Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0692852	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hill Regional Hospital	101 Circle Drive, Hillsboro, 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 April 30, 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of microbiology worksheets, laboratory policy, patient preliminary and final reports, and confirmed in interview, the laboratory failed to have a step-by-step policy for the accurate and reliable idenfication of presumptive organisms three of sixteen patients with urine cultures reviewed from November 2024 to January of

	2025. The findings included: 1. Review of microbiology worksheets used in patient urine microbiology culture workups included the following space at the top of the sheet: "Presumptive ID:_____" 2. Review of laboratory microbiology policies did not include a step-by-step procedure for the presumptive identification of organisms. Surveyor asked what the microbiologist used for presumptive identification, and testing personnel (8) stated the laboratory did not make presumptive identifications. 3. Review of laboratory worksheets and patient reports included the following three patients with urine cultures that included a presumptive organism identification: Date - Patient ID - Culture Source - Presumptive ID 11/01/2024: 10104601 - Urine Culture - E. coli 11/22/2024: 10106129 - Urine Culture - E. coli 01/10/2025: 10109400 - Urine Culture - E. coli 4. In an interview on 4/29/2025 at 15:20 hours, in the conference room, Technical Consultant (TC) 1 confirmed that the laboratory had provided presumptive organism identifications for the above patients, and that a policy was not in place to support the identification of the organisms. Key: E. coli - Escherichia coli
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 the Vitros chemistry analyzer verification studies, manufacturer instructions, and interview with the Technical Consultant, the laboratory failed to perform studies to verify the patient normal ranges were appropriate for the patient population for four of four randomly reviewed analytes. The findings included: 1. Based on the Vitros verification study glossary, under Reference Interval (Normal Range), the manufacturer stated the following: "Some regulations require that the reference interval for each analyte be verified before results are reported out on the instrument. This is interpreted to mean that the normal range for endogenous analytes be validated. Dude to the difficulty in obtaining specimens, validation of reference intervals for therapeutic drugs and some other analytes is not required. Validation is not recommended for assays that have been assigned medical decision limits for health patients (i.e. Cholesterol, HDL, LDL, Triglycerides, Hgb A1c). Normal ranges are typically established from a study which calculates the central 95 percent of results measured on specimens obtained from health persons (minimum of 120 persons). The validation study assumes that this range is correct for the lab's population. Using a minimum of 20 specimens, the validation study proposes the reference interval is consistent for the samples tested." 2. Based on review of the two Vitros chemistry analyzer verification studies, Serial Number 34500706 (Vitros 3400) was approved by the previous laboratory director on 4/6/2023 and Serial Number 76001374 (Vitros XT 7600) was approved on 2/23/2023. Review of the instrument verification studies for the Vitros 3400 and Vitros 7600 found no Reference Interval (Patient Normal Range) studies were performed. Four assays were randomly reviewed: uric acid, chloride, alkaline phosphatase, and total protein. 3. In an interview at 11:42 hours on 4/29/2025, the Technical Consultant stated the laboratory

	had changed methodologies from Siemens chemistry analyzers to Vitros chemistry analyzers and could not find any studies specifically verifying patient normal ranges for the four assays that were randomly reviewed: uric acid, chloride, alkaline phosphatase, and total protein. Key: HDL - high density lipoprotein LDL - low-density lipoprotein Hgb A1c - glycosylated hemoglobin
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: Based on review of laboratory policy, laboratory blood bank temperature charts, and confirmed in interview, the laboratory failed to ensure that the continuous monitoring system recorded the temperature for four of nine weeks for records reviewed in 2024. The findings included: 1. Review of the laboratory blood bank policy titled "Blood Bank Refrigerator" included the following information: "C. Blood units will be stored at 1-6C. D. The temperature is to be monitored on a continuous basis ... E. The temperature recorder chart will be monitored on a daily basis. The chart will be changed on a weekly basis and the change recorded on the Blood Bank Maintenance Log. The tech who changes the chart will write on the chart the date it is changed. Any fluctuations in temperature must be noted and explained." 2. Review of the laboratory's continuous monitoring temperature recorder charts included the following four weeks where the temperature chart had been changed as according to policy, and removed after seven days, with no visible record of the temperature being recorded. 07 /08/2024 to 07/15/2024 at 0001 hours 07/15/2024 to 07/22/2024 at 0001 hours 07/22 /2024 to 07/29/2024 at 0001 hours 07/29/2024 to 08/05/2024 at 0001 hours Surveyor asked as to why the temperature recorder chart had failed to mark the temperature and the technical consultant (TC) 1 stated the pen on the continuous monitoring system must have run out of ink or malfunctioned. 3. In an interview on 4/29/2025 at 16:15 hours, in the conference room, TC 1 confirmed that the temperature had not been recorded on the chart for the above weeks to document continuous temperature acceptability for the blood products stored inside of the refrigerator.
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, coagulation quality control records, and interview with the Technical Consultant, the laboratory failed to document all

