Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0485200	11/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Glen Rose Medical Center	1021 Holden Street, Glen Rose, 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	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a validation survey completed on November 11, 2025.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 direct observation and confirmed in interview, the laboratory failed to remove 20 of 31 expired sodium (Na) citrate (blue top) vacutainer tubes used in patient blood draws for patient testing from use. The findings included: 1.During a tour of the laboratory, on 11/10/2025 at 13:50 hours, the surveyor found 20 following expired tubes in draw station 3: BD Vacutainer Lot 4344934, exp 2025-09-30, Na Citrate 2. In an interview on 11/10/2025 at 13:55 hours, in draw station 3, the general supervisor (GS) 2 confirmed the tubes were expired and were available for patient use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of the Aerospray Hematology Pro Model 7152 Applications Manual, laboratory maintenance logs, and interview with laboratory personnel, the laboratory

	failed to perform and document 20 of 20 weekly maintenance procedures and 5 of 5 monthly maintenance procedures from March 1, 2025, through July 31, 2025. The findings included: 1. Based on review of the Aerospray Hematology Pro Model 7152 Applications Manual, under Section 5 - PREVENTIVE MAINTENANCE AND SAFETY, page 60, the manual stated the following: Weekly Maintenance 1. Wipe the carousel tray and lid using 70-100 percent alcohol. 2. Perform a Volume Test (Section 6.4) 3. Perform a Hub Pattern Testing (Section 4.1). NOTE: If staining will not be performed immediately run a clean cycle after Volume and Hub Pattern tests. 4. Manually clean the nozzles if necessary. 5. Wipe the carousel tray and lid using 70 to 100 percent alcohol 6. Slowly pour 200-300 mL of water into instrument drain to prevent buildup of paper fibers, precipitates, etc. Verify drain is flowing properly and not allowing fluid to back up in bowl or flow out of air vent on case back. 7. Ensure the maintenance procedures listed on the Maintenance Log have been performed and entered into the chart or log." Under Monthly Maintenance, the manual stated the following on page 61: "1. Disassemble and manually clean all nozzles. Refer to Nozzle Disassembly and Cleaning (Section 6.1). 2. Perform a Volume Test (Section 6.4) and Hub Pattern Test (Section 4.1) Section 4.1). NOTE: If staining will not be performed immediately run a clean cycle after Volume and Hub Pattern tests. 3. Disinfect any reagent bottle that is being reused (Section 5.5) 4. Ensure the maintenance procedures in the Preventative Maintenance (PM) log have been performed and entered into the PM chart of log." 2. Based on review of Aerospray Hematology Pro stainer maintenance logs from March 1, 2025, through July 31, 2025, 20 of 20 weekly maintenance procedures were not performed and documented and 5 of 5 monthly maintenance procedures were not performed and documented. 3. In an interview at 11:55 hours on 11/11/2025, the laboratory manager confirmed the missing maintenance had not been documented elsewhere and stated there had been a transition between hematology department leads that may account for the missing maintenance on the hematology slide stainer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, MEDTOX Scan Reader user manual, laboratory quality control records, laboratory patient testing records, and interview with laboratory personnel, the laboratory failed to perform both positive and negative qualitative control each day of patient testing for 29 of 34 days of testing between May 1, 2025, and July 31, 2025. The findings included: 1. Based on review of the laboratory's policy, "1967 MEDTOX Drugs of Abuse Test System", under section V. Quality Control, the policy stated the following: "External controls are urine-based control materials that contain the drugs to be tested at concentrations above the cutoff (positive control) or contain no drug (negative control). Run external controls as they were patient samples. External controls should be ran routinely or as needed for any of the following reasons: To practice the test with a known control. When you open a new lot of devices. Once per week. This is recorded int he LIS. If you suspect that the reader or test device is not working properly. If you have had a repeated unexpected test result. If you suspect that the test devices have been stored improperly. If external controls do not perform as expected, no patient testing is to be performed until the source of the failed QC is identified." 2. Based on review of the MedTox Scan Reader User manual, on page 26, under Quality Control, the manual stated the following:

