Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2053955	07/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Baylor Scott & White The Heart Hospital Mckinney	5268 W University Dr, Mckinney, 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 entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments for 4 of 4 technical consultants (TC-1, TC-2, TC-3 and TC-4). Findings included: 1. The laboratory policy titled, "Assessing Competency of Testing Personnel and Supervisory Staff" (Origination Date: 1/2016) stated the following: "Performance Assessment of Supervisors/Consultants: The performance of section

	directors/technical supervisors, general supervisors, technical consultants, and clinical consultants is assessed and satisfactory ...This performance assessment be assessed for each CAP/CLIA number where these responsibilities are performed ...The assessment is performed at least annually and may take the form of a checklist or other record of performance of responsibilities, as defined by the individual's job description ..." 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed four Technical Consultants (TC). 3. Review of personnel records revealed there was no documented annual competency assessments for the duties performed as a technical consultant for TC-1, TC-2, TC-3 and TC-4. 4. During an interview on 07 /13/2021 at 11:26 am in the conference room, the Point of Care Coordinator was asked to provide documentation of competency assessment for the four technical consultants. No documentation was provided. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policies, laboratory environmental records (03/2020, 12/2020, and 01/2021), and staff interview, the laboratory failed to ensure room temperatures were within manufacturer's specifications for 73 of 73 days. Findings included: 1. During a tour of the testing areas on 07/15/2021 at 01:00 pm, the following eight i-STAT analyzers and two Avoximeter 1000E whole blood oximeters were observed: a. i-STAT Serial Numbers: 339111, 337416, 322395, 401715, 402639, 402662, 402620, 401717 b. Avoximeter 1000E Serial Numbers: 6736, 3802 2. The manufacturer's instructions for the iSTAT analyzer (Rev. Date: 02-Aug-12) stated the following: "Specifications: Operating temperature 16-30C (61-86F) for i-STAT cartridge testing" The manufacturer's instructions for the Avoximeter 1000E whole blood oximeter (AP1001EN-03-Nov 2018) stated the following: "Instrument Specifications: Operating Temperature - Room temperature (15C to 30C, 59F to 86F)" 3. The laboratory policy titled, "iSTAT General Operating Procedure" stated the following: "Reagents-Cartridge Storage and Stability ...Manufacturer room temperature is (18-30C, 64-86F) ...The analyzer's operating temperature is 16-30C (61-86F)." The laboratory policy titled, "IQCP-Quality Control Plan for Avoximeter 1000E" stated the following: "Monitoring of Test Environment and Reagents ...Reagent ....Cuvettes are stored in a closed bag at room temperature (15-30C/59-86F)" 4. Review of the laboratory environmental records (03/2020, 12/2020, and 01/2021) revealed the following areas where analyzers were located: Cath Lab, Room 1; Cath Lab, Room 2, Cath Lab Room 3, and Cath Lab Room 4 Further review of the environmental records revealed an "approved temp" of less than or equal to 73F and the temperature reading was documented with a check mark for 73 of 73 days. The laboratory failed to ensure room temperatures were within manufacturer's specifications for the iSTAT and Avoximeter analyzers. 5. During an interview on 07/13/2021 at 12:35 pm in the conference room, the Point of Care Coordinator was asked to provide documentation

	of a defined room temperature range that was within manufacturer's specifications. No documentation was provided. This confirmed the above findings.
