Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2294296	08/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Texas Institute For Surgery, Llp	7115 Greenville Ave, Dallas, 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.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of CASPER Report 155D Individual Proficiency Testing report, laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to report PT results for three of three regulated analytes reviewed in 2024. Findings include: 1. Review of CASPER Report 155 determined the laboratory did not have a PT score for pH, pCO2 and pO2 for Routine Chemistry for the first testing event of 2024. 2. Review of the laboratory policy titled "Proficiency Testing Protocol" determined the laboratory failed to have a policy in place for PT result reporting. 3. Review of the laboratory's API PT Chemistry Core performance summary in 2024 (first event) determined the following analytes as not reported to the PT program: Chemistry Core 1st Event 2024 Method: i-STAT Analytes: pH PCO2 pO2 4. The laboratory director stated the laboratory is reporting pH, pCO2, and pO2 for patient results. The laboratory director also stated the laboratory is performing proficiency testing for the above analytes but did not report them to the proficiency

	testing provider during an interview on 08/11/2024 at 1055 hours in the conference room. The proficiency testing provider, API, confirmed the laboratory is enrolled in proficiency testing for pH, pCO2, and pO2 but did not submit results during an interview on 08/22/2024 at 1046 hours over the phone. Key: API - American Proficiency Institute pH - potential of hydrogen (measurement of acidity or alkalinity) pCO2 - partial pressure of carbon dioxide pO2 - partial pressure of oxygen
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 Center for Medicare and Medicaid Services (CMS)-116, laboratory policy, verification studies, and confirmed in interview, the laboratory failed to have a policy in place for verification study performance for three of three test systems performed in 2024. Findings Included: 1. Review of CMS-116 form submitted at time of survey, 08/21/2024, revealed the laboratory performed three non-waived test systems: a. Hematology/Coagulation b. Chemistry (Siemens Dimension) c. Point of Care (i-Stat) 2. Review of the laboratory policy manual on 08/21/2024, revealed the laboratory failed to provide a verification study policy for the three test systems listed above. The surveyor requested verification study policies for the above test systems, on 08/21/2024 at 02:15 PM, and none were provided. 3. Review of the chemistry verification study performed in November 2023, revealed the laboratory failed to perform an accurate reportable range verification study for eight of eight randomly reviewed analytes in 2024. Refer to D5421. 4. During an interview on 08/21/2024 at 02:35 PM, in the conference room, the laboratory director confirmed the laboratory failed to have a policy in place for verification study performance for three of three test systems performed in 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor observation, manufacturer's instructions, laboratory policy, chemistry verification studies, patient annual volumes, and confirmed in interview, the laboratory failed to perform an accurate reportable range verification study for eight of eight randomly reviewed analytes in 2024. Findings Included: 1. During a tour of the facility on 08/21/2024 at 10:10 AM, the surveyor observed one Siemens Dimension EXL 200 chemistry analyzer (Serial Number: DR275294) performing patient testing. Further observation revealed the following randomly selected analytes performed on the analyzer: a. Aspartate Aminotransferase (AST) b. Blood Urea Nitrogen (BUN) c. Calcium (CA) d. Creatinine e. Glucose (Glu) f. Potassium (K) g. Sodium (Na) h. Total Protein (TP) 2. Review of manufacturer's