiplastin) lot number in use..." And, ""Enter your current geometric Mean of Normal Reference Interval." And: "If the INR calculation is not properly set up, then erroneous patient results may be reported." 3. Review of laboratory's "ACL Top INR Calculation" (Policy 1353.04.23) revealed: "This procedure is to be performed ... ... With a change of the thromboplastin lot number." And, "The ACL Top use the mean of the normal reference interval and the ISI (international sensitivity index) value to determine the correct INR... ...Note that each lot number of reagents will have a unique ISI value and mean of normal reference interval..." The policy did not address manual verification of instrument's INR calculation, to ensure all parameters' input (mean of the normal reference interval and ISI) and the instrument's calculations were appropriate to achieve the correct result. 4. Review of laboratory's new reagent lot roll-over studies from June 2022 to December 2023 revealed the Recombiplastin new lot studies were performed on 07/27/2023 for lot number N0421616 (expiration 2024-04). The studies did not have documentation of manual verification of instrument's INR calculation to ensure all parameters' input and the instrument's calculations were appropriate to achieve the correct result. 5. Review of the ACL Top 350 (serial number 20102327) hemostasis analyzer's establishment studies performed in January 2021 revealed the studies did not have documentation of manual verification of instrument's INR calculation. 6. Review of laboratory's INR patient test records from September to December of 2023 revealed the laboratory reported 317 INR results calculated by the ACL Top 350 instrument. 7. In an interview on 01/31/2024 at 1140 hours in the conference room, the laboratory's General Supervisor (as listed on submitted form CMS 209) confirmed the findings.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, quality control (QC) records, patient test records and volumes, and staff interview, the laboratory failed to document quality control each day of testing of ABO and Rh (D) blood typing for 3 of 579 days reviewed from June 2022 to December 2023. Findings included: 1. Review

	of laboratory's "Quality Assurance" policy (document number 1353.08.04) revealed: "ABO/Rh typing sera are tested initially and each day of use against Confidence QC material known to be positive and negative for the respective antigen." 2. Review of laboratory's QC records and patient test logs from June 2022 to December 2023 revealed QC was not documented on the following days patient samples were tested: Date: 07/14/2022 Patient tested: 514213 Date: 06/10/2023 Patient tested: 03110 Date: 06/28/2023 Patient tested: 83110 3. Review of laboratory's submitted patient test volumes revealed the laboratory performed 328 ABO/Rh typing procedures annually. 4. In an interview on 02/01/2024 at 1135 hours in the conference room, Testing Person number 14 (as listed on submitted form CMS 209) confirmed the findings.
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: A. Based on review of laboratory's temperature records, policies/procedures, Blood Bank (BB) refrigerator alarm check records, BB refrigerator's continuous temperature monitoring wheel charts and staff interview, the laboratory failed to ensure 4 of 4 BB refrigerator alarm checks from January to December 2023 were activated and recorded at the correct temperature. Findings included: 1. Review of laboratory's temperature records revealed the laboratory used continuous recording wheel charts to document temperature for the Blood Bank refrigerator where blood products were stored. 2. Review of laboratory's "Blood Bank Temperature &(and) Alarm Checks" policy (document number 1353.08.19) revealed: "The alarm will sound on the refrigerator when the temperature is grated than 5.5C (degrees Celsius) and less than 1.5C." And, "For low activation: Place the with the Thermocouple and thermometer in a pan containing ice and water slush at a temperature of -4C. ... For high activation: Place the with the Thermocouple and Thermometer in a pan containing water at 12-15C. ... The Temperature change for the Low and High Activation should occur slowly enough that the measurements are accurate." 3. Review of laboratory's "Blood Bank Quarterly Alarm Check" records for January to December 2023 revealed the following alarm activation/deactivation temperatures: January 2023 Alarm Check performed: 01/16/2023 Low activation documented as: activated at 1.0C, deactivated at 4.0C (alarm set to sound at 1.5C; alarm check did not activate/deactivate the alarm at the correct temperature) High activation documented as: activated at 2.9C, deactivated at 3.4C (alarm set to sound at 5.5C; alarm check did not activate /deactivate the alarm at the correct temperature) April 2023 Alarm Check performed: 04/15/2023 Low activation documented as: activated at 1.0C, deactivated at 3.7C (alarm set to sound at 1.5C; alarm check did not activate/deactivate the alarm at the correct temperature) High activation documented as: activated at 2.9C, deactivated at 3.8C (alarm set to sound at 5.5C; alarm check did not activate/deactivate the alarm at the correct temperature) July 2023 Alarm Check performed: 07/17/2023 Low activation documented as: activated at 3.6C, deactivation unclear (alarm set to sound at 1.5C; alarm check did not activate/deactivate the alarm at the correct temperature) High activation documented as: activated at 2.4C, deactivated at 3.0C (alarm set to

