Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	66D0662224	07/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Commonwealth Health Ctr - Laboratory	1178 Hinemu' St Garapan, Saipan Mariana Islands, MP	

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 an announced CLIA recertification survey from July 23, 2025 to July 25, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations, and the following condition level and standard level deficiencies were cited.
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 Centers for Medicare and Medicaid Services (CMS) Form 209, laboratory policies, competency assessments, and confirmed in interview, the laboratory failed to have documentation of a policy to address competency assessments for two of two technical supervisors (TS) also serving as General Supervisors (GS) in 2023 and 2024. Findings Included: 1. Review of the CMS-209 form submitted by the laboratory at the time of survey, revealed two technical supervisors (TS-1 and TS-2) also serving as General Supervisors (GS-1 and GS-2). 2. Review of the laboratory's policies revealed no documentation of a policy to address competency assessment performance of individuals in the TS and GS roles in 2023 and 2024. 3. Review of the laboratory's competency assessments revealed no competency documentation for TSs and GSs. 4. In an interview on 7/23/2025 at 2:07 PM, the Laboratory Director (LD) confirmed the laboratory did not have an established policy for TS and GS competency assessment and did not assess competency for these positions.
D5300	PREANALYTIC SYSTEMS

	CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of laboratory records, observations of the laboratory, lack of records, and interviews with laboratory staff, the laboratory failed to meet preanalytic system(s) requirements in 493.1241 and 493.1242 for two of two years (July 2023 to July 2025). Findings Included: Refer to D5311 - Failure to establish specimen transportation procedures and specimen transportation criteria. Refer to D5317 - Failure to establish a client service manual.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on observation of received specimen, lack of laboratory procedures, and interview with the laboratory director (LD), the laboratory failed to establish a procedure for specimen storage and transport criteria for five of five specimen received on July 23, 2025. Findings Included: 1. On July 23, 2025 at 5:30 pm, the laboratory received patient specimens fromfrom Tinian, Northern Mariana Islands in a cooler that stated "frozen" that included the following specimens: a. Order#493104 - Collection date 07/23/2025 - Collection Time: 0705 - Tests Requested: Kidney panel. b. Order#495079 - Collection date 07/23/2025 - Collection Time: 0710 - Tests Requested: Vitima B12, Folate and T4Free. c. Order#475960 - Collection date 07/23 /2025 - Collection Time: 0800 - Tests Requested: TSH and T4Free. d. Order#495016 - Collection date 07/22/2025 - Collection Time: 1645 - Tests Requested: Wound Culture and Senetivity. e. Order#495321 - Collection date 07/23/2025 - Collection Time: 1423 - Tests Requested: Amylase. 2. The laboratory received the specimens with an ice pack, documented the receipt as "frozen", and failed to document the receipt temperature and disposition. 3. The LD on July 25, 2025 at 3:00 pm confirmed the laboratory did not have procedure for the conditions for specimen transportation and did not define specific temperature ranges for room temperature, refrigerated and frozen dispositions. Key: TSH = Thyroid Stimulating Hormone. T4Free = Thyroxine. 47107 II. Based on observation of received specimen, review of laboratory procedures, testing records, and interview with the laboratory director (LD), the laboratory failed to establish a procedure for the conditions for specimen transportation for six of six patient samples received (random sampling) for the Chemistry section on July 23, 2025. Findings Included: 1. On July 23, 2025 at 5:30

	pm, the laboratory received patient specimens from Tinian, Northern Mariana Islands in a cooler that stated "frozen" that included the following specimens: a. Hospital Patient Number #706082, 7/23/25, Iron Profile. b. Hospital Patient Number #701822, 7/23/25, TSH. c. Hospital Patient Number #708194, 7/23/25, TSH. d. Hospital Patient Number #307539, 7/23/25, Iron Profile. e. Hospital Patient Number #303658, 7/23/25, Lipid Panel. f. Hospital Patient Number #158139, 7/23/25, TSH. 2. The laboratory recieved the patient specimens on ice pack and documented as refrigerated, and did not document the disposition of the sample when it was received. 3. Review of the laboratory test records showed an annual test volume of 84,944 for the speciality of Chemistry. 4. In an interview on July 25, 2025 at 3:00 pm, the LD confirmed the laboratory did not have procedure or written instructions to their clients for the conditions for specimen transportation, and did not establish acceptable ranges for specimens received as room temperature, refrigerated or frozen for chemistry specimens. Key: TSH = Thyroid Stimulating Hormone.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of a client service manual, and interviews with laboratory director (LD), the laboratory failed to ensure the laboratory has provided written instructions to each client that sends specimens and test requests for 2 of 2 years (July 2023 to July 2025). Finding Included: 1. Review of laboratory procedures on July 23, 2025 at 12:00 pm revealed test procedures included specific requirements for specimen storage and transport. 2. The laboratory was asked to provide instructions given to clients that included specimen handing (e.g., collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances). No documentation was provided. 3. By interview with LD on July 25, 2025 at 3:00 pm, laboratory staff confirmed the laboratory does not have a client service manual.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of laboratory records, observations of the laboratory, lack of records and interviews with laboratory staff, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for two of two years (July 2023 to July 2025). Findings Included: 1. Refer to D5401 - Failure to follow procedure manual. 2. Refer to D5411 - Failure to follow manufacturer's