instructions, "Siemens Dimension: Flex reagent cartridge" for the above analytes revealed the following: a. Aspartate Aminotransferase (AST) (Reference: DF41A) "Analytical Measurement Range (AMR): 0-1000 U/L" b. Blood Urea Nitrogen (BUN) "Analytical Measurement Range (AMR): 0-150 mg/dL" c. Calcium (CA) "Analytical Measurement Range (AMR): 5-15.0 mg/dL" d. Creatinine "Analytical Measurement Range (AMR): 0-20.0 mg/dL" e. Glucose (Glu) "Analytical Measurement Range (AMR): 0-500mg/dL" f. Potassium (K) "Analytical Measurement Range (AMR): 1-10 mmol/L" g. Sodium (Na) "Analytical Measurement Range (AMR): 50-200 mmol/L" h. Total Protein (TP) "Analytical Measurement Range (AMR): 2-12.0 g/dL" 3. Review of the following laboratory policies, "Chemistry Manual" for the above analytes, revealed the following: a. "Chemistry Manual: Aspartate Aminotransferase (AST)" (Approved by the Laboratory Director on 06/13/2024): " ...Analytical Measurement Range (AMR): 0-1000 U/L" b. "Chemistry Manual: Blood Urea Nitrogen (BUN)" (Approved by the Laboratory Director on 06/13/2024): " ...Analytical Measurement Range (AMR): 0-150 mg/dL" c. "Chemistry Manual: Calcium (CA)" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 5-15.0 mg/dL" d. "Chemistry Manual: Creatinine" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 0-20.0 mg/dL" e. "Chemistry Manual: Glucose" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 0-500 mg/dL" f. "Chemistry Manual: Potassium (K)" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 1-10 mmol/L" g. "Chemistry Manual: Sodium (Na)" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 50-200 mmol/L" h. "Chemistry Manual: Total Protein TP)" (Approved by the Laboratory Director on 06/13/2024): "Analytical Measurement Range (AMR): 2-12.0 g/dL" 4. Review of Siemens Dimension verification studies performed in November 2023, revealed the following reportable range verified by the laboratory's instrumentation: a. Aspartate Aminotransferase (AST) Reportable Range: 10.0-47.0 U/L b. Blood Urea Nitrogen (BUN) Reportable Range: 10.00-40.00 mg/dL c. Calcium (CA) Reportable Range: 8.60-9.80 mg/dL d. Creatinine Reportable Range: 0.62-2.56 mg/dL e. Glucose (Glu) Reportable Range: 64.0-226.0 mg/dL f. Potassium (K) Reportable Range: 3.60-4.80 mmol/L g. Sodium (Na) Reportable Range: 132.0-144.0 mmol/L h. Total Protein (TP) Reportable Range: 5.8-7.7 g/dL The surveyor requested documentation of manufacturer reportable range verification performance by the laboratory, on 08/21/2024 at 02:30 PM, and none was provided. The laboratory was also asked to provide a verification study policy, and none was provided. Refer to D5403. 5. During an

	interview on 08/21/2024 at 02:35 PM, in the conference room, the Laboratory Director confirmed, the laboratory failed to perform an accurate reportable range verification study for eight of eight randomly reviewed analytes in 2024. Word Key U /L- units per liter mg/dL- milligrams per deciliter mmol/dL- Millimoles per liter g/dL- grams per deciliter
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on surveyor observation, laboratory policy, patient final reports and confirmed in interview, the laboratory failed to perform two levels of acceptable quality control (QC) on the i-Stat analyzer, using the Chem 8+ cartridge, prior to patient testing, for eight of eight days in 2024. Findings Included: 1. During a tour of the facility on 08/21/2024 at 10:06 AM, the surveyor observed the following three i-Stat analyzers currently in use for patient testing on the Chem 8+ cartridge: a. i-Stat 1 Location: Radiology Serial Number: 345087 b. i-Stat 2 Location: PACU Serial Number: 332229 c. i-Stat 3 Location: Pre-Op Serial Number: 370795 Further review revealed the following analytes performed on the cartridge: Na (Sodium); K (Potassium); Cl (Chloride); Glu (Glucose); BUN (Blood Urea Nitrogen); Hct (Hematocrit) 2. Review of laboratory policy, "I-Stat, Chem 8+, Creatinine, & Glucose