Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	64D0724937	08/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lbj Tropical Medical Center	1234 Paul Turner Dr, Pago Pago, AS	

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	Federal Surveyors from the Centers for Medicare& Medicaid Services (CMS) Survey Branch conducted a recertification survey on 8/13/2025 to 8/15/2025 and 8/18/2025 The following standard level deficiencies were cited.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, interview with technical supervisor #3 and laboratory director, the laboratory failed to follow manufacturer's instructions for reconstituting the STA Coag plus controls with distilled water as indicated by the manufacturer as evidenced by: 1.In review of the manufacturer's instructions for the STA coag plus stated, "Reconstitute each vial of reagent 1 and 2 with exactly 2ml of distilled water." 2. In an interview with technical supervisor #3 on 8/15/2025 at 1023 she demonstrated that they use deionized (DI) water from the chemistry instrument water system. 3. In an interview with the laboratory director at on 8/15/2025 at 1026 she confirmed that they used DI water and that they were in process of ordering new water recommended from the manufacturer for their controls. 47107 II. Based on direct observation, review of manufacturer instructions, test volume records, and interview with the General Supervisor (GS)-10, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow the manufacturer's instructions of using a high intensity incandescent lamp for 1 of 1 test methodology (Arlington Scientific RPR Card Test). Findings Included: 1. In direct observation on 8 /14/2025 at 11:18 AM in the laboratory, the Rapid Plasma Reagin (RPR) workbench was seen located in a dim corner of the room and did not have a high intensity

	incandescent lamp for RPR card test readouts. 2. Review of the manufacturer's instruction from Arlington Scientific RPR Card Test for Syphilis stated the following requirements: "Assay Protocol - Qualitative 6. Immediately read results macroscopically in the "wet" state under a high intensity light source." 3. Review of the laboratory's test records provided revealed 11 RPR tests run from 06/01/2024 to 08 /14/2025, and a total annual test volume of 11,348 for Diagnostic Immunology. 4. In an interview on 8/14/2025 at 11:19 AM, GS-10 confirmed that an incandescent lamp was not utilized for RPR testing, in accordance with the manufacturer's instructions.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: I. Based on direct observation, manufacturer's instructions, temperature records, and interview with the Laboratory Director (LD), according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define, monitor and document the temperature in the Microbiology hallway, and phlebotomy room, where 30 of 30 boxes of Becton Dickinson (BD) Vacutainer tubes and 24 of 24 boxes of Biomerieux BACT/ALERT FN Plus bottles were stored. Findings Included: 1. In direct observation on 8/13/2025 at 9:53 AM, the following supplies with storage temperature requirements were seen in storage: Phlebotomy Room: a. 13 boxes of Gold BD Vacutainer SST Blood Collection Tubes, Lot #4353605, Manufacturer storage requirements 4 to 25 degrees Celsius b. 9 boxes of Purple BD Vacutainer K2E 5.4 mg Tubes, Lot #4344045, Manufacturer storage requirements 4 to 25 degrees Celsius c. 4 boxes of Red BD Vacutainer Serum Blood Collection Tubes, Lot #5098300, Manufacturer storage requirements 4 to 25 degrees Celsius. d. 4 boxes of Pink BD Vacutainer K2E 10.8 mg Tubes, Lot #5076222, Manufacturer storage requirements 4 to 25 degrees Celsius. Hallway outside of the Microbiology section: e. 8 boxes Biomerieux BACT/ALERT PF Plus blood culture tubes, Lot #0004103132, Manufacturer storage requirements 15 to 30 degrees Celsius. f. 8 boxes Biomerieux BACT/ALERT FN Plus blood culture tubes, Lot #0004063172, Manufacturer storage requirements 15 to 30 degrees Celsius. g. 8 boxes Biomerieux BACT/ALERT FA Plus blood culture tubes, Lot #0004103282, Manufacturer storage requirements 15 to 30 degrees Celsius. 2. Review of the laboratory's temperature records revealed no temperature ranges defined, monitored or documented in the hallway outside of the microbiology section or phlebotomy room. 3. In an interview on 8/13/2025 at 9:55 AM, the LD confirmed that both areas where the temperature dependent supplies were stored, did not have defined temperature ranges and were not monitored or documented. II. Based on direct observation, manufacturer's instructions, temperature records, and interview with General Supervisor (GS)-10 of the Immunology/Serology section, according to the CMS Form 209, the laboratory failed to define, monitor and document humidity in the Immuno-Serology section of the laboratory where two of two temperature dependent analyzers were in use. Findings Included: 1. In direct