	sound at 5.5C; alarm check did not activate/deactivate the alarm at the correct temperature) October 2023 Alarm Check performed: 10/30/2023 Low activation documented as: activated at 3.9C, deactivated at 1.0 (alarm set to sound at 1.5C; alarm check did not activate/deactivate the alarm at the correct temperature) High activation documented as: activated at 3.0C, deactivated at 2.8C (alarm set to sound at 5.5C; alarm check did not activate/deactivate the alarm at the correct temperature) 4. Review of Blood Bank refrigerator's continuous temperature monitoring wheel charts revealed the wheel charts' recorded temperature for alarm check dates was 5.5-6C. There were no peaks recorded on the wheel charts corresponding to the activation /deactivation temperatures documented on the Blood Bank Quarterly Alarm Check log to indicate temperature changes were detected for the dates the alarm checks were performed. 5. In an interview on 02/01/2024 at 1130 hours in the conference room, Testing Person number 14 (as listed on submitted form CMS 209) confirmed the findings. B. Based on review of laboratory's temperature records, Blood Bank refrigerator's continuous temperature monitoring wheel charts and staff interview, the laboratory failed to document continuous monitoring of blood products' storage for 2 of 365 days reviewed in 2023. Findings included: 1. Review of laboratory's temperature records revealed the laboratory used continuous recording wheel charts to document temperature for the Blood Bank refrigerator where blood products were stored. 2. Review of laboratory's Blood Bank refrigerator's continuous temperature monitoring wheel charts from January to December 2023 revealed the following gaps in blood storage temperature monitoring for 2 of 365 days reviewed: Date: 04/20/2023 Temperature stopped recording 0500 hours Temperature started recording 0830 hours Time without documentation of blood product temperature monitoring: 3.5 hours Date: 05/31/2023 Temperature stopped recording 0300 hours Temperature started recording 0700 hours Time without documentation of blood product temperature monitoring: 4 hours There was no documentation to explain the gaps in temperature monitoring. 3. In an interview on 02/01/2024 at 1130 hours in the conference room, Testing Person number 14 (as listed on submitted form CMS 209) confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, Blood Bank refrigerator's continuous temperature monitoring wheel charts, corrective action records, ABO Transfusion Service test volumes and staff interview, the laboratory failed to document corrective action for 7 of 7 Blood Bank refrigerator out of range temperatures from January to December 2023. Findings included: 1. Review of laboratory's "Blood Bank Temperature &(and) Alarm Checks" policy (number 1353.08.19) revealed: "If the temperature is only 1 C (Degrees Celsius) over the acceptable range, CONFIRM THE DOOR IS CLOSED and monitor the temperature closely. Initial the chart with the date and time of occurrence, and document the reason for the elevation at the deviation point. Fill out a Blood Bank Temperature alarm variance sheet." And, "If the temperature is greater than 1 C over the acceptable range,... and the cause of the problem is not found, the reagents and the blood will be relocated... Document the action by writing "units removed" and the date and time on

	the round temperature chart on the front of the blood bank refrigerator. Initial the chart at the deviation point. Monitor the temperature in 30 minutes. If the temperature is still out of range, notify the supervisor or the Laboratory Director. Arrange for corrective action as instructed. Document the condition and the corrective actions on the Blood Bank Temperature Alarm Variance Sheet." 2. Review of Blood Bank refrigerator's continuous temperature monitoring wheel charts revealed the following times the Blood Bank refrigerator temperature was out of range from January to December 2023: 07/07/2023 at 1600 hours Temperature spiked to 9C Duration of out-of-range temperature: approximately 1 hour 08/27/2023 at 2000 hours Temperature spiked to 8.5C Duration of out-of-range temperature: approximately 1-1.5 hours 09/16 /2023 at 0900 hours Temperature spiked to 9C Duration of out-of-range temperature: approximately 1 hour 09/16/2023 at 1300 hours Temperature spiked to 8C Duration of out-of-range temperature: approximately 2 hour 11/08/2023 at 1300 hours Temperature spiked to 9C Duration of out-of-range temperature: approximately 1-1.5 hours 12/04/2023 at 1600 hours Temperature dropped to 0C Duration of out-of-range temperature: approximately 30 min 12/04/2023 at 1700 hours Temperature spiked to 15C Duration of out-of-range temperature: approximately 1 hour No corrective action was documented on the round wheel charts on the days out of range temperature was recorded. 3. Review of laboratory's corrective action records revealed the laboratory did not fill out the required Blood Bank Temperature Alarm Variance Sheets for the above days/times. The laboratory was asked to provide corrective action records for the above out of range temperatures and no such documentation was available for review at time of survey exit. 4. Review of laboratory's ABO Transfusion Services test volumes revealed testing was performed for 136 ABO Transfusion Services in 2023. 4. In an interview on 02/01/2024 at 1130 hours in the conference room, Testing Person number 14 (as listed on submitted form CMS 209) 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 review of laboratory's quality assessments and staff interview, the laboratory's quality assessment failed to identify and correct issues with reagent stability, instrument maintenance/function checks, quality control, temperature monitoring and corrective actions for 3 of 3 laboratory's hematology /immunohematology test platforms in use from June 2022 to December 2023. Refer to D5417, D5429, D5435, D5545, D5551, D5555 and D5785.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units