Whole Blood Testing using Electrochemical Methods" (Approved by the Laboratory Director on 06/13/2024) revealed the following: " ...10.0 Quality Control See POC 1.022, iSTAT Instrument Guide Procedure for Quality Control procedures and documentation." Review of laboratory policy, "i-Stat Instrument Guide: POC 1.022" (Approved by the Laboratory Director on 06/13/2024) revealed the following: " ... Aqueous assayed controls are intended for use with the i-STAT Portable Clinical Analyzer to monitor the accuracy and precision of cartridges. Controls are used by certified operators to check the cartridges: 1. On any new shipment or lot before it is put into use, every 30 days or major system maintenance. 2. On the lot in use if patient results are questioned. 3. After semi-annual CLEW update." The surveyor requested documentation on 08/22/2024 at 08:26 AM, to support the reduction in QC on the i-Stat analyzers for Chem 8+ cartridge testing, and none was provided. 3. Review of patient final reports, revealed the following days patients were tested on the i-Stat analyzers: a. 07/25/2024 i-Stat Serial Number: 370795 Patient 1 (See Patient Alias List) Patient 2 i-Stat Serial Number: 332229 Patient 3 b. 07/29/2024 i-Stat Serial Number: 332229 Patient 4 c. 07/30/2024 i-Stat Serial Number: 332229 Patient 5 d. 08 /01/2024 i-Stat Serial Number: 332229 Patient 6 Patient 7 e. 08/06/2024 i-Stat Serial Number: 332229 Patient 8 f. 08/07/2024 i-Stat Serial Number: 332229 Patient 9 Patient 10 g. 08/08/2024 i-Stat Serial Number: 332229 Patient 11 Patient 12 h. 08/09 /2024 i-Stat Serial Number: 370795 Patient 13 Patient 14 The surveyor requested QC documentation for the above eight days when patients were tested using the Chem 8+ cartridge on the i-Stat analyzers, and none was provided. 5. During an interview on 08 /22/2024 at 09:10 AM, in the conference room, the laboratory manager confirmed, the laboratory failed to perform two levels of acceptable quality control (QC) on the i-Stat analyzer, using the Chem 8+ cartridge, prior to patient testing, for eight of eight days

	in 2024. II. Based on surveyor observation, laboratory policy, quality control documentation, patient final reports and confirmed in interview, the laboratory failed to perform two levels of acceptable quality control (QC) on the Sure-Vue hCG Serum Test Kit, prior to patient testing, for four of four days in 2024. Findings Included: 1. During a tour of the facility on 08/21/2024 at 10:10 AM, the surveyor observed Sure-Vue hCG Serum test kits available for patient testing (Lot Number: 0788119 and 0702332). 2. Review of laboratory policy, "Human Chorionic Gonadotropin (hCG) Test by SURE-VUE Serum/Urine hCG-Stat" (Approved by the Laboratory Director on 06/13/2024) revealed the following: " ...B. External Quality Control Two levels of each type of Quality Control are analyzed by certified operators on every new shipment of reagent, every new lot number, and whenever there are questionable test results, at a minimum of 30 days." 3. Review of Sure-Vue quality control documentation in August 2024, revealed the laboratory failed to have documentation of QC performance for four of four days serum patients were tested in August 2024. The surveyor requested the above QC documentation prior to patient testing in August 2024, and none was provided. 4. Review of patient final reports in August 2024, revealed the following patients tested for serum hCG, with no external quality control documented prior to testing: a. 08/01/2024 Patient 15 (See Patient Alias List) b. 08/09 /2024 Patient 16 c. 08/13/2024 Patient 17 d. 08/21/2024 Patient 18 5. During an interview on 08/22/2024 at 10:02 AM, in the conference room, the laboratory manager confirmed, the laboratory failed to perform two levels of acceptable quality control (QC) on the Sure-Vue hCG Serum Test Kit, prior to patient testing, for four of four days in 2024. Word Key hCG- Human Chorionic Gonadotropin