	observation on 8/14/2025 at 10:40 AM, the following analyzers were seen in use: a. 1 Roche Cobas e411 (Serial Number #1072-24) b. 1 Beckman Coulter Access 2 Immunoassay System (Serial Number #510230) 2. Review of the manufacturer's instruction stated the following humidity requirements for the Roche Cobas e411 analyzer: "Cobas e411 analyzer specifications: Operating conditions - Ambient humidity: 20-80%" 3. Review of the Beckman Coulter manufacturer's instructions titled 'Quality Forward Convenience Forward Lab Forward Access 2 Immunoassay System' stated the following humidity requirements on page 4 of 4: "Power and Environmental Requirements: Ambient Operating Environment: Relative Humidity 20 to 80% relative, non-condensing" 4. Review of the laboratory's humidity records revealed no humidity ranges defined, monitored or documented in the immuno-serology room of the laboratory. 5. In an interview on 8/14/2025 at 10:41 AM in the immune-serology room, GS-10 confirmed the section did not define, monitor or document humidity. III. Based on direct observation, manufacturer's instructions, temperature records, and interview with Technical Supervisor (TS)-1 of the Chemistry section, the laboratory failed to define freezer temperature ranges consistent with the manufacturer's instructions, for nine of nine Quidel Triage Total 5 Control boxes. Findings Included: 1. In direct observation on 8/15/2025 at 1:41 PM in the Chemistry section, one freezer was observed in use for mixed-use reagent storage between the chemistry and immuno-serology section of the laboratory, set to a temperature of -18 degrees celsius and colder. The following chemistry control reagents were seen in storage, with corresponding manufacturer storage temperature requirements: a. 9 Quidel Triage 5 Control boxes, Lot #C4120AN, Manufacturer storage temperature requirements -20 degrees celsius or colder. 2. In an interview on 8/15/2025 at 1:42 PM, TS-1 of the chemistry section of the laboratory confirmed the freezer temperature range was not defined in accordance with manufacturer storage requirements of reagent controls stored within. IV. Based on direct observation, manufacturer's instructions, temperature records, and interview with General Supervisor (GS)-10 of the Chemistry section, the laboratory failed to define freezer temperature ranges consistent with the manufacturer's instructions, for 7 of 7 Bio-Rad Liquichek Tumor Marker Control reagents. Findings Included: 1. In direct observation on 8/14/2025 at 1:27 PM in the Chemistry section, one freezer was observed in use for mixed-use reagent storage between the chemistry and immuno-serology section of the laboratory, set to a temperature of -18 degrees Celsius and colder. The following immuno-serology control reagents were seen in storage, with corresponding manufacturer storage temperature requirements: a. 1 box Bio-Rad Liquichek Tumor Marker Control Level 1, Lot #94981, manufacturer storage temperature requirements -70 to -20 degrees celsius b. 4 boxes Bio-Rad Liquichek Tumor Marker Control Level 2, Lot #94982, manufacturer storage temperature requirements -70 to -20 degrees celsius c. 2 boxes Bio-Rad Liquichek Tumor Marker Control Level 3, Lot #94983, manufacturer storage temperature requirements -70 to -20 degrees celsius 2. In an interview on 8/14 /2025 at 1:28 PM, GS-10 of the immuno-serology section of the laboratory confirmed the freezer temperature range was not defined in accordance with manufacturer storage requirements of reagent controls stored within.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer instructions, and confirmed in interview with the Technical Supervisor (TS) -1 of Chemistry according to the Form CMS-209, the laboratory failed to ensure the labeling of new preparation/open dates for four of four bottles of quality control (QC). Findings Included: 1. In direct observation on 8/13/2025 at 2:28 PM, in the Chemistry 2 to 8 degrees Celsius refrigerator, the following reagent bottles were observed with no preparation dates labeled: a. One bottle Microgenics Corporation MAS PAR TDM Level 1 control, Lot #TDA25081A, Expiry date 2025-08-31 b. One bottle Microgenics Corporation MAS PAR TDM Level 2 control, Lot #TDA250830, Expiry date 2025-08-31 c. One bottle Microgenics Corporation MAS Uricheck Level 1 control, Lot #UC25111A, Expiry date 2025-11-30 d. One bottle Microgenics Corporation MAS Uricheck Level 2 control, Lot #UC25112A, Expiry date 2025-11-30 2. Review of manufacturer's instructions for the Microgenics Corporation MAS controls stated the following storage and stability requirements: "Storage and Stability Store MAS PAR TDM at 2-8 degrees Celsius. Unopened vials are stable until expiration date on the label. Once opened, vials of controls are stable for 30 days when stored tightly capped at 2-8 degrees Celsius. Do not freeze." 