Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0052243	**(X3) Date Survey Completed** 08/28/2024
Name of Provider or Supplier Tyler County Hospital Laboratory	**Street Address, City, State** 1100 West Bluff Street, Woodville, 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 8/27/2024 and 08/28/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 review of laboratory verification studies, laboratory reference ranges, and confirmed in interview, the laboratory failed to verify reference ranges for two of two new analyzers put into use in January 2023, the Sysmex XN-10 hematology analyzer and the Vitros 5600 Chemistry analyzer, before reporting patient test results. The findings included: 1. Review of the laboratory test and instrument menu listed the following two new analyzers and their implementation dates: A. The Vitros 5600 Chemistry analyzer, put into use January 2023 B. The Sysmex XN-10 Hematology analyzer, put into use January 2023 A. 1. Review of the "Vitros System Verification", signed by the laboratory director January 22, 2023, binder did not include a reference range verification for patient testing. A. 2. Review of laboratory policy and patient final reports included the following reference range (RR) for the chemistry analytes glucose, potassium, sodium, Carbon dioxide (CO2), calcium, chloride, alkaline phosphatase (ALP), and aspartate aminotransferase (AST): Analyte: Policy RR [Final Report RR] Glucose: 74 - 106 [75 - 115] md/dL Potassium: 3.5 - 5.1 [3.5 - 5.0] mmol /L Sodium: 137 - 145 [135 - 147] mmol/L CO2: 22 - 30 [24 - 32] mmol/L Calcium:

	8.4 - 10.2 [8.4 - 10.7] mg/dL Chloride: 98 - 107 [95 - 108] mmol/L ALP: 38 - 126 [40 - 170] U/L AST: 15 - 46 [9 - 34] U/L B 1. Review of the Application Manual for the Sysmex XN-10 hematology analyzer introductions included the following instruction: "It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency: The following protocols are provided: ... Reference Range Verification." B 2. Review of the laboratory verification studies did not include a reference range verification. Surveyor asked for the study to verify that the laboratory's reference was appropriate on the new Sysmex XN-10 hematology analyzer and none was provided. B 3. Review of patient final reports included the following reference range on the patient final report: Analyte [Reference range] WBC [5.0-10.0 K/uL] RBC [4.20 - 6.20 M/uL] Hemoglobin [12.0 - 16.0 g/dL] Hematocrit [37.0 - 47.0%] MCV [82.0 - 92.0 fL] MCH [27.0 - 31.0 pg] MCHC [32.0 - 40.0g/dL] Platelets [140 - 440 K/uL] RDW [11.5 - 14.5 %] %Neutrophils [37.0 - 90%] % Lymphocytes [10 - 50%] %Monocytes [0.0 - 12.0%] %Eosinophils [0.0 - 3.0%] % Basophils [0.0 - 2.0%] %Immature Granulocytes [0 -5%] 2. Surveyor asked for a laboratory policy to outline new instrument implementation procedures, and none was provided. 3. In an interview on 8/27/2024 at 14:15 hours, in the office, the general supervisor confirmed that a reference range verification had not been performed on the Vitros 5600 chemistry analyzer or the Sysmex XN-10 hematology analyzer.
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 review of the instrument maintenance activities list, maintenance records, and confirmed in interview, the laboratory failed to perform monthly maintenance on the Vitros 5600 chemistry analyzer for two of seven months reviewed from January 2024 to July 2024. The findings included: 1. Review of the periodic maintenance activity list on the Vitros 5600 chemistry system included the following 11 tasks to be performed monthly: M1: Clean VersaTip Supply M2: Inspect/Clean Supply 3 Pack Opener M3: Inspect/Clean uIA Reagent Supply Top Cover M4: Clean Cuvette Arm M5: Clean Cuvette Incubator M6: Clean PM Discard Chute M7: Clean PM Incubator Slot and Insert Blade Channels M8: Clean/Replace PM Evaporation Caps M9: Clean MicroSensor Cover and Ring Area M10: Inspect/Clean Reagent Cooler filter M11: Perform System Backup 2. Review of the "Periodic Maintenance - Review Log" for January to July 2024 included the following two months where monthly maintenance was not performed: May 2024 July 2024 3. In an interview on 8/28/2024 at 16:20 hours, in the laboratory, the general supervisor confirmed that the monthly maintenance for May and July 2024 had not been performed.
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 review of laboratory policy, blood bank quality control (QC) records, laboratory policy, patient test worksheets, and confirmed in interview, the laboratory failed to include a negative control for nine of nine reagents used in patient ABORh blood grouping and indirect Coombs antibody detection for records reviewed from January 2024 to July 2024. The findings included: 1. Review of the laboratory policy titled "Blood Bank Policy #1121"; section "Quality Control" stated the following: "1. Each day of testing a known positive and negative must be tested. For indirect coombs use a known positive and negative antibody samples with appropriate red cells. Reactivity must be present only in the positive sample." 2. Review of the blood bank worksheets titled "ORTHO Confidence System Blood Bank Quality Control Record" from January to July 2024 included the following nine reagents used in ABORh blood grouping and antibody detection without a negative control: Ortho A/B/D and Reverse Grouping Card containing wells with Anti-A, Anti-B, Anti-D A1 Cell and B Cell suspension for reverse ABO grouping Screen cell 1 (SC1) and screen cell 2 (SC2) for indirect Coombs antibody detection 3. Review of patient test records included the following 39 patients with ABORh blood grouping and antibody detection tested on days where a negative QC was not performed: Date Patient MRN 01/01/2024 10122284-17427 01/02/2024 10122314-2092 01/13/2024 10122754-36494 01/16 /2024 10122754-36494 01/20/2024 10122961-72840 01/26/2024 10123167-11918 01 /27/2024 10123169-71416, 10123201-13382 02/02/2024 10123410-813 02/06/2024 10123410-813 02/07/2024 10123561-75866 03/01/2024 10124332-9681 03/04/2024 10124442-18248 03/06/2024 10124519-2092 03/10/2024 10124639-24207, 10124645-26731 03/25/2024 10125115-3585 04/01/2024 10125338-2092, 10125368-813 04/07/2024 10125574-25834 04/08/2024 10125586-36494 04/16/2024 10125887-26826 04/28/2024 10126307-56231 05/07/2024 10126555-2092 05/08/2024 10126608-11228 05/22/2024 10127042-84977 05/23/2024 10127090-82544 06/05 /2024 10127469-85051 06/07/2024 10127514-43969 06/08/2024 10127567-85064 06 /12/2024 10127627-67434 06/19/2024 10127958-813 06/25/2024 10128138-85169 07 /18/2024 10128860-30112 07/22/2024 10128952-75800 07/25/2024 10129099-82315, 10129068-813 07/28/2024 10129164-36494 07/29/2024 10129161-85343 4. In an interview on 8/28/2024 at 10:35 AM, in the office, the general supervisor confirmed that a negative QC had not been performed for ABORh blood grouping and antibody detection.