Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0883365	11/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Texas Oncology - Arlington South	515 West Mayfield Suite 101, Arlington, 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 substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 laboratory polices, laboratory annual test volume records, and confirmed in staff interview, the laboratory failed to establish a procedure for staining peripheral blood smears for one of one QuickLink Wright's Stain reagent. Findings included: 1. Review of the laboratory's policy manual did not include a written policy for staining peripheral blood smears using the QuickLink Wright's Stain reagent with

	the following components: a) Preparation of the slides and solutions used in testing. On 11/19/2024 at 12:41 p.m., the laboratory was asked to provide a policy for staining peripheral blood smears using the QuickLink Wright's Stain reagent. No policy was provided. 2. Review of the laboratory's test volume records revealed an annual volume of 785 manual differentials performed on peripheral blood smears. 3. During an interview on 11/19/2024 at 12:41 p.m., Technical Supervisor-1 stated the laboratory did not have a policy for the staining of peripheral blood smears using the QuickLink Wright's Stain reagent. This confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure three of three reagents stored in secondary containers were labeled with proper identification and poured/expiration dates. Findings included: 1. During a tour of the laboratory on 11/19/2024 at 12:03 p.m., the surveyor observed on the counter next to the sink in the laboratory: Three coplin jars labeled as follows: Jar #1: "11-15-24" "11-23-24" "Methanol" "Danger- Poison and Flammable" "May be fatal if swallowed. Harmful if inhaled or absorbed through the skin. Vapor harmful. May cause blindness. Causes irritation to skin and respiratory tract. Upon contact - immediately flush with water for at least 15 minutes. If inhaled - move to fresh air and call a physician. If swallowed - induce vomiting and call a physician. MSDS located in MSDS manual." Jar #2: "11-11-24" "11-22-24" "Accustain" "Danger- Poison and Flammable" "Contains methyl alcohol. May be fatal or cause blindness if swallowed. Upon contact - immediately flush exposed area with soap and water. If inhaled - move to fresh air and call a physician. If swallowed - induce vomiting and call a physician. MSDS located in MSDS manual. Change every other week or as needed." Jar #3 "Water" "change as needed" The laboratory failed to label the secondary containers with lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container. 2. During the exit interview on 11/19/2024 at 1:30 p.m., Technical Supervisor 1 and 2 confirmed the laboratory failed to ensure secondary containers were labeled with proper identification and poured/expiration dates.