

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0675381	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Pittsburg Hospital, Llc	Street Address, City, State 2701 Us Hwy 271 North, Pittsburg, 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	
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of reagent instructions for use (IFU), laboratory policy, laboratory documents, and confirmed in an interview, the laboratory failed to follow its own policy for acceptability criteria for 13 of 20 patients used in establishing a new normal patient range for one of one Prothrombin Time (PT) coagulation reagent lot rollover reviewed in 2022. The findings included: 1. Review of the PT reagent, RecombiPlasTin 2G, instructions for use, section "Instrument/test procedures" had the following caution statement: "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot." 2. Review of the laboratory policy titled "Protime" had the following form titled "Medication History Form For Normal Range Study" and the following questions: "1. Are you taking any antibiotics: Yes No If yes, please list antibiotics: _____ 2. Do you take Vitamin K? Yes No 3. Do you take birth control? Yes No 4. Do you take thyroid medication? Yes No 5. Do you take aspirin? Yes No 6. Does your diet consist of a large amount of green leafy vegetables (10-12 servings), per week? Yes No If any of the above questions were answered "yes", this specimen is invalid for the normal range study. Collect a different patient specimen." 3. Review of laboratory documents for RecombiPlastin 2G, lot number N1117610, normal range study evaluated on 8/18/2022 had the following 13 patients who answered yes to one or more questions but were included in the normal range study: Patient 1: Answered 'yes' to taking Vitamin K, and daily Aspirin. Patient 4:</p>

Answered 'yes' to taking thyroid medication and a diet of 10-12 servings a week of green leafy vegetables. Patient 5: Answered 'yes' to taking thyroid medication, daily aspirin, and a diet of 10 to 12 servings a week of green leafy vegetables. Patient 6: Answered 'yes' to taking vitamin K. Patient 7: Answered 'yes' to taking vitamin K. Patient 8: Answered 'yes' to taking vitamin K. Patient 10: Answered 'yes' to taking thyroid medication and daily aspirin. Patient 12: Answered 'yes' to taking birth control. Patient 14: Answered 'yes' to taking vitamin K and aspirin. Patient 15: Answered 'yes' to a diet of 10 to 12 servings a week of green leafy vegetables. Patient 16: Answered 'yes' to taking vitamin K and a diet consisting of 10-12 servings a week of green leafy vegetables. Patient 17: Answered 'yes' to antibiotics. Patient 25: Answered 'yes' to taking daily aspirin. 4. In an interview on 5/10/2023 at 09:45 hours, in the conference room, the Director of Laboratory Services confirmed that patients who did not meet the acceptability criteria for a normal range study had been utilized in the new lot RecombiPlastin Prothrombin Time normal patient range study.

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:
Based on review of instrument operator's manuals, laboratory maintenance logs, and interview with facility personnel, the laboratory failed to perform and document all required monthly maintenance procedures for 5 of 12 months reviewed between May 2022 and May 2023. The findings included: 1. Based on review of the Dimension EXL chemistry analyzer operator's manual, in Chapter 7 - Maintenance, under Monthly Maintenance, the manual stated: "The seven monthly maintenance procedures are: 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 wash station Cleaning the R2 and R3 drains" 2. Based on review of laboratory maintenance logs, the laboratory failed to perform and document the following maintenance procedures: July 2022 - Replace IMT Pump Tubing, Replace/Clean air filters, Stylette HM Wash Probes, Replace HM Pump heads, Clean R2 Drain August 2022 - Clean the R2 Drain December 2022 - Replace IMT Pump tubing, Clean IMT System, Replace/Clean air filters, Stylette HM Wash Probes, Replace HM Pump heads, Clean R2 Drain February 2023 - Replace HM Pump Heads and Clean R2 Drain April 2023 - Clean the R2 Drain 3. In an interview at 15:00 hours on 5/10/23 in the laboratory, General Supervisor 2 (as listed on the CMS-209 Laboratory Personnel Report) stated the "if it wasn't documented on the log, it may not have got done."