Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0488872	03/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ballinger Memorial Hospital/Laboratory	608 Avenue B, Ballinger, 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 onsite recertification survey conducted March 25 & 26, 2025, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. .
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: A. Based on review of the Vidas 3 instrument operator's manual, laboratory maintenance logs, and interview with laboratory personnel, the laboratory failed to perform and document required monthly maintenance for 12 of 12 months in 2024 for the Vidas 3 analyzer. The findings included: 1. Based on review of the Vidas 3 operator's manual (PRN 052733 - Rev.01.A), on pages 3.2 and 3.3, the manual describes a monthly maintenance procedure for cleaning the SPR Blocks. 2. Based on review of maintenance records for 2024, there were no records of the laboratory performing the monthly SPR cleaning maintenance. 3. In an interview at 09:19 hours on March 26, 2025, the Laboratory Manager stated the laboratory cleaned the SPR blocks as necessary but did not realize the cleaning was monthly requirement. B. A. Based on review of the Siemens Dimension EXL instrument operator's manual, laboratory maintenance logs, and interview with laboratory personnel, the laboratory failed to perform and document required monthly maintenance for four of four months between September through December in 2024 for the Siemens Dimension chemistry analyzer. The findings included: 1. Based on review of the Siemens Dimension EXL operator's manual, on pages 5-8 through 5-20, the manual describes required monthly maintenance procedures including: Cleaning the Clot Check Drain on the IMT Port Replacing IMT Pump Tubing Cleaning the IMT System Replacing Instrument Air filters Styletting HM Wash Probes Replacing HM Pump Heads on the wash station Cleaning the R1, R2, and R3 (if RMS Equipped) Drains. 2. Based on a review of

	maintenance records from September 2024 to December 2024, the laboratory did not document required monthly maintenance procedures for four of four months. 3. In an interview at 11:47 hours on March 26, 2025, the Laboratory Manager confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control records, patient testing records, and interview with laboratory personnel, the laboratory failed to evaluate patients tested since the last acceptable quality control value for 26 of 26 patients tested between September 5, 2024, to September 17, 2024. The findings included: 1. Based on review of the laboratory policy "Quality Control", under Corrective Measures for Random and Systemic Errors, the policy stated: "DOCUMENT ALL CORRECTIVE ACTIONS TAKEN IN EITHER THE QUALITY CONTROL LOG SHEETS OR THE LIS PROGRAM IN THE RESPECTIVE ANALYTE. All control values must fall within the set control limits. If the control values are outside the set limits, the following steps should be taken to evaluate the problem: Check to ensure all preventative maintenance has been performed. Check to ensure the current, calibrated lot of reagents is in use. Rerun the control. Make up or open new controls and run them. Make up or open new reagents(s) and run test. Recalibrate method. Let another technologist make up and run reagents and/or controls. Call technical support for the instrument." The policy did not have an instruction to evaluate all patient results obtained in an unsuccessful run back to the last acceptable quality control values. 2. Based on a review of quality control records from September 2024 for Blood Urea Nitrogen (BUN), the laboratory documented the following corrective actions that would require a review of patient results back to the last acceptable quality control run: 9/6/2024 - Level 3 - 01:00 hours - "Rerun - New Reagent". Level 3 is within control limits at 04:48 hours on 9/6/24. The last acceptable Level 3 value was obtained on 9/5/2024 at 20:52 hours. Patients run between the last acceptable quality control run and the unsuccessful run that required reagent replacement included: 10077616 - Ran at 22:26 hours on 9/5/24 10077804 - Ran at 22:39 hours on 9/5/24 9 /10/2024 - Level 3 - 06:40 hours - "Rerun - New Reagent" The last acceptable Level 3 value was obtained on 9/9/2024 at 06:30 hours. Patients run between the last acceptable quality control run and the unsuccessful run that required reagent replacement included: 10076148 - Ran at 07:11 hours on 9/9/24 10077610 - Ran at 07: 11 hours on 9/9/24 10077875 - Ran at 08:04 hours on 9/9/24 10077876 - Ran at 08:04 hours on 9/9/24 10077877 - Ran at 08:04 hours on 9/9/24 10077879 - Ran at 08:28 hours on 9/9/24 10077880- Ran at 09:01 hours on 9/9/24 10077882 - Ran at 13:55 hours on 9/9/24 10077890 - Ran at 13:55 hours on 9/9/24 10077893 - Ran at 13:54 hours on 9/9/24 10077894 - Ran at 13:55 hours on 9/9/24 10077896 - Ran at 11:17 hours on 9/9/24 On 9/17/24, Level 3-06:16 hours - "Rerun- Calibrated Assay" The last acceptable Level 3 value was obtained on 9/16/2024 at 06:20 hours. Patients run between the last acceptable quality control run and the unsuccessful run that required

	reagent recalibration included: 10077987 - Ran at 13:51 hours on 9/16/24 10078189 - Ran at 08:13 hours on 9/16/24 10078190 - Ran at 08:14 hours on 9/16/24 10078197 - Ran at 09:21 hours on 9/16/24 10078198 - Ran at 10:03 hours on 9/16/24 10078201 - Ran at 13:27 hours on 9/16/24 10078202 - Ran at 13:27 hours on 9/16/24 10078204- Ran at 10:00 hours on 9/16/24 10078205 - Ran at 13:30 hours on 9/16/24 10078206 - Ran at 11:55 hours on 9/16/24 10078208 - Ran at 13:30 hours on 9/16/24 10078213- Ran at 11:12 hours on 9/16/24 10078216 - Ran at 13:39 hours on 9/16/24 3. In an interview at 13:47 hours on March 26, 2025, the Laboratory Manager confirmed the findings.