	"External controls are urine-based control materials that contain the drugs to be tested at concentrations above the cutoff (positive control) or contain no drug (negative control). Run external controls as they were patient samples. Refer to the instructions that accompany the external controls. You should run external controls routinely or as needed for any of the following reasons: (1) to practice the test with a known control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the Reader or test device is not working properly, (5) if you have had a repeated unexpected test result, or (6) if you suspect that the test devices have been stored improperly. External quality control materials are available from MEDTOX and other commercial sources." 3. Based on review of MEDTOX quality control records, positive and negative controls were performed on the following dates between May 1, 2025, and July 31, 2025: 05/02/2025 05/07/2025 05/21/2025 05/28/2025 06/04/2025 06/11/2025 06/18/2025 06/25/2025 07/01/2025 07/09/2025 07/16/2025 07/23/2025 07 /30/2025 4. Based on review of patient records, 43 patients were tested between May 1, 2025, and July 31, 2025. The laboratory performed patient testing on 34 days during this time, and quality control was not performed on 29 of the 34 days. The following 34 patients were tested on days when quality control was not performed: Patient Date 59845 5/4/2025 93767 5/6/2025 164942 5/18/2025 147352 5/19/2025 165003 5/22/2025 165055 5/27/2025 155487 5/29/2025 14223 6/3/2025 165161 6/7 /2025 93843 6/8/2025 87137 6/13/2025 131846 6/20/2025 30834 6/22/2025 39206 6 /22/2025 165319 6/24/2025 55059 6/29/2025 165365 6/29/2025 57115 6/30/2025 131519 6/30/2025 62706 7/3/2025 165424 7/5/2025 37446 7/6/2025 116026 7/6/2025 144198 7/8/2025 30822 7/12/2025 67949 7/12/2025 165496 7/14/2025 159003 7/15 /2025 92692 7/17/2025 165579 7/22/2025 163177 7/24/2025 165598 7/25/2025 11452 7/26/2025 165658 7/31/2025 5. In an interview at 11:50 hours on 11/11/2025, the Laboratory Manager confirmed the laboratory had not established an individualized quality control plan to reduce quality control frequency for the MEDTOX Drugs of Abuse System and that quality control was performed weekly, not each day of patient testing.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) (d)(8) Test control materials in the same manner as patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer instructions for the Germaine Laboratories, Inc. AimTab Ketone Tablets, patient testing records, and interview with laboratory personnel, the laboratory failed to run a serum matrix control when running serum patient samples for 13 of 13 patients tested between May 1, 2025, and July 31, 2025. The findings included: 1. Based on review of the laboratory policy "490 Acetest AimTab Ketone Tablets", under Section VII - Quality Control, the policy stated the following: "BioRad Bilevel Urinalysis 1 (Negative) and 2 (Positive) must perform as expected. A positive result will turn the tablet a dark purple. A negative result will be indicated by the tablet remaining colorless. Controls must be ran alongside each patient sample and results entered into the LIS> QC must be performed on all new lot numbers and shipments before patient samples are run." 2. In contrast, the laboratory's individualized quality control plan (IQCP) titled "Acetone Serum Ketone", under Quality Control, stated the following: "JCO requires policy to be performed to as described in WT.01.01.01 EP1, policy was formed on the basis of the manufacturer's package insert and recommendations. Manufacturer states to use with each new lot and operator. GRMC policy states to run external negative and positive controls (Sure

	Vue Mono HCG controls for serum), with each new lot, each new shipment, with each new operator, and minimally every 30 days. This IQCP to address serum testing only." 4. Based on a review of the manufacturer's instructions-for-use of the "AimTab Ketone Tablets", under QUALITY CONTROL, the instructions stated the following: 'Performance can be confirmed by using commercially available positive and negative control materials. Contact Germine Laboratories at 210-692-4192 for a list of acceptable control materials." The Germaine Laboratories, Inc. document "Approved List of Controls for AimTab Ketone Tablets" listed the following acceptable serum control materials: Reference 13112 Ketone Serum Controls by Germaine Laboratories - Serum 5. Based on a review of patient testing performed between May 1, 2025, and July 31, 2025, the laboratory tested the following 13 patient samples for serum ketones: Sample ID Performed On 1271193 05/28/2025 1272097 06/03/2025 1272309 06/04/2025 1272659 06/05/2025 1273407 06/11/2025 1274476 06/18/2025 1274983 06/22/2025 1276237 06/25/2025 1277547 07/04/2025 1277631 07/05/2025 1278210 07/09/2025 1278380 07/10/2025 1278543 07/12/2025 6. In an interview at 10:52 hours on 11/11/2025, the Laboratory Manager confirmed the laboratory was not using a serum matrix control when performing quality control for the Germaine AimTab Ketone tablets when performing patient testing for serum ketones.