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: I. Based on review of laboratory's verification records for the Avoximeter 1000E whole blood oximeters (Serial Numbers 6736 and 3802) and staff interview, it was revealed the laboratory failed to ensure reportable ranges for 2 of 2 analytes measured were verified by the laboratory's verification studies. Findings included: 1. Review of the laboratory's verification studies for the Avoximeter 1000E whole blood oximeter revealed the analyzers measured total hemoglobin and oxyhemoglobin analytes. The study was approved by the laboratory director on 07/26/2019. 2. In an interview on 07/13/2021 at 12:00 pm, the Point of Care Coordinator was asked to provide documentation of verification of reportable ranges (or analytical measurement range-AMR) for the two Avoximeter 1000E whole blood oximeters (Serial Numbers 6736 and 3802). She stated that the laboratory used the AMR in the operator's manual. This confirmed the above findings. II. Based on review of laboratory's verification records for the i-STAT analyzers (Serial Numbers: 339111, 337416, 322395, 401715, 402639, 402662, 402620, 401717) and staff interview, it was revealed the laboratory failed to ensure the reportable ranges verified by the laboratory were utilized for 9 of 9 analytes tested on the iSTAT analyzer. Findings included: 1. Review of the laboratory's verification records for the iSTAT analyzer revealed the laboratory measured the following 9 analytes using the iSTAT analyzer: a. i-STAT CG8+ Cartridge measured analytes: Sodium (Na); Potassium (K); Ionized Calcium (iCa); Glucose (Glu); Hematocrit (Hct); pH, Oxygen Partial Pressure (pO2); and Carbon dioxide Partial Pressure (pCO2) b. i-STAT Creat Cartridge measure analyte: Creatinine (Creat) 2. Review of the laboratory verification document titled, "iSTAT AMR Verification" revealed the following: Analyte; iSTAT AMR; iSTAT range verification low, high for each measured analyte: Sodium; 100-180 mmol/L; Low 100 High 178 Potassium; 2.0-8.0 mmol/L; Low 2.3 High 7.8 Ionized Calcium; 0.25-2.50 mmol/L; Low 0.35 High 2.27 Glucose; 20-600 mg/dL; Low (no number documented) High 572 Hematocrit; 15-70%; Low 12 High 67 pH; 6.50-8.00; Low 6.553 High 7.912 pO2; 12-600 mmHg; Low 16 High 712 pCO2; 14-90 mmHg; Low 17.5 High 89.4 Creatinine; 0.2-14.0 mg/dL; Low 0.3 High 16.1 Further review of the reportable ranges used by the laboratory revealed the laboratory used the iSTAT AMR as the reportable range. The laboratory failed to ensure the reportable ranges verified by the laboratory were utilized for the analytes tested on the iSTAT analyzer. 3. In an interview on 07/13/2021 at 12:07 pm, the Point of Care Coordinator was asked to provide documentation of verification of reportable ranges (or analytical measurement range-AMR) and how the reportable ranges were determined for the analytes measured on the iSTAT. She stated that the

	laboratory measured each analyte to determine high and low measurements and if those measurements were within an allowable error, the laboratory used the AMR defined in the operator's manual. This confirmed the above findings.
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 direct observation, review of laboratory policy, laboratory's calibration verification records for the iSTAT analyzers from 2020 and staff interview, it was revealed that the laboratory failed to have documentation of performing calibration verification at least every 6 months for 6 of 8 iSTAT analyzers. Findings included: 1. During a tour of the testing areas on 07/15/2021 at 01:00 pm, the following eight i-STAT analyzers were observed: Serial Numbers: 339111, 337416, 322395, 401715, 402639, 402662, 402620, 401717 2. The laboratory policy titled, "iSTAT General Operating Procedure' stated the following: "Calibration ...Full calibration verification is performed by Point of Care Coordinator under any of the following circumstances ... Every six months." 3. A review of the calibration verification records for the iSTAT analyers revealed the calibration verification was performed on 11/23/2020 using devices 322395 and 401715. 4. In an interview on 07/13/2021 at 12:35 pm, the technical consultant was asked to provide documentation of calibration verification performed 11/23/2020 on devices 339111, 337416, 402639, 402662, 402620, and 401717. No documentation was provided. The Point of Care Coordinator stated that she did not perform calibration verification on each iSTAT. This confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on review of laboratory records, review of laboratory policy, a random review of laboratory quality control (QC) records for the Avoximeter 1000E whole blood oximeter (07/2020, 08/2020, 12/2020, 01/2021, and 04/2021), patient records, and staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of Avoximeter 1000E test performance with current and accurate statistical parameters for 1 of 5 weeks in 07 /2020, 1 of 5 weeks in 12/2020, and 1 of 4 weeks in 01/2021. Findings included: 1. Review of laboratory records revealed the laboratory utilized the following 2 Avoximeter 1000E whole blood oximeters: Avoximeter 1000E; Serial Number 3802 Avoximeter 1000E; Serial Number 6736 2. Review of the laboratory policy titled, "IQCP-Quality Control Plan for Avoximeter 1000E" (approved 07/01/2019) stated the following: "Liquid Control Solution: A minimum of one level of liquid QC material will be analyzed weekly ..." 