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 surveyor observation, laboratory policy, quality control (QC) documentation, corrective action log (July 2024), and confirmed in interview, the laboratory failed to document all corrective actions taken when chemistry instrumentation failed to perform within desired specifications for 12 of 31 days in July 2024. Findings Included: 1. During a tour of the facility on 08/21/2024 at 10:10 AM, the surveyor observed one Siemens Dimension EXL 200 chemistry analyzer (Serial Number: DR275294) performing patient testing. Further observation revealed the following randomly selected analytes performed on the analyzer: a. Creatinine Kinase (CKI) b. Hemoglobin A1C (A1C) c. Free T4 (FT4) d. Troponin (TNIH) 2. Review of laboratory policy, "Quality Control Procedure" (Approved by the Laboratory Director on 06/13/2024) revealed the following: " ...4.2.6 General Guidelines for QC Failures ...4.2.6.1.6. Record each QC failure in the "Corrective Action" notes on the QC Problem Log. Explain concisely the action(s) taken to remedy the problem. ...4.2.6.1.9. Document a summary of the QC failure(s) and

	actions taken on the Quality Investigation form and submit the [sic] laboratory director for approval." 3. Review of chemistry quality control documentation from July 2024, revealed the following QC failures: a. CKI BioRad QC Level 3 Acceptable 2SD (standard deviation) range: 538.0-600.8 07/24/2024 QC Results and instrument comments: 05:27 AM: 514.9 "Low" 06:00 AM: 522.0 "Low" 06:16 AM: 525.0 "Low" 09:09 AM: 621.4 "Hi" 07/30/2024 QC Results and instrument comments: 05:49 AM: 602.9 "Hi" 06:25 AM: 614.3 "Hi" 07:34 AM: 607.2 "Hi" b. A1C BioRad QC Level 3 Acceptable 2SD range: 5.17-5.51 07/02/2024 QC Results and instrument comments: 05:50 AM: 5.16 "Low" 07/16/2024 05:55 AM: 5.15 "Low" 07/29/2024 06:59 AM: 5.53 "Hi" 08:13 AM: 5.54 "Hi" c. FT4 BioRad QC Level 1 Acceptable 2SD range: 1.174-1.270 07/01/2024 06:00 AM: 1.158 "Lo" 07/24/2024 05:27 AM: 1.298 "Hi" 07: 48 AM: 1.312 "Hi" 07/25/2024 05:18 AM: 1.284 "Hi" 07/26/2024 05:37 AM: 1.157 "Hi" d. TNIH BioRad QC Level 1 Acceptable 2SD range: 96.47-119.59 07/03/2024 05:53 AM: 20211.2 "Hi" 06:59 AM: 21646.4 "Hi" 09:15 AM: 20314.0 "Hi" 07/08 /2024 11:01 AM: 122.54 "Hi" 07/11/2024 07:03 AM: 120.02 "Hi" 07/16/2024 05:55 AM: 120.43 "Hi" 06:22 AM: 126.33 "Hi" 07/30/2024 12:20 PM: 214.23 "Hi" 01:13 PM: 278.01 "Hi" 01:52 PM: 196.38 "Hi" 02:26 PM: 195.91 "Hi" 07/31/2024 05:50 AM: 196.57 "Hi" 4. Review of Siemens Dimension EXL chemistry analyzer "Weekly QC Surveillance" corrective action form, revealed the laboratory failed to document corrective actions taken when chemistry instrumentation failed to perform within desired specifications for the above 12 days in July 2024. The survey requested the above corrective action documentation, on 08/21/2024, and none was provided. 5. During an interview on 08/21/2024 at 03:35 PM, in the conference room, the laboratory director confirmed the laboratory failed to document all corrective actions taken when chemistry instrumentation failed to perform within desired specifications for 12 of 31 days in July 2024.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, review of competency records, and confirmed in interview, the technical consultant failed to perform competency assessments for 34 of 34 events in 2023 and 2024 (random review). Findings include: 1. Review of the CMS-209 form determined the laboratory has 121 testing personnel performing moderate complexity testing: 2. A random review of testing personnel records determined the following competency assessments were performed in 2023 and 2024: a) TP-13 Task: HCG on Urine or Serum (Non-Waived) Date: 01/9/2023 Competency frequency: Annual Competency assessed by: TP-117 b) TP-13 Task: i-STAT (Non-Waived) Date: 01/09/2023 Competency frequency: Annual Competency assessed by: TP-117 c) TP-99 Task: i-STAT (Non-Waived) Date: 01/17/2024 Competency frequency: Annual Competency assessed by: TP-117 d) TP-99 Task: HCG on Urine or Serum (Non-Waived) Date: 01/17/2024 Competency frequency: Annual Competency assessed by: TP-117 e) TP-11 Task: HCG on Urine or Serum (Non-Waived) Date: 01/17/2024 Competency frequency: Annual Competency assessed by: TP-117 f) TP-11 Task: i-STAT (Non-Waived) Date: 01/17/2024 Competency frequency: Annual Competency assessed by: TP-117 g) TP-49 Task: HCG on Urine or Serum (Non-Waived) Date: 01/17/2024 Competency frequency: Annual