3. In an interview on 8/13/2025 at 2:30 PM, TS-1 could not confirm the date when bottles were opened, and the bottles expiration dates were not based on manufacturer instructions.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and interview with Technical Supervisor (TS)-4, according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to establish performance specifications after modifying manufacturer storage temperatures for nine of nine KwikStix American Type Culture Collection (ATCC) organism control boxes. Findings Included: 1. In direct observation on 8/18/2025 at 9:17 AM, in the microbiology freezer, the following ATCC organism control boxes were seen in storage at -20 to -8 Celsius: a. One KwikStik ATCC P. aeruginosa box, Lot #353-558-62 b. One KwikStik ATCC K. quasipneumoniae box, Lot #784-86-24 c. One KwikStik ATCC S. maltophilia box, Lot #759-78-22 d. One KwikStik ATCC E. casseliflavus box, Lot #761-85-22 e. One KwikStik ATCC N. gonorrhoeae box, Lot #429-89-32 f. One KwikStik ATCC N. gonorrhoeae box, Lot #378-108-22 g. One KwikStik ATCC S. aureus box, Lot #365-133-23 h. One KwikStik ATCC C. albicans box, Lot #443-1609-66 i. One KwikStik ATCC S. saprophyticus box, Lot #945-64-2 2. Review of the manufacturer's

	instruction for the KwikStik ATCC organisms labeled "KwikStik Instructions for Use" revealed the following requirements for storage: "Storage and Expiration Store KWIK-STIK Plus microorganisms at 2 to 8 degrees Celsius in the original, sealed vial or pouch containing the desiccant, KWIK-STIK Plus microorganisms should not be used if: -Stored improperly -There is evidence of excessive exposure to heat or moisture -The expiration date has passed ..." 3. TS-4 was unable to provide stability studies to confirm the modification to storage requirements did not affect test sensitivity or specificity. 3. In an interview on 8/18/2025 at 9:20 AM, TS-4 stated the microbiology section stored the ATCC organisms in the freezer due to space and resource constraints, which never affected their QC results.
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. This STANDARD is not met as evidenced by: Based on direct observation, review of Quality Control (QC) records, test records, and interview with the Technical Supervisor (TS-1), according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to have control procedures that 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 process for 51 of 51 analytes tested in the Chemistry section. Findings Included: 1. In direct observation on 8/13/2025 at 2: 27 PM, the following 2 Beckman Coulter chemistry analyzers were seen in use: a. Beckman Coulter DXC 700 AU (Serial Number #2024054345) b. Beckman Coulter AU 680 (Serial Number #2014093435) 2. Review of the laboratory's QC records showed recalibrations performed after QC failures, but no record of QC standard deviations outliers in the instruments' Levy-Jennings (LJ) graph settings for all 51 analytes tested in the Chemistry section. The following example recalibrations were performed due to QC failure, with no record of the QC failures in the LJ chart: a. QC Failure, Recalibration, Test Name TBIL-C, 6/25/2025, 12:44 AM, Device No. 0093435 b. QC Failure, Recalibration, Test Name TBIL-C, 6/26/2025, 1:34 AM, Device No. 0093435 3. Review of the laboratory's test records revealed the following volumes for testing performed on the following analytes (sample of 9 analytes out of 51 total): a. January 1 - December 31, 2024 (713,385) - Albumin (37,542) ALP (36,011) Amphetamine (875) Amylase (5,083) Bilirubin, T (33,323) BUN (38,004) Calcium, T (40,465) Carbamazepine (44) CO2 (40,860), etc. b. January 1 - July 31, 2025 (490,108) - Albumin (23,691) ALP (23,503) Amphetamine (322) Amylase (3,316) Bilirubin, T (21,879) BUN (24,460) Calcium, T (58,250) Carbamazepine (5) CO2 (26,734), etc. 4. In an interview on 8/13/2025 at 3:01 PM, TS-1 confirmed she permanently deleted QC LJ standard deviation outliers once a QC re-run and/or re-calibration came in within range again and could not accurately monitor the accuracy and precision of the test system over time.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Control (QC) records, test records and interview with the General Supervisor (GS)-10, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to perform controls of known titered reactivity for 1 of 11 Rapid Plasma Reagin (RPR) tests run from 6/01/2024 to 8/14/2025 (Random review). Findings Included: 1. Review of the laboratory QC records showed RPR QC being performed to signify a 'Weak Reactive' titer as 1:2, and a 'Reactive Titer' as 1:8. 