Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0913925	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Oncology And Hematology	4383 Medical Drive, San Antonio, 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
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, review of manufacturer's instructions, laboratory policy, current PT (Prothrombin Time) thromboplastin (Dade Innovin) lot roll over, patient final reports, and confirmed in interview, the laboratory failed to follow laboratory policy for determining MNPT (Mean Normal Prothrombin Time) for two of two lots put into use in January 2022 and February 2023. Findings Included: 1. During a tour of the facility on 03/12/2024 at 09:14 a.m., the surveyor observed 1 Siemens Sysmex CA-620 coagulation analyzer in the patient testing area (Serial Number: 23771). 2. Review of thromboplastin reagent manufacturer's instructions, "Siemens Dade Innovin" (Revision 2018-08) revealed the following: "The mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing an MNPT." Review of manufacturer's instructions, "Siemens Healthcare Diagnostics Sysmex CA-600 System" (Revision 08/2018; Approved by the Laboratory Director on: 10/2019) revealed the following: "XIV. Lot Roll Over Procedures Verification of Reference Range: A. 20 Normal Individuals: 10 males; 10 females representing reference population. 20 is the minimum requirement for a statistically valid study. Fresh samples preferred but frozen platelet poor plasma may be used if prepared and thawed per CLSI Guidelines. Note medication history. After review, history may be used for excluding aberrant results. B. Assay samples on current and new lot number reagents

	simultaneously or within 1 hour of each other. C. Calculate mean and 2SD range ... ... A skewed data pool is most likely the result of improper specimen type and additional samples may be required." 3. Review of laboratory policy, "Sysmex CA 620" (Reviewed by the Laboratory Director on 02/16/2023) revealed the following: "Hemostasis Reagent New Lot Number Roll-Over Verification I. Normal Range Study a. 20 Normal Individuals b. 10 males; 10 females representing reference population. c. Fresh samples preferred, frozen samples may be used if prepared and thawed per CLSI (NCCLS) Guidelines for platelet poor. d. Medication History: no Aspirin, hormones, herbal supplements e. 20 is the minimum requirement for a statistical validity." 4. Review of laboratory thromboplastin lot roll overs, "New Coag. Lot Testing" in January 2022 (Approved by the Laboratory Director on 01/18/2022) and February 2023 (Approved by the Laboratory Director on 02/14/2023) revealed the following: a. Dade Innovin Performed: 01/18/2022 New Lot Number: 564605A Expiration Date: 09/16/2024 Review of the lot rollover documentation revealed the laboratory failed to document exclusion or partition criteria for the reference individuals used in the study (i.e., sex, geographical location, medical history, etc.). The surveyor requested the above documentation, and none was provided. b. Dade Innovin Performed: 02/14/2023 New Lot Number: 564605A Expiration Date: 09/16 /2024 Review of the lot rollover documentation revealed the laboratory failed to document exclusion or partition criteria for the reference individuals used in the study (i.e., sex, geographical location, medical history, etc.). The surveyor requested the above documentation, and none was provided. 6. Review of patient final reports revealed the laboratory performed 6,050 PT patient tests from 02/2022-12/31/2023. 7. During an interview on 03/12/2024 with GS-1 at 09:14 a.m., in the laboratory, GS-1 confirmed the laboratory failed to document exclusion and partition criteria for reference individuals used in the lot roll over studies in 2022 and 2023. This confirmed the laboratory failed to follow laboratory policy for determining MNPT for two of two lots put into use in January 2022 and February 2023. Word Key: CLSI-Clinical & Laboratory Standards Institute SD- Standard Deviation Sec- Seconds N-Number of reference individuals GS- General Supervisor Coag-Coagulation NCCLS-National Committee for Clinical Laboratory Standards 49553 Based on review of laboratory policy, laboratory records and staff interview, the laboratory failed to establish a written policy/procedure for instrument comparison for the Siemens Dimension chemistry analyzer for 4 of 4 events in 2022 and 2023. Findings include: 1. Review of laboratory records for instrument comparisons "MC3 vs MC2 Lab Comparison Testing Guide" had the following chemistry analytes in which comparisons are to be performed between analyzers in use: SN: 272024 and SN: DR272014: Na (Sodium) K (Potassium) Cl (Chloride) ECO2 (Carbon Dioxide) Glucose BUN (Blood Urea Nitrogen) Creatinine Calcium Total Protein Albumin ALP (Alkaline Phosphatase) ASP (Aspartate Transaminase) ALT (Alanine Transferase) Bilirubin, Total LDH (Lactate Dehydrogenase) Magnesium GGT (Gamma Glutamyltransferase) Phosphorous Bilirubin, Direct Instrument comparisons were reviewed by the laboratory director on the following dates: 03/28/2022 01/05/2023 (performed late in lieu of September 2022) 03/22/2023 09/20/2023 2. The laboratory was asked to provide a policy/procedure for instrument comparisons and defining acceptability criteria and none was provided. 3. The technical supervisor confirmed the laboratory failed to establish a written policy/procedure for performing calibration verification and defining acceptability criteria for the Siemens Dimension EXL chemistry analyzer conducted on 03/12/2024 at 1600 hours in the conference room. Key: SN: Serial Number
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 policy and staff interview, the laboratory failed to establish a written policy/procedure for performing calibration verification required on four of four analytes for the Siemens Dimension chemistry analyzers. Findings include: 1. Review of laboratory policy "OPERATION OF THE DIMENSION EXL" determined the laboratory failed to establish a written policy/procedure for calibration verification including defining acceptability criteria. The laboratory was asked to provide a policy on calibration verification and defining acceptability criteria and none was provided. 2. The following chemistry analyzers required calibration verification: SN: DR272014 a. Sodium b. Potassium c. Chloride d. Uric Acid SN: 272024 a. Sodium b. Potassium c. Chloride d. Uric Acid 3. The technical supervisor confirmed the findings on 03/12/2024 at 1536 hours by phone. Key: SN: Serial Number
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to

	identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instruction for assays performed on the Siemens Dimension chemistry analyzer, the laboratory's chemistry calibration verification records from 2022 to 2023, and staff interview, the laboratory failed to have documentation of performing calibration verification every six months for one of four analytes in 2022 and 2023. Findings include: 1. Review of the manufacturer's instruction for assays for uric acid for the Siemens Dimension chemistry analyzer for uric acid utilized two calibrators. 2. Review of the laboratory's quality control records from 2022 and 2023 determined the laboratory tested two levels of uric acid quality control material daily. Therefore, calibration verification was required. 3. A review of the laboratory's calibration records from 2022 and 2023 determined the laboratory failed to have documentation of calibration verification for uric acid during the period. 4. The technical supervisor confirmed the findings in an interview conducted on 03/12 /2024 at 1538 hours in the conference room.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records for the Dimension EXL 200 (serial number DR272014) from February 1, 2024 to March 11, 2024, and staff interview, the laboratory failed to have documentation of performing corrective actions for temperatures documented out of acceptable range 14 of 27 test days. The findings include: 1. A review of the laboratory's Dimension EXL 200 temperature records from February 1, 2024 to March 11, 2024 identified the manufacturer's acceptable temperature range for the instrument's cuvettes was listed as 36.8 - 37.2 Celsius. 2. Further review of the records identified 14 of 27 test dates where the documented cuvette temperature was outside the manufacturer's required range. They were: Date Temperature 2/20 36.7C 2/21 36.7C 2/22 36.7C 2/22 36.6C 2/26 36.7C 2 /29 36.6C 3/1 36.6C 3/4 36.7C 3/5 36.6C 3/6 36.6C 3/7 36.6C 3/8 36.7C 3/11 36.7C 3. The laboratory was asked to provide documentation of performing corrective actions on the listed days. No documentation was provided. 4. The technical supervisor confirmed the findings on 03/13/2024 at 1200 hours in the conference room.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 surveyor observation, laboratory policy, quality control (QC) records (November 2023), corrective action logs, patient final reports, and confirmed in interview, the laboratory failed to evaluate patients, since the last acceptable quality control, when QC failed to fall within acceptable ranges and instrument maintenance and calibrations were performed, for 45 of 45 patients tested on the Advia 2120i hematology analyzer in November 2023. Findings Included: 1. During a tour of the facility on 03/12/2024 at 09:16 a.m., the surveyor observed 1 Advia 2120i hematology analyzer in the 3rd floor patient testing area (Serial Number: IRL14841924). 2. Review of laboratory policy, "CBC and WBC Differential Analysis using the ADVIA 2120i Hematology System" (Reviewed by the Laboratory Director on 07/07/2023) revealed the following: " ...Troubleshooting Out-of-Range QC Values ...If control results fail to meet the laboratory's established criteria for acceptability, you must evaluate all patient test results obtained in the unacceptable test run to determine if the patient results were adversely affected." 3. Review of laboratory QC records for November 2023 revealed the following: 11/29/2023 CBC Tech Hematology Controls Lot Number: OC6434 Expiration Date: 12/05/2023 Level High MCV Acceptable Range: 84.0-92.0 fL Result: 92.6 fL (A high flag was displayed by the result, indicating the QC was out of range.) The statement, "After back flush and cleaned RBC chamber" was documented on the QC form. 11/30/2023 CBC Tech Hematology Controls Lot Number: OC6434 Expiration Date: 12/05/2023 Level High MCV Acceptable Range: 84.0-92.0 fL Result: 89.0 fL The statement, "After calibration" was documented on the QC form. The surveyor requested patient evaluation documentation, since the last acceptable quality control (11/28/2023), when QC failed to fall within acceptable ranges and calibrations were performed, and none was provided. 4. Review of laboratory, "QC Action Worksheet" for November 2023, revealed the laboratory failed to document patient evaluation since the last acceptable QC when QC failed to fall within acceptable ranges and instrument maintenance and calibrations were performed. 5. Review of patient final reports revealed 45 patients tested for MCV on 11/28/2023. Refer to Patient Alias Sheet 1. 6. During an interview on 03/12/2024 with TS-1 at 10:22 a.m., in the conference room, TS-1 confirmed the above findings. Word Key CBC- Complete Blood Count WBC- White Blood Cell RBC- Red Blood Cell fL- femtoliters MCV- Mean Corpuscular Volume
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's testing personnel competency assessments performed in 2022, 2023, and 2024 and staff interview, the laboratory failed to include the observation of test performance in 1 of 8 assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022, 2023, and 2024 determined the observation of test performance was not part of 1 of 8 competency assessments. It was: Testing personnel #3 Assessment: 12/2022 Test system: serum pregnancy 2. The laboratory was asked to provide documentation of the required observation being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessments performed in 2022, 2023, and 2024 and staff interview, the laboratory failed to include the review of records in 2 of 8 assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022, 2023, and 2024 determined the review of records was not part of 2 of 8 competency assessments. They were: Testing personnel #2 Assessment: 10/2023 Test systems: Hematology, Chemistry Testing personnel #5 Assessment: 12/2022 Test systems: Chemistry, Coagulation 2. The laboratory was asked to provide documentation of the required review being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessments performed in 2022, 2023, and 2024 and staff interview, the laboratory failed to include the observation of maintenance in 1 of 8 assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022, 2023, and 2024 determined the observation of maintenance was not part of 1 of 8 competency assessments. It was: Testing personnel #2 Assessment: 10/2023 Test systems: Hematology, Chemistry 2. The laboratory was asked to provide documentation of the required observation being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessments performed in 2022, 2023, and 2024 and staff interview, the laboratory failed to include the assessment of testing known samples in 4 of 8 assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022, 2023, and 2024 determined the testing of known samples was not part of 4 of 8 competency assessments. They were: Testing personnel #2 Assessment: 10/2023 Test system: Hematology Testing personnel #3 Assessment: 12/2022 Test System: Serum pregnancy Testing personnel #4 Assessment: 12/2023 Test System: Serum pregnancy Testing personnel #5 Assessment: 12/2023 Test system: Hematology 2. The laboratory was asked to provide documentation of the required testing being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessments performed in 2022, 2023, and 2024 and staff interview, the laboratory failed to include problem solving skills in 1 of 8 assessments. The findings include: 1. A review of the laboratory's competency assessments from 2022, 2023, and 2024 determined problem solving skills was not part of 1 of 8 competency assessments. It was: Testing personnel #2 Assessment: 3/2024 Test system: Chemistry 2. The laboratory was asked to provide documentation of the required assessment being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of annual competency assessments in 2022 and 2023 for 1 of 5 testing personnel. The findings include: 1. A review of the

	laboratory's personnel records determined the laboratory failed to have documentation of annual competency assessments for testing personnel number 1 (as listed on Form CMS 209) in 2022 and 2023. 2. The laboratory was asked to provide documentation of the competency assessments being performed. No documentation was provided. 3. Technical consultant number #2 (as listed on Form CMS 209) confirmed the findings in an interview conducted 3/12/2024 at 1040 hours in the conference room.