	Competency assessed by: TP-117 h) TP-49 Task: i-STAT (Non-Waived) Date: 01/17 /2024 Competency frequency: Annual Competency assessed by: TP-117 i) TP-38 Task: i-STAT (Non-Waived) Date: 01/23/2024 Competency frequency: Annual Competency assessed by: TP-117 j) TP-28 Task: HCG on Urine or Serum (Non-Waived) Date: 01/23/2024 Competency frequency: Annual Competency assessed by: TP-117 k) TP-28 Task: i-STAT (Non-Waived) Date: 01/23/2024 Competency frequency: Annual Competency assessed by: TP-117 l) TP-22 Task: HCG on Urine or Serum (Non-Waived) Date: 01/23/2024 Competency frequency: Annual Competency assessed by: TP-117 m) TP-22 Task: i-STAT (Non-Waived) Date: 01/23/2024 Competency frequency: Annual Competency assessed by: TP-117 n) TP-30 Task: HCG on Urine or Serum (Non-Waived) Date: 01/24/2024 Competency frequency: Annual Competency assessed by: TP-117 o) TP-30 Task: i-STAT (Non-Waived) Date: 01/24/2024 Competency frequency: Annual Competency assessed by: TP-117 p) TP-60 Task: i-STAT (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 q) TP-18 Task: i-STAT (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 r) TP-18 Task: HCG on Urine or Serum (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 s) TP-62 Task: i-STAT (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 t) TP-62 Task: HCG on Urine or Serum (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 u) TP-74 Task: i-STAT (Non-Waived) Date: 02/05/2024 Competency frequency: Annual Competency assessed by: TP-117 v) TP-74 Task: HCG on Urine or Serum (Non-Waived) Date: 02 /05/2024 Competency frequency: Annual Competency assessed by: TP-117 w) TP-67 Task: i-STAT (Non-Waived) Date: 03/18/2024 Competency frequency: Annual Competency assessed by: TP-117 x) TP-67 Task: HCG on Urine or Serum (Non-Waived) Date: 03/18/2024 Competency frequency: Annual Competency assessed by: TP-117 y) TP-45 Task: i-STAT (Non-Waived) Date: 03/19/2024 Competency frequency: Annual Competency assessed by: TP-117 z) TP-45 Task: HCG on Urine or Serum (Non-Waived) Date: 03/19/2024 Competency frequency: Annual Competency assessed by: TP-117 aa) TP-20 Task: i-STAT (Non-Waived) Date: 03/19/2024 Type of competency: Annual Competency assessed by: TP-117 bb) TP-13 Task: HCG on Urine or Serum (Non-Waived) Date: 3/19/2024 Competency frequency: Annual Competency assessed by: TP-117 cc) TP-13 Task: i-STAT (Non-Waived) Date: 03/19 /2024 Competency frequency: Annual Competency assessed by: TP-117 dd) TP-43 Task: i-STAT (Non-Waived) Date: 03/25/2024 Competency frequency: Annual Competency assessed by: TP-117 ee) TP-105 Task: HCG on Urine or Serum (Non-Waived) Date: 07/16/2024 Type of competency: 6-month Competency assessed by: TP-3 ff) TP-101 Task: i-STAT (Non-Waived) Date: 07/16/2024 Competency frequency: 6-month Competency assessed by: TP-3 gg) TP-101 Task: HCG on Urine or Serum (Non-Waived) Date: 07/16/2024 Competency frequency: 6-month Competency assessed by: TP-3 hh) TP-103 Task: i-STAT (Non-Waived) Date: 07/18 /2024 Competency frequency: 6-month Competency assessed by: TP-117 The laboratory was asked to provide competency documentation performed by the technical consultant. No documentation was provided. 3. The laboratory director, TP-3, and TP-117 confirmed the findings in an interview on 08/21/2024 at 1155 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services TP - testing person