corrective actions taken for 25 of 33 quality control values that were outside acceptable limits between February 1, 2023, through March 31, 2023, for the Protime, fibrinogen, and D-dimer assays. The findings included: 1. Based on review of the laboratory policy titled "Lab,hem.08", Attachment VI described actions to take for quality control values that were outside of acceptable limits. The policy did not describe where to record corrective actions for unacceptable quality control values. 2. Based on a review of quality control values from February 1, 2023, through March 31, 2023, the following 25 quality control values were outside of acceptable limits. D-Dimer Control Level 1 2/12/2023 at 15:57:08 hours = the value of 539 ng/mL is -2.1 standard deviations below the mean and outside of acceptable limits. The D-Dimer Level 1 control is within acceptable limits at 16:19:31 hours on 2/12/2023. No corrective actions were documented for the quality control value that was outside of acceptable limits. 2/26/2023 at 16:19:29 hours = the value of 532 ng/mL is -2.4 standard deviations below the mean and outside of acceptable limits. The D-Dimer Level 1 control is within acceptable limits at 16:28:24 hours on 2/26/2023. No corrective actions were documented for the quality control value that was outside of acceptable limits. 2/28/2023 at 08:09:44 hours = the 523 ng/mL value is -2.6 standard deviations below the mean and outside of acceptable limits. 2/28/2023 at 08:19:01 hours - the 529 ng/mL value is -2.5 standard deviations below the mean and outside of acceptable limits. The D-Dimer Level 1 control is within acceptable limits at 08:29:25 hours on 2/28/2023. No corrective actions were documented for the quality control value that was outside of acceptable limits. Protime Normal Control 2/25/2023 at 00: 09:49 = the 10.5 second value is -2.2 standard deviations below the mean and outside of acceptable limits. 2/25/2023 at 00:35:27 = the 10.3 second value is -2.6 standard deviations below the mean and outside of acceptable limits. 2/25/2023 at 00:52:30 = the 10.3 second value is -2.6 standard deviations below the mean and outside of acceptable limits. The Protime Normal control is within limits on 2/25/23 at 01:40:15. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. Fibrinogen Low Control 3/18/2023 at 09:03:06 hours - the 76 mg/dL is -2.5 standard deviations below the mean and outside of acceptable limits. The Fibrinogen Low control is within limits at 10:32:55 hours on 3 /18/2023. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. Fibrinogen Normal Control 3/18/2023 at 09:02:53 hours - the 190 mg/dL is -3.6 standard deviations below the mean and outside of acceptable limits. The Fibrinogen Normal control is within limits at 10:32: 40 hours. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. 3/30/2023 at 09:02:53 hours - the 223 mg /dL is -2.5 standard deviations below the mean and outside of acceptable limits. The Fibrinogen Normal control is within limits at 10:32:40 hours on 3/30/2023. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. Protime Abnormal Control 3/19/2023 at 08:03:04, the 40.6 second value is 2.4 standard deviations above the mean and outside of acceptable limits. 3/19/2023 at 08:22:00, the 40.4 second value is 2.3 standard deviations above the mean and outside acceptable limits. The Protime Abnormal control is within limits on 3/19/23 at 08:27:48 hours. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. Protime Abnormal Control 3/21/2023 at 08:05:59 hours, the 40.1 second value is 2.1 standard deviations above the mean and outside acceptable limits. 3/21/2023 at 08:15:12 hours, the 40.8 second value is 2.5 standard deviations above the mean and outside acceptable limits. At 08:20:25 hours on 3/21/25, the Protime Abnormal Control is within limits. No corrective actions were documented for the quality control values that were outside laboratory acceptability limits. Protime Abnormal Control 3/30/2023 at 08:07:48 hours, the 45.2 second value is 6.1 standard deviations above the means and outside of

	acceptable limits. 3/30/2023 at 08:14:46 hours, the 44.4 second value is 5.6 standard deviations above the means and outside of acceptable limits. 3/30/2023 at 08:40:43 hours, the 43.8 second value is 3.5 standard deviations above the means and outside of acceptable limits. The Protime Abnormal control is within limits at 09:06:06 hours on 3/30/2023. No corrective actions were documented for the values that were outside laboratory acceptability limits. Protime Abnormal Control 3/30/2023 at 16:03:08 hours, the 45.1 second value is 2.4 standard deviations above the means and outside of acceptable limits. At 16:13:58 hours on 3/30/2023, the Protime Abnormal Control is within acceptable limits. No corrective actions were documented for the quality control values that were outside of laboratory acceptability limits. Protime Abnormal Control 3/31/2023 at 00:03:01 hours, the 45.3 second value is 2.5 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 00:15:03 hours, the 47.7 second value is 4.2 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 00:39:58 hours, the 44.8 second value is 2.1 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 01:39:28 hours, the 44.7 second value is 2.1 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 01:45:49 hours, the 45.3 second value is 2.5 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 01:51:01 hours, the 44.9 second value is 2.2 standard deviations above the means and outside of acceptable limits. 3/31/2023 at 02:09:52 hours, the 45.2 second value is 2.4 standard deviations above the means and outside of acceptable limits. At 03:32:15 hours, the Protime Abnormal Control is within acceptable limits. No corrective actions were documented for the quality control values that were outside of laboratory acceptability limits. 3. In an interview on 04/29/2025 at 15:00 hours, the Technical Consultant 1 confirmed that coagulation analyzer corrective actions should have been documented in the quality control records that were reviewed. Key: ng/mL - nanograms per milliliter mg/dL - milligrams per deciliter
D5813	TEST REPORT CFR(s): 493.1291(g) (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, microbiology worksheets, patient final reports, and confirmed in interview, the laboratory failed to ensure the documentation of gram stain results, for 9 of 12 blood cultures that were flagged as positive for growth for records reviewed in October 2024 and January 2025. The findings included: 1. Review of the laboratory policy titled "Processing, Workup, Notifying, Resulting a Positive Blood Culture and Documenting a Critical Value" included the following instructions: "V. Processing a Positive Blood Culture 1. Upon detection of a blood positive blood culture, laboratory personnel should acknowledge the yellow positive bottle that on the display screen after hearing the positive blood culture alarm. After carefully removing the bottle, verify the patient's accession number on the bottle to the patients succession order. 2. Label all in order; Blood, Chocolate, MacConkey, Thioglycolate fluid medium, following the gram stain slide all with the patient's hospital identifiers, for no misidentification. ... 9. After smearing the blood specimen on the slide and placing it on the slide warmer to dry, perform the gram stain and use the reagents next to the sink. Rinse with deionized water allow it to dry again on a slide warmer. 10. Once the smear is dry, drop the immersion oil in place under the

microscope and examine. Observe the description of or color of the bacteria: purple for gram positive or pink slash red for gram negative. Observe the morphology of the bacteria, which appears to be cocci, rods, spirals, or yeast seen. Observe the arrangement of the bacteria as single, clusters, and chains or any additional features in the background." Section "VI. Notifying and Resulting a Positive Blood Culture Gram Stain Critical." Included the following statements: "When notifying a health care provider about the positive blood culture, it is important to communicate clearly and concisely. Here's a suggested approach: 1. The responsible health care provider managing the patient's care is the only one to notify. The infection control team may also be applicable and for additional consultation needed, the microbiologist. 2. Suggested Wording for the Call 'Hello, this is (your name) from the lab. I am calling to inform you about a positive blood culture result for (patient's name, date of birth, and hospital ID) collected on (date and time). The culture has grown in the (pedi, aerobic, and anaerobic bottle) in (set 1 or 2). The grams stain shows (Gram positive cocci in clusters or gram negative rods). Further testing and evaluations will be available the next day.' " 2. Review of laboratory blood culture worksheets and patient reports included the following nine patients with blood cultures flagged for positive growth with no documentation of the gram stain result in the patient report: October 2024 Date Collected, Patient ID, Accession Number 10/07/2024, 10102789, 65001: Review of the "Microbiology Specimen Worksheet" did not indicate which blood culture bottle (aerobic, anaerobic, or pediatric blood culture bottle) came off as positive. Review of the patient final report did not include the gram stain result for each culture bottles that came off positive. 10/09/2024, 10102951, 65579: Review of the "Microbiology Specimen Worksheet" indicated that both the aerobic and anaerobic blood culture bottles came off positive for growth. There is no documentation that each bottle was gram stained. Review of the patient final report did not include the gram stain result for each culture bottles that came off positive. 10 /15/2024, 10103374, 67037: Review of the "Microbiology Specimen Worksheet" did not indicate which blood culture bottle came off as positive or gram stain results. Review of the patient report did not include a gram stain result. 10/15/2024, 10103374, 67032: Review of the "Microbiology Specimen Worksheet" did not indicate which blood culture bottle came off positive or gram stain results. Review of the patient final report did not include a gram stain result. January 2025 Date Collected, Patient ID , Accession Number 01/08/2025, 10109246, 89225: Review of the "Specimen Submission Worksheet" did not indicate which blood culture bottle came off positive. Review of the patient final report did not include the gram stain result. 01/20/2025, 10110006, 92630: Review of the "Microbiology Specimen Worksheet" included check marks next to the words "aerobic" and "anaerobic" (bottles) to indicate they came off positive. Review of the patient final report did not include the gram stain result for each culture bottles that came off positive. 01/20 /2025, 10110006, 92637: Review of the microbiology worksheet included check marks next to the words "aerobic" and "anaerobic" (bottles) to indicate they came off positive. Review of the patient final report did not include the gram stain result for each culture bottles that came off positive. 01/27/2025, 10110399, 94269: Review of the "Microbiology Specimen Worksheet" included check marks next to the words "aerobic", "anaerobic", and "pediatric" (bottles) to indicate they came off positive. Review of the patient report did not include the gram stain results for each blood culture bottle that came off as positive for growth. 01/27/2025, 10110399, 94276: Review of the "Microbiology Specimen Worksheet" included check marks next to the words "aerobic", "anaerobic", and "pediatric" (bottles) to indicate they came off positive. Review of the patient report did not include the gram stain results for each culture bottle that came off as positive for growth. 4. In an interview on 4/29/2025 at 13:10, in the conference room, technical consultant (TC) 1 confirmed the gram stain

	results were not on the patient final report as part of the critical reporting process after a blood culture bottle comes off positive for growth.