Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0918494	06/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Texas Oncology Lab-Beaumont	3010 Harrison Ave, Beaumont, 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 announced survey of the laboratory was conducted on 06/05/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer instructions, laboratory's policies/procedures, verification studies, specimen transport records, test volumes and staff interview the laboratory failed to document monitoring of specimen transport conditions to ensure specimen stability for samples used to perform 24,956 of 513,312 (4.9%) tests in 2023, collected at facility's satellite specimen collection sites in Jasper and Port Arthur. Findings included: 1. Surveyor's observations on 06/05/2024 at 1315 hours in the laboratory revealed a bag of patient samples was delivered from the facility's satellite specimen collection site in Jasper. The specimens were batched by collection device (tube type) in individual biohazard plastic bags. These batched bags were then placed in another larger biohazard plastic bag which was transported in a backpack to the laboratory. There were no icepacks or insulated devises involved in the transportation of these samples. The specimen transport log for this run did not have any indication of storage conditions of the samples prior to shipment to the facility. There was no documentation of specimen conditions during transport or upon arrival. A random sampling of the delivered patient samples included: Patient

(medical record number): 10949035 Sample ID (identification number): 240750872 Tests ordered: CBC (complete blood count) w/Auto Diff w/Reflex, CMP (complete metabolic panel) Patient: 10810362 Sample ID: 240750848 Tests ordered: CBC w /Auto Diff w/Reflex, CMP Patient: 11074585 Sample ID: 240750832 Tests ordered: CBC w/Auto Diff w/Reflex, CMP Patient: 10948985 Sample ID: 240423983 Tests ordered: CBC w/Auto Diff w/Reflex, CMP Patient: 10911912 Sample ID: 240750928 Tests ordered: CBC w/Auto Diff w/Reflex, CMP Patient: 11109057 Sample ID: 240750858 Tests ordered: CBC w/Auto Diff w/Reflex, Smear Rev., CMP 2. In an interview on 06/05/2024 at 1315 hours in the laboratory, when asked, the specimen transport courier stated that the trip from Japer takes approximately 1 hour and 15 minutes without traffic. 3. Review of manufacturer instructions for the Sysmex XN-1000 hematology analyzer (revised February 2014) revealed: "If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2-8C (Degrees Celsius) until it can be analyzed." 4. Review of manufacturer instructions for the tests included in the CMP test order revealed: For Siemens Dimension Flex reagent cartridge Albumin (document REF DF13, Issue Date 2019-04-22): "Specimens are stable for 8 hours at room temperature, 2 days at 2-8C." For Siemens Dimension Flex reagent cartridge Alkaline Phosphatase (document REF DF150, Issue Date 2019-04-08): "Specimens are stable for 8 hours at room temperature, 7 days at 2-8C and 6 months when frozen at -20C or colder." For Siemens Dimension Flex reagent cartridge Alanine Aminotransferase (document REF DF143, Issue Date 2019-04-30): "Separated samples are stable for 7 days refrigerated at 2-8C." For Siemens Dimension Flex reagent cartridge Aspartate Aminotransferase (document REF DF41A, Issue Date 2019-04-01): "Separated specimens are stable for 3 days at 20-25C, 7 days at 2-8C." For Siemens Dimension Flex reagent cartridge Urea Nitrogen (document REF DF21, Issue Date 2019-04-01): "Blood urea nitrogen is stable in separated serum or plasma at room temperature for 3-5 days, 7 days at 4C and indefinitely at -20C." For Siemens Dimension Flex reagent cartridge Calcium (document REF DF23A, Issue Date 2019-05-21): "Specimens are stable for 8 hours at room temperature, 2 days at 2-8C." For Siemens Dimension Flex reagent cartridge Creatinine (document REF DF33B, Issue Date 2019-04-16): "Separated serum and plasma specimens are stable for 24 hours at room temperature, 7 days at 2-8C." For Siemens Dimension Flex reagent cartridge Enzymatic Carbonate (document REF DF137, Issue Date 2019-04-01): "Unopened, separated samples may be stored for 8 hours at room temperature, 2 days at 2-8C." For Siemens Dimension Flex reagent cartridge Glucose (document REF DF40, Issue Date 2019-04-01): "In separated, nonhemolyzed (sic) sterile serum, the glucose concentration is generally stable for 8 hours at 25C and up to 72 hours at 4C." For Siemens QuikLYTE Sodium, Potassium, Chloride (document REF S600, Issue Date 2019-07-19): "Sodium and potassium in serum and plasma (removed form cells) are stable for at least one week either at room or refrigerator (2-8C) temperature. Chloride in serum is stable at either room or refrigerator temperature for 1 week." The manufacturer did not specify the range for "room temperature". 5. Review of laboratory's policy "Transport of Laboratory Specimens" (policy number LAB-SPC-009, last revised 02/19/2024) revealed: "Specimens are then placed in a climate controlled rigid container with temperature regulated supplies i.e. cool packs and/or dry ice." The policy did not specify requirements for documentation of specimen storage, transport conditions to ensure verification of stability. 6. Review of laboratory's "Specimen Transport Storage and Stability Table" (document SPC-009 Attachment B, revised 02/23/2023) revealed the laboratory did not define "room temperature" or "refrigerated temperature" acceptability ranges for storage or transport. It also revealed that laboratory's instructions for CBC sample storage/stability were "8 hours at room temperature, 24 hours refrigerated". This did not match manufacturer instructions above for sample

	stability for the Sysmex XN-1000 hematology analyzer. 7. Review of the laboratory's Sysmex XN-1000 hematology analyzer's verification studies (completed July 2023) did not include sample stability studies to justify deviations from manufacturer instructions. 8. Review of laboratory's specimen transport records revealed there was no documentation of the samples' storage conditions outside the facility prior to their shipment to the laboratory, their conditions during transport or upon arrival. 9. Review of laboratory's annual test volume statistics for 2023 revealed 24,956 of 513,312 (4.9%) tests annually were performed on samples collected and stored at the facility's outlying collection centers in Jasper and Port Arthur. 10. In an interview on 06/05/2024 at 1400 hours in the conference room, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid