

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0966458	(X3) Date Survey Completed 10/09/2023
Name of Provider or Supplier Uthealth East Texas Hope Cancer Center	Street Address, City, State 115 Medical Circle Suite 106, Athens, 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 survey conducted 10/09/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory maintenance documents, and confirmed in interview, the laboratory failed to ensure the retention of daily, weekly, monthly, and quarterly maintenance for the Architect c4000 chemistry analyzer for 6 of 18 months reviewed from May 2022 to September 2023. The findings included: 1. Review of the laboratory policy titled "Quality Assessment Program" section "Record Retention" stated the following: "All routine laboratory records are kept for at least 2 years." 2. Review of maintenance activities for the Architect c4000 chemistry analyzer had the following maintenance items to be performed daily, weekly, monthly: Daily: Procedure: 6024 Check 1 mL Syringes Procedure: 6028 Check DI Water Purity Procedure: 6070 Daily Maintenance Weekly: Procedure: 6019 Check ICT Components Procedure: 6021 Clean Mixers Procedure: 6023 Clean Sample /Reagent Probes Procedure: 6056 Clean Cuvettes with Detergent Procedure: 6308 Check HC Wase Pump Tubing Monthly: Procedure: 6016 Check Dispense components Procedure: 6018 Clean Cuvette Washer Nozzles Procedure: 6026 Check Syringes and Valves Procedure: 6300 Clean ICT Drain Tip 3. Review of the laboratory "Maintenance History Report" for the Architect c4000 from May 2022 to September 2023 had the following months with missing documentation of one or more of the above procedures: May 2022: No daily documentation was retained for procedure 6028 "Check DI Water Purity" and procedure 6070 "Daily Maintenance".</p>

No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. June 2022: No daily documentation was retained for procedure 6028 "Check DI Water Purity" and procedure: 6070 "Daily Maintenance". No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. July 2022: No daily documentation was retained for procedure 6028 "Check DI Water Purity" and procedure: 6070 "Daily Maintenance". No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. August 2022: No daily documentation was retained for procedure 6028 "Check DI Water Purity" and procedure: 6070 "Daily Maintenance". No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. September 2022: No daily documentation was retained for procedure 6024 "Check 1 mL Syringes" and procedure: 6070 "Daily Maintenance". No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. October 2022: No daily documentation was retained for procedure 6028 "Check DI Water Purity" and procedure: 6070 "Daily Maintenance". No weekly maintenance documentation was retained. No monthly maintenance documentation was retained. The surveyor queried about the missing maintenance reports and the technical consultant (TC) 2 stated the Architect c4000 chemistry analyzer had been performed but the reports had not been printed to include a complete record of the maintenance for the months above. 4. In an interview on 10/9/2023 at 14:30 hours, in the office, the TC2 confirmed that the laboratory failed to ensure the retention of maintenance documentation for the Architect c4000 chemistry analyzer.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:
Based on surveyor observation, laboratory policy, and confirmed in an interview the laboratory failed to follow its policy for the documentation of the date opened for use for three of three stains observed on October 9, 2023. The findings included: 1. A review of the laboratory policy titled "Labeling of Reagents" had the following instructions: "Requirements for reagents obtained from vendors: Date received. Date opened. Expiration date if different than printed on reagent." 2. In a tour of the laboratory on 10/9/2023 at 11:15 hours surveyor observed the following three stains opened and in use without documentation of when the stain was opened for use: Stat Lab Hema-Diff #1 Fixative, Lot 165212, received 2/10/2023, expired 8/31/2024 Stat Lab Hema-Diff #2 Xanthene, Lot 15172, received 7/5/2022, expired 12/31/2023 Stat Lab Hema-Diff #3 Thiazine, Lot 149829, received 7/5/2022, expired 11/30/2023 3. In an interview on 10/9/2023 at 11:15 hours, in the laboratory, the technical consultant (TC) 2 confirmed that the stain was in use for patient testing and that personnel had failed to document when it had been opened for use.

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 a review of maintenance records, the Centers for Medicare and Medicaid (CMS) form 116, and confirmed in interview, the laboratory failed to document weekly maintenance for the Sysmex XS-1000i hematology analyzer for 30 of 61 weeks reviewed from July 2022 to August 2023. The findings included: 1. Review of the laboratory maintenance form titled "Sysmex XS-1000i Maintenance Log" (LSS-10-6115_April 2017_XS-1000i) had the following maintenance tasks to be performed: Daily: Perform Shutdown Verify Background Verify Pressure/Vacuum Perform Quality Control Weekly: Power Down IPU Monthly Maintenance: Perform Monthly Rinse (1,200 cycles) 30,000 Cycle Maintenance: Replace Air Pump Replace Piercer 2. Review of laboratory maintenance records from July 2022 to August 2023 had the following seven months where weekly maintenance was not documented: February 2023 March 2023 April 2023 May 2023 June 2023 July 2023 August 2023 3. A review of the laboratory provided CMS 116, section VII "Non-Waived Testing" listed the estimated annual test volume for hematology at 47,742. 4. In an interview on 10/9/2023 at 14:15 hours, in the office, the technical consultant (TC) 2 confirmed that powering down the IPU was part of the weekly maintenance and that the laboratory had failed to document it for the above months. Key: IPU - Information Processing Unit