3. A random review of laboratory quality control (QC) records for the Avoximeter 1000E whole blood oximeter (07/2020, 08/2020, 12/2020, 01/2021, and 04/2021) revealed the laboratory failed to perform weekly QC for the following instruments and weeks: a. 07/2020 Instrument 6736; Week of 07/22/2020 - 07/29/2020 b. 2/2020 Instrument 3802; Week of 12/20/2020 - 12/31/2020 Instrument 6736; Week of 12/20/2020 - 12/31/2020 c. 01/2021 Instrument 3802; Week of 01/17 /2021 - 01/23/2021 Instrument 6736; Week of 01/17/2021 - 01/23/2021 The laboratory's system in place failed to ensure detection of immediate errors, monitor errors over time, and the accuracy and precision of Avoximeter 1000E test performance with current and accurate statistical parameters. 4. A review of patient records from 07/2020, 08/2020, 12/2020, 01/2021, and 04/2021 revealed no patients were tested during the weeks listed above. 5. In an interview on 07/13/2021 at 01:20 pm, the Point of Care Coordinator agreed that weekly QC was not performed on the weeks listed above. This confirmed the above findings. II. Based on review of laboratory records and a random review of laboratory quality control (QC) records for the iSTAT analyzer (04/2019 and 05/2019) revealed the laboratory failed to have a system in place to detect immediate errors and monitor over time the accuracy and precision of test performance for the iSTAT analyzer for 2 of 2 months in 2019. Findings included: 1. Review of laboratory records revealed the laboratory utilized 8 iSTAT analyzers i-STAT (Serial Numbers: 339111, 337416, 322395, 401715, 402639, 402662, 402620, 401717) using the following cartridge: I-STAT CG8+ cartridge measured analytes: Sodium (Na); Potassium (K); Ionized Calcium (iCa); Glucose (Glu); Hematocrit (Hct); pH, Oxygen Partial Pressure (pO2); and Carbon dioxide Partial Pressure (pCO2) 2. Review of the iSTAT quality control records from 04/2019 and 05/2019 revealed the laboratory performed quality control on the following dates and analyzers: a. 04/02/2019 CG8+ cartridge QC performed on Analyzer 339111 and 337416 The laboratory failed to perform quality control on analyzer 322395, 401715, 402639, 402662, 402620, and 401717. b. 05/30/2019 CG8+ cartridge QC performed on Analyzer 402620, 401715, 402639, 401717, and 402622. The laboratory failed to perform quality control on analyzer 339111, 337416, and 322395. The laboratory failed to ensure that quality control was performed on each

	iSTAT analyzer. The laboratory failed to have a system in place to detect immediate errors and monitor over time the accuracy and precision of test performance for all iSTAT analyzers. 3. In an interview on 07/13/2021 at 01:20 pm, the Point of Care Coordinator stated the she did not perform monthly QC on each iSTAT analyzer. She stated the she rotated the analyzers for performance of QC. This confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory records, laboratory policy, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to monthly for the iSTAT analyzer CG8+, Creat, and ACT-K cartridges Findings included: 1. Review of laboratory records revealed the laboratory utilized 8 iSTAT analyzers (Serial Numbers: 339111, 337416, 322395, 401715, 402639, 402662, 402620, 401717) using the following cartridges: a. i-STAT CG8+ cartridge measured analytes: Sodium (Na); Potassium (K); Ionized Calcium (iCa); Glucose (Glu); Hematocrit (Hct); pH, Oxygen Partial Pressure (pO2); and Carbon dioxide Partial Pressure (pCO2) b. i-STAT Creat cartridge measure analyte: Creatinine (Creat) c. i-STAT ACT-K cartridge measured: Kaolin Activated Clotting Time 2. The laboratory policy titled, "IQCP-Quality Control Plan for iSTAT", (approved 07/01 /2019) stated the following: "Liquid Controls: At least two levels of liquid controls are run in the following circumstances Each shipment, Each new lot of cartridges, When a problem is suspected, At least monthly." 3. Review of the laboratory's IQCP record titled, "Authorization of IQCP (iSTAT)", (signed by the laboratory director 08/02 /2019), revealed the performed QC using liquid controls on the following dates for the CG8+, Creat, and ACT-K cartridges: CG8+ cartridge 05/22/2019 06/06/2019 06/12 /2019 06/30/2019 07/01/2019 07/26/2019 07/30/2019 08/01/2019 Creat cartridge 05 /22/2019 06/19/2019 07/30/2019 08/01/2019 ACT-K cartridge 05/22/2019 06/06 /2019 07/01/2019 07/26/2019 The laboratory failed to provide QC data for iSTAT testing to support the laboratory's decision to reduce the frequency of QC testing to monthly. 4. In an interview on 07/13/2021 at 12:35 pm, the Point of Care Coordinator was asked to provide QC data documentation to support reduction of the frequency of QC testing to monthly. No documentation was provided. This confirmed the above findings. II. Based on review of laboratory records, laboratory policy, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed in interview, the laboratory's IQCP failed to support its reduction in frequency to weekly for the Avoximeter 1000E. Findings included: 1. Review of laboratory records revealed the laboratory utilized 2 Avoximeter 1000 E whole blood oximeters (Serial Numbers: 3802 and 6736) to measure hemoglobin and oxyhemoglobin. 2. Review of the laboratory policy titled, "IQCP-Quality Control