2. Review of the laboratory's test records from 6/01/2024 to 8/14/2025, revealed a total of 11 RPR tests run, and 1 RPR test performed on 7/09/2025, with the following controls and results reported as higher titers than the 1:8 reactive titer control run: a. 6/28/2024; Patient ID 10021945, TPPA-Reactive, RPR - Reactive 1:16 Controls 'Weak Reactive' 1:2; Reactive 1:8. 3. In an interview on 8/14/2025 at 2:06 PM, GS-10 confirmed the laboratory did not run reactive controls beyond 1:8, but at times reported out results to patients at 1:16 and above.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control QC records, patient testing records, and interview with testing person # 25, the laboratory failed to perform QC on Bact/Alert FA Plus and Bact/Alert PF Plus blood culture bottles two of two shipments received in 2025 as evidenced by: 1. In review of the QC records or BACT/Alert FA plus #410852 100 per box, and Bact/Alert PF #410853 100 per box, the blood culture bottles were received on 4/2/2025.The laboratory did not perform QC on the plastic blood culture media. The laboratory did not have an Individual Quality Control Plan (IQCP) for blood culture media. 2. In review of the QC records for BACT/Alert FA plus lot #0004103282 100 per box, and Bact/Alert PF lot# 0041803132 100 per box , blood culture bottles were received on 6/5/2025. The laboratory did not perform QC on the plastic blood culture media. The laboratory did not have an Individual Quality Control Plan (IQCP) for blood culture media. 3.The following random sampling of patients were tested without quality control performed on bottle culture: a.Test date 7/29/2025 Hospital number 203193 accession # 12687 b. Test date 7/31/2025 Hospital number #250012659 accession #12659 c.Test date 7/31/2025 Hospital number # 92329 d.Test date 7/31/2025 accession #12656 4. In an interview with testing person #25 confirmed on 8/18/2025 at 1050 that they did not do QC on the blood culture bottles.

D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, blood bank temperature records, and confirmed in interview with technical supervisor #2, the laboratory failed to perform temperature probe audio alarm check and establish a frequency on when to perform the audio alarm check for the Helmer refrigerator containing blood products for 7 of 7 months (2025) reviewed as evidenced by: 1.In review of the laboratory policy, "Equipment Maintenance: Alarm Quality Control Check on Helmer Fridge (Blood Units), the laboratory did not have a step by step process on how to perform the alarm checks using ice and warm (on the probe) to check the alarm's audible parameters set at 5.5 degrees C and 1.5 degrees. The laboratory did not establish a frequency on how often they perform the temperature probe audio alarm check. 2.In review of the laboratory's blood bank temperature records from January 2025 to the date of the survey, there were no temperature spikes recorded on the blood bank continuous temperature monitoring charts. 3.In interview with technical supervisor # 2 at 8/13 /2025 at 1315 confirmed that the audio alarm check was not reflected on the continuous temperate monitoring chart from the Helmer refrigerator in 7 of 7 months reviewed in 2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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: I. Based on direct observation, review of the laboratory quality control records, laboratory policies and procedures, test volume records, and confirmed in interview with the Technical Supervisor (TS-1), according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to take corrective action necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run, after 2 of 2 unacceptable quality control (QC) failures requiring recalibration for Total Bilirubin (TBIL-C), from June 1, 2025 to August 18, 2025 (random review). Findings Included: 1. In direct observation on 8/13/2025 at 2:27 PM, the following two Beckman Coulter chemistry analyzers were seen in use: a. 1 Beckman Coulter DXC 700 AU (Serial Number #2024054345) b. 1 Beckman Coulter AU 680 (Serial Number #2014093435) 2. Review of quality control records revealed QC failures requiring recalibration for the analyte TBIL-C on the following dates /times, with no patient evaluation to last acceptable test run: a. Recalibration, Test