	of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of the laboratory's test menu for Cobas pro chemistry analyzer, patient reports performed on cobas pro in November, 2023, and confirmed in an interview, the laboratory failed to include specimen sources for 20 of 20 patient reports reviewed. The findings were: 1. Review of the laboratory's test menu revealed 70 analytes were performed on Cobas pro chemistry analyzer, including ISE analytical unit, c503 analytical unit. and e801 analytical unit. Acetaminophen Alanine aminotransferase Albunin Alkaline phosphatase Ammonia Amylase Aspartate aminotransferase Beta-HCG Bilirubin-Total Calcium Carbon dioxide Cholesterol Creatinine Kinase (CK) Elecsys CK-MB Creatinine Digoxin Ethanol Free thyroxine (FT4) Gamma glutamyl transferase (GGT) Glucose High density lipoprotein (HDL Cholesterol) Hemoglobin A1C Sodium Potassium Chloride Latate dehydrogenase (LDH) Lactate (Lactic Acid) Low density lipoprotein (LDL) Lipase Lithium Magnesium Myoglobin Phenobarbital Phosphorus Prostate specific antigen (PSA) Salicylate Total protein (Serum/plasma) Total protein (Urine) Triglycerides Vitamin D Cortisol DHEA-S Ferritin Follicle-stimulating hormone (FSH) Folate Free triiodothyronine (FT3) Unsaturated Iron-Binding Capacity (UIBC) Progesterone Prolactin Triiodothyronine total (T3) Testosterone Thyroxine (T4) Troponin T Thyroid stimulating hormone (TSH) T-Uptake Urea nitrogen (BUN) Uric acid Valproic acid Vancomycin Vitamin B12 Urine Creatinine Urine microalbumin Urine sodium Urine potassium Urine chloride Urine Amphetamines Urine Barbiturates Urine Benzodiazepines Urine Cannabinoids II (THC) Urine Cocaine Urine Methadone II Urine opiates Urine phencyclidine (PCP) 2. Random review of the patient reports in November, 2023 revealed the laboratory failed to include specimen sources for 20 of 20 patient reports reviewed. 11/1/2023 MRN#: 121323 11/3/2023 MRN#: 501035 11/4/2023 MRN#: 522774 11/7/2023 MRN#: 87491 11/7/2023 MRN#: 527332 11/9/2023 MRN#: 527351 11/9/2023 MRN#: 93796 11/10/2023 MRN#: 526246 11/13/2023 MRN#: 527406 11/14/2023 MRN#: 518412 11/15/2023 MRN#: 525756 11/17/2023 MRN#: 512283 11/17/2023 MRN#: 527441 11/20/2023 MRN#: 518729 11/21/2023 MRN#: 87491 11/21/2023 MRN#: 79307 11/21/2023 MRN#: 518059 11/23/2023 MRN#: 76971 11/27/2023 MRN#: 87491 11/30/2023 MRN#: 504265 3. An interview with the testing personnel #14 on 01/31/2024 at 2:14 pm in the conference room confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records, test/reagent verification studies and staff interview, the Laboratory's Director failed to ensure laboratory's QC was maintained for 2 of 2 hematology/immunohematology laboratory's test platforms in use from June 2022 to December 2023. Refer to D5545 and D5551.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assessments and staff interview, the Laboratory Director failed to ensure the laboratory assessments maintained, identified, and corrected issues in quality of testing for 2 of 2 hematology/immunohematology laboratory's test platforms in use from May 2022 to December 2023. Refer to D5793.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the laboratory's Technical Supervisor failed to document semiannual competency assessment for 2 of 16 testing personnel employed by the laboratory in 2022 and 2023. Findings included: 1. Review of laboratory's personnel records revealed: a. Testing Person number 1 (TP1) was employed by the laboratory from 02/14/2022 to current date. b. Testing Person number 9 (TP9) was employed by the laboratory from 03/21/2022 to 08/01 /2023. 2. Review of training records revealed: a. TP1 training was completed in April 2022. b. TP9 training was completed in September 2022. 3. Review of personnel's competency assessment records for 2022 and 2023 revealed: a. TP1 competencies were documented as follows: - Competency Assessments' date: 10/30/2022 Type of review: marked as "Annual" - Competency Assessments' date: 11/30/2023 Type of review: marked as "Annual" There was no documentation of competency assessment marked as "6 month" (semiannual). b. TP9 competencies were documented as follows: - Competency Assessments' date: 09/12/2022 Type of review: marked as "Orientation" and "6 month" There was no documentation of competency assessment in March 2023 (semiannual) or after, until termination of employment in August 2023. 4. Surveyor requested semiannual competency assessments for TP1 and TP9 on 01/30/2023, 01/31/2023 and 02/01/2023 and no such documentation was available for review prior to survey exit. 5. In an interview on 02/01/2024 at 1417 hours in the conference room, Testing Person number 14 (as listed on submitted form CMS 209) confirmed the laboratory could not locate semiannual competency assessments for TP1 and TP9.