	Plan for Avoximeter 1000E" (approved 07/01/2019) stated the following: "Liquid Control Solution: A minimum of one level of liquid QC material will be analyzed weekly ..." 3. Review of the documentation provided for the laboratory's IQCP revealed: Level 1 quality control material (Lot number 84859, expiration date 2020 /03) was run 20 times on 07/25/2019 on device 3802 and 6736. Level 2 quality control material (Lot number 84855, expiration date 2020/03) was run 20 times on 07/25 /2019 on device 3802 and 6736. Level 3 quality control material (Lot number 85051, expiration date 2020/03) was run 20 times on 07/25/2019 on device 3802 and 6736. The laboratory failed to provide QC data for Avoximeter 1000E testing to support the laboratory's decision to reduce the frequency of QC testing weekly. 4. In an interview on 07/13/2021 at 12:35 pm, the Point of Care Coordinator was asked to provide QC data documentation to support reduction of the frequency of QC testing to weekly. No documentation was provided. This confirmed the above findings.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on direct observations, review of laboratory policies, review of manufacturer's instuctions, review of laboratory records, and staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory director failed to ensure room temperatures were within manufacturer's specifications. Refer to D5413. 2. The laboratory director failed to ensure reportable ranges for 2 of 2 analytes measured were verified by the laboratory's verification studies. Refer to D5421, I 3. The laboratory director failed to ensure the reportable ranges verified by the laboratory were utilized for 9 of 9 analytes tested on the iSTAT analyzer. Refer to D5421, II 4. The laboratory director failed to have documentation of performing calibration verification at least every 6 months for 6 of 8 iSTAT analyzers. Refer to D5439. 5. The laboratory director failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of Avoximeter 1000E test performance with current and accurate statistical parameters for 1 of 5 weeks in 07 /2020, 1 of 5 weeks in 12/2020, and 1 of 4 weeks in 01/2021. Refer to D5441, I 6. The laboratory director failed to ensure that a system was in place to detect immediate errors and monitor over time the accuracy and precision of test performance for the iSTAT analyzer for 2 of 2 months in 2019. Refer to D5441, II. 7. The laboratory director failed to ensure the laboratory's IQCP supported its reduction in frequency to monthly for the iSTAT analyzer CG8+, Creat, and ACT-K cartridges. Refer to D5445, I 8. The laboratory director failed to ensure that laboratory's IQCP supported its reduction in frequency to weekly for the Avoximeter 1000E. Refer to D5445, II.
D6053	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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, laboratory policy, a random review of laboratory personnel records, and in staff interview, the technical consultant failed to perform testing personnel competency assessments at least semiannually during the first year of patient testing for 9 of 12 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS-209 form included Testing Person 1 through Testing Person 40 listed to perform moderate complexity testing. 2. The laboratory policy titled, "Assessing Competency of Testing Personnel and Supervisory Staff" (Origination Date: 1/2016) stated the following: "Non-Waived Testing: During the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed at least annually. Competency is assessed at each laboratory (CAP/CLIA) where testing is performed." 3. A random review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments at least twice the first year of patient testing for the following 9 of 12 testing personnel (as listed on Form CMS-209) who performed moderate complexity: a. Testing person 5; Date of Training 06/26/2019; Next documented competency assessment 08/06/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing. b. Testing person 7; Date of Training 06/26/2019; Next documented competency assessment 08/28/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing. c. Testing person 10; Date of Training 01/03/2020; Next documented competency assessment 08/06/2020 No documentation of personnel competency assessment at least semiannually during the first year of patient testing. d. Testing person 17; Date of Training 07/31/2019; Next documented competency assessment 09/10/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing. e. Testing person 18; Date of Training 07/26/2019; Next documented competency assessment 09 /10/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing f. Testing person 26; Date of Training 07/11/2019; Next documented competency assessment 08/28/2020 No documentation of personnel competency assessments after 6 months in the first year of patient testing g. Testing person 28; Date of Training 04/16/2020 No documentation of personnel competency assessment at least semiannually during the first year of patient testing. h. Testing person 28; Date of Training 01/27/2020 No documentation of personnel competency assessment at least semiannually during the first year of patient testing. i. Testing person 34; Date of Training 06/26/2019; Next documented competency assessment 01 /02/2020 No documentation of personnel competency assessment at least semiannually during the first year of patient testing. 3. During an interview on 07/13 /2021 at 10:35 am in the conference room, the Point of Care Coordinator was asked to provide documentation of personnel competency assessments at least semiannually the first year of patient testing at this facility. No documentation was provided. This confirmed the above findings.