	instructions. 3. Refer to D5413 - Failure to monitor humidity and temperature per the manufacturer. 4. Refer to D5415 - Failure to document new stability expiration dates. 5. Refer to D5417 - Failure to discard expired reagents, media, laboratory materials, etc. 6. Refer to D5421 - Failure to assess instruments for functionality when moved to a new locations. 7. Refer to D5439 - Failure to perform calibration verification after major preventative maintenance. 8. Refer to D5445 - Failure to perform quality control each day of patient testing. 9. Refer to D5783 - Failure to perform patient evaluation after unacceptable QC, recalibration, etc.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 direct observation, review of laboratory policy, quality control (QC) records, test records, and interview with Testing Personnel (TP)-4, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to follow its own policy to perform patient controls (PCs) every two hours for 22 of 23 days reviewed (July 1 - July 23, 2025). Findings Included: 1. In direct observation on 7/25/2025 at 9: 06 AM, within the Hematology section of the laboratory, Two Sysmex XN "A" and Sysmex XN "B" analyzers (Serial Numbers #s 21720, 21721) were observed in use. 2. Review of the laboratory's policy titled 'Commonwealth Health Center Laboratory Standard Operating Procedures, Category: Hematology, Subject: Hematology Quality Control, Code: HE 21' stated the following QC requirements for the Sysmex XN Hematology analyzer on page 1 of 3: "Quality Control: 2. A Within Run (Patient) control is run every 2 hours using a normal patient sample. a. Due to decreased workload from 2300-0700 Within Run QC may not be run if there are no patient samples." 3. Review of the Sysmex XN-49728-A QC records from 7/1/25 to 7/23/25 revealed the following days patient controls were not run every 2 hours, with some being run every 3, 4 or 5 hours apart: a. 7/1/25 - 09:15, 11:41, 13:31, 14:38, 15:21, 18: 31, 20:42, 22:41, 23:47 b. 7/2/25 - 09:10, 11:11, 13:18, 15:16, 17:47 c. 7/3/25 - 09:10, 11:09, 13:44, 15:20, 17:38, 19:46, 22:08 d. 7/4/25 - 09:22, 11:14, 13:09, 15:15, 17:36, 20:31, 23:35 e. 7/5/25 - 09:23, 10:56, 14:02, 15:47, 18:38, 19:38, 21:43, 23:15 f. 7/6 /25 - 08:13, 08:49, 11:30, 13:10, 16:19, 17:22, 18:43, 20:53, 23:31 g. 7/7/25 - 09:07, 11:05, 13:34, 15:46, 17:29, 19:14, 21:11, 23:27 h. 7/8/25 - 09:20, 11:15, 13:22, 15:15, 17:35, 20:31, 22:36 i. 7/9/25 - 09:10, 11:03, 13:15, 15:05, 17:36 j. 7/10/25 - 09:03, 11: 04, 13:19, 15:27, 17:30, 20:26, 22:44 k. 7/11/25 - 11:03, 13:43, 16:01, 18:23, 21:18, 23:20 l. 7/12/25 - 09:28, 11:18, 13:10, 15:04, 17:40, 20:44, 23:52 m. 7/13/25 - 08:34, 10:14, 12:59, 14:37, 16:33, 18:21, 20:36, 23:09 n. 7/15/25 - 09:03, 09:25, 11:11, 13: 35, 15:13, 17:10 o. 7/16/25 - 09:03, 11:02, 14:35, 16:06, 18:38, 20:31, 23:22 p. 7/17 /25 - 09:05, 11:15, 13:49, 15:24, 18:24, 20:07, 22:41, 23:43 q. 7/18/25 - 9:09, 11:09, 13:15, 15:11, 19:55 r. 7/19/25 - 20:14 s. 7/20/25 - 09:40, 12:48, 13:07, 15:12, 17:15, 19:59, 21:21, 23:13 t. 7/21/25 - 10:00, 11:32, 16:00, 17:16, 19:52, 22:19, 23:55 u. 7/22 /25 - 09:49, 10:39, 12:57, 16:56, 20:51, 22:58 v. 7/23/25 - 00:04, 09:17, 12:21, 13:25, 16:00, 17:44, 21:19, 23:19 4. Review of laboratory test records revealed an annual patient test volume of 30,541 for the specialty of hematology. 5. In an interview on 7 /25/2025 at 9:06 AM, TS-4 confirmed the findings that QC patient controls were not run on the Sysmex XN hematology analyzers within two hours, as per their policy