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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. This STANDARD is not met as evidenced by: I. Based on laboratory policy, manufactures instructions for use, review of blood bank temperature recorder charts, and confirmed in interview, the laboratory failed ensure quarterly alarm verifications were performed appropriately by biomed for the blood banks continuous monitoring system for one of one refrigerator where blood and blood products were stored for records reviewed in 2024. The findings included: 1. Review of the laboratory policy titled "Blood Bank Maintenance Schedule" section "Quarterly" included the following instructions: "1. Blood Bank Refrigerator: Alarm Verification will be performed by Glen Rose Medical Center's Biomedical personnel. Records of this maintenance are kept in the Maintenance Director's office. 2. Blood Bank Freezer: Alarm Verification will be performed by Glen Rose Medical Center's Biomedical personnel. Records of this maintenance are kept in the Maintenance Director's office. The procedure can be found on page 6 of the Jewett Hema Pro Digital Temperature Power Monitor manual. This manual is in the Blood Bank Equipment Manual binder located in the cabinet above the Blood Bank computer." 3. The following refrigerator was available for the storage of blood and blood products: Helmer Scientific Refrigerator, ID: DFW100639 2051595 4. Surveyor asked for the documentation biomed quarterly alarm verification for 2024 and 2025 for the Helmer Scientific Blood Bank Refrigerator and was provided with documentation for an annual PM in March 2024 that did not include documentation of an alarm verification. Review of the blood bank continuous temperature wheel charts for the duration of March 2024 did not include documentation of a temperature shift to indicate a temperature challenge for the alarm verification. 5. In an interview on 11/11/2025 at 14:58 hours, in the conference room via phone, the biomed representative confirmed

	that the blood bank refrigerator only received annual preventive maintenance, and that the temperature verifications were not documented appropriately. II. Based on laboratory policy, manufactures instructions for use, review of blood bank temperature recorder charts, and confirmed in interview, the laboratory failed ensure quarterly alarm verifications were performed appropriately by biomed for the blood banks continuous monitoring system for one of one freezer where blood and blood products were stored for records reviewed in 2024. The findings included: 1. Review of the laboratory policy titled "Blood Bank Maintenance Schedule" section "Quarterly" included the following instructions: "1. Blood Bank Refrigerator: Alarm Verification will be performed by Glen Rose Medical Center's Biomedical personnel. Records of this maintenance are kept in the Maintenance Director's office. 2. Blood Bank Freezer: Alarm Verification will be performed by Glen Rose Medical Center's Biomedical personnel. Records of this maintenance are kept in the Maintenance Director's office. The procedure can be found on page 6 of the Jewett Hema Pro Digital Temperature Power Monitor manual. This manual is in the Blood Bank Equipment Manual binder located in the cabinet above the Blood Bank computer." 3. The following refrigerator was available for the storage of blood and blood products: Jewett - Freezer, ID:DFW100638 U23U-143040-UU 4. Review of the "Jewett Hema Pro Digital Temperature Power Monitor", page 6, included the following instructions: "1. Hemapro Low Alarm Activation (Always check the low activation first) a. Fill an 8 ounce glass half full of chilled water (+4(degrees) C.). b. Crush ice 1/8/" particles in a separate container. c. Remove the thermistor sensor from the solution bottle, tape or rubber band the probe to test the thermometer (NBS Certified) then insert into the glass. The thermistor sensor and test the thermometer must be at the same level. d. Slowly add crushed ice at the proper rate to provide a temperature drop of no more than 0.5(degrees)C. per minute (approximately 1 teaspoonful every 15 to 25 seconds). e. Stir the test thermometer and thermistor in a circular motion, keeping the ends in the lower liquid, not in the upper ice slurry. f. Log the low alarm activation. 2. HemaPro High Alarm Activation a. Slowly add warm water to the ice slurry (refrigerators) or a container of pre-cooled (-30(degrees) C.) antifreeze solution (freezers) at the proper rate to provide a temperature rise of no more than 0.5(degrees) C. per minute. b. Stir the test thermometer and thermistor in a circular motion, keeping the ends in the lower liquid not the upper ice slurry. c. Log the high alarm activation. 3. Check and log the reaction of the remote monitor during these test procedures if applicable." 5. Surveyor asked for the documentation biomed quarterly alarm verification for 2024 for the Jewett Blood Bank Freezer and was provided with documentation for an annual PM in March 2024 that did not include documentation of an alarm verification. Review of the blood bank continuous temperature wheel charts for the duration of March 2024 did not include documentation of a temperature shift to indicate a temperature challenge for the alarm verification. 6. In an interview on 11 /11/2025 at 14:58 hours, in the conference room via phone, the biomed representative confirmed that the blood bank freezer only received annual preventive maintenance, and that the temperature verifications were not documented appropriately.