	Name TBIL-C, 6/25/2025, 12:44 AM, Device No. 0093435 b. Recalibration, Test Name TBIL-C, 6/26/2025, 1:34 AM, Device No. 0093435 3. Review of test records revealed the following specimens in the last acceptable run reported, with no evaluation after QC failure requiring recalibration: a. Specimen 1251760210, Order #1032658, TBIL-C, Results 0.62 mg/dL, 6/25/2025 12:06 PM b. Specimen 11251760409, Order #1033063, TBIL-C, Results 0.56 mg/dL, 6/25/2025 21:38 PM c. Specimen 11251760229, Order #1032681, TBIL-C, Results 0.65 mg/dL, 6/25/2025 12:39 PM d. Specimen 11251760252, Order #1029008, TBIL-C, Results 0.30 mg/dL, 6/25/2025 12:05 PM e. Specimen 11251760245, Order #1032693, TBIL-C, Results 0.64 mg/dL, 6/25/2025 12:08 PM 4. Review of the laboratory's procedures for the Chemistry section revealed no instruction on performing an evaluation to the last acceptable run after QC failures requiring recalibrations. 5. Review of laboratory test volume records showed a total of 2,869 T-BIL C tests run in June 2025, and a total of 21,879 tests run from January 1, 2025 to July 31, 2025. 6. In an interview on 8/13 /2025 at 3:01 PM, TS-1 confirmed the laboratory did not evaluate patient test results obtained since the last acceptable QC when QC failures requiring recalibration occurred. II. Based on direct observation, review of the laboratory quality control records, laboratory policies and procedures, and confirmed in interview with the General Supervisor (GS)-10, according to the Centers for Medicare and Medicaid Services (CMS) Form-209, the laboratory failed to take corrective action necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run, after 3 of 3 unacceptable quality control (QC) failures requiring recalibration for Triiodothyronione (TotT3), Carcinoembryonic antigen (CEA2), Prostate-specific antigen (PSA), and from 7/01/2025 to 7/31/2025 (random review). Findings Included: 1. In direct observation at 8/14/2025 at 10:40 AM, one Beckman Coulter Access 2 Immunoassay System (Serial Number #510230) was seen in use. 2. Review of quality control records revealed QC failures requiring recalibration for the analytes PSA, CEA2, and TotT3 on the following dates/times, with no patient evaluation to last acceptable test run: a. TotT3 - 7/08/25 03:59 PM, Recalibration performed after 2x QC failures b. CEA2 - 7/15/25 04:46 PM, Recalibration performed after QC failure c. PSA - 7/31/25 1:09 PM, Recalibration performed after QC failure 3. Review of test records revealed the following specimens in the last acceptable run reported, with no evaluation after QC failure requiring recalibration: a. Sample ID: 192897, TotT3, Results 0.77 ng/mL, 7/1/2025 6:10 PM b. Sample ID: 17251910061, CEA2, Results 2.0 ng/mL, 7/11/25 8:18 AM c. Sample ID: 17252050083, PSA, Results 0.847 ng/mL, 7/24/25 10:32 AM 4. Review of the laboratory's procedures for the Immuno-serology section revealed no instruction on performing an evaluation to the last acceptable run after QC failures requiring recalibrations. 5. In an interview on 8/14/2025 at 10:41 AM, GS-10 confirmed the laboratory did not evaluate patient test results obtained since the last acceptable QC when QC failures requiring recalibration occurred.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by:

	Based on review of manufacturer's instructions, patient test reports, test volume records, and interview with the Technical Supervisor (TS)-1, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to include the date and time of specimen receipt into the laboratory for five of five Lactate tests performed in Chemistry from 6/01/2025 to 8/18/2025 (Random review). Findings Included: 1. A review of manufacturer's instructions titled 'Beckman Coulter AU/DxC Instructions for Use Lactate' revealed the following instructions for specimen stability on page 2 of 10: "Specimen Storage and Stability: Keep the sample on ice and separate plasms from cells within 15 minutes of collection. Analyze the sample immediately. Avoid hemolysis. Plasma: Analyze fresh. CDF: Analyze fresh." 2. A review of patient test reports from 06/01/2025 to 08/18/2025 (Random review) revealed the following five Lactate tests run with no specimen receipt date and time into the laboratory recorded: a. 6/25/2025 Index Time: 12:06 AM, Patient ID: 11251760380, Results Lactate 10.1 mg/dL b. 7/14/2025 Index Time: 12:16 AM , Patient ID: 11251960325, Results Lactate 12.1 mg/dL c. 7/17/2025 Index Time: 02:18 AM, Patient ID: 11251980353, Results Lactate 15.5 mg/dL d. 7/18/2025 Index Time: 12:41 AM, Patient ID: 11251990253, Results Lactate 15.1 mg/dL e. 7/18/2025 Index Time: 12:41 AM, Patient ID: 11251990262, Results Lactate 29.9 mg/dL 2. Review of the laboratory's test volume records revealed a total of 8,044 Lactate tests performed in 2024, and 5085 Lactate tests performed in 2025 (1/1/2025-7/31/2025). 3. In an interview on 8/18/2025 at 11:18 AM, the TS-1 of Chemistry confirmed the findings by stating the ER and other hospital wards directly sent Lactate specimens to her to spin down and perform, and did not record the specimen receipt time and date into the laboratory.