	requirement, for the aforementioned dates reviewed. 38555 II. Based on review of laboratory procedures and interview with testing personnel (TP) #3, the laboratory failed to establish control procedures in four of eight microscopic examinations procedures from July 25, 2023 to July 25, 2025 (two of two years). Findings Included: 1. Review of laboratory procedures from July 23, 2025 to July 25, 2025 revealed, the laboratory microscopic examinations procedures failed to include control procedures for the following microscopic examinations: a. Microscopic Urinalysis. b. Semen Post Vasectomy c. Stool for white blood cells. d. Urine wet mounts. 2. From July 1, 2023 to July 25, 2025, the following number for examinations were performed: a. Microscopic Urinalysis - 16,217. b. Semen Post Vasectomy - One. c. Stool for white blood cells - 109. d. Urine wet mounts - 377. 3. By interview on July 25, 2025 at 3:00 pm, TP#3 confirmed the above findings.
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: Based on review of manufacturer's instructions, laboratory policy and procedures, calibration records, test records, and interview with the Testing Personnel (TP)-4 the laboratory failed to follow the manufacturer's instruction in establishing a new patient normal mean for two of two new lots used of Dade Innovin reagent for the Sysmex CA-600 analyzers. Findings Included: 1. Review of the manufacturer's package insert titled 'Siemens Healthineers Dade Innovin 11528733_en Rev. 13' stated the following instructions on page 4 of 9: "The mean normal Prothrombin Time (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, if applicable. Use of CLSI guideline is recommended." 2. Review of the manufacturer's package insert titled 'Siemens Healthineers PT-Multi Calibrator 11531301_en Rev. 06' stated the following instructions on page 1 of 7: "Principles of procedure: ...The MNPT is in accordance with the ISTH (International Society on Thrombosis and Haemostasis) the geometric mean of the PT of at least 20 healthy adults." Page 6 of 7: "Limitations: The reference curve is valid only for the particular PT. Multi CALIBRATOR lot and lot of Siemens Healthineers thromboplastin reagent. The calibration is instrument and reagent specific. For every new lot of thromboplastin reagent a new calibration is required. A new calibration is further required with change in experimental conditions, software, and after maintenance and repairs of the instrument." 3. Review of the laboratory's policy titled 'CHC Laboratory Document, Establishment of New Patient Normal Mean for PT/INR Testing, Document # CO 110.01 3/2009' stated the following on page 3 of 3: "Procedure: 1. Set up one instrument to run the new low number of reagent. Do not use this instrument to run patients. 2. Following the specimen requirements list above; collect samples from 20 healthy normal people . The samples should be collected from both men and women covering as broad of an adult group as possible. 3. Aliquot and freeze samples when finished testing. 4. Record results on the Coagulation Calibration/Verification Worksheet found elsewhere in this manual. Attach all results to the back of the worksheet. 5. Calculate the average PT of the 20 patients. This is

	the new patient normal mean. 6. Verify the results with the Section Supervisor or Lab Director before programming into the Siemens Sysmex CA560 Analyzers. Procedure Notes: 1. Use one instrument for the new lot number of reagent to establish the mean. Continue using the other instrument to run patient samples. Conspicuously post a notice on the machine running the new lot so patient tests are not performed on it. 2. The newly established mean normal patient PT must be programmed into both Siemens Sysmex CA560 Analyzers prior to testing patient results. 3. Manually calculate the INR to make sure the calculation in the analyzer is working correctly. Record the results on the Coagulation Calibration/Verification Worksheet." 4. Review of the laboratory's calibration records showed the following lots of Innovin used: a. 8/1 /2024 to 11/9/2024 - Lot #84740 b. 11/9/2024 to 6/24/2025 - Lot #84760 No patient normal mean calculation could be retrieved for the two lots in use. 4. Review of the laboratory's test records revealed a total annual patient test volume of 30,054 for the specialty of hematology. 5. In an interview on 7/24/2025 at 4:14 PM, TP-4 confirmed he completed the normal patient mean calculation using an arithmetic mean, not geometric mean in accordance with the manufacturer, when first validating the test years ago, and did not perform the calculation with each new lot in use. In addition, TP-4 confirmed the laboratory failed to define specific healthy adult criteria within their policy.
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 observation of the laboratory, review of manufacturer instrument / equipment manuals, and interview with technical supervisor (TS) #2 and testing personnel (TP) #3, the laboratory failed to monitor and document humidity for a sampling of testing areas in the laboratory (four of four). Findings Include: 1. Observations of the laboratory from July 23, 2025 at 10:00 am to July 25, 2025 at 3: 00 pm revealed, the laboratory areas were set up into different spaces based on the type of testing performed, the following areas were observed that did not monitor humidity: a. Microbiology. b. Urinalysis. c. Hematology. d. Immunohematology (Blood bank). 2. The following instrument / equipment manufacturer manuals stated the following humidity requirements: a. Microbiology - July 23, 2025 at 10:00 am. - BioMerieux Biofire Torch operator manual, performance specifications stated, "15 C to 30 C at 20 to 80% relative humidity". - Olympus BX46 clinical microscope instructions, 9. Operating Environment, stated "Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C (99F), to 50% relative humidity at 40C (104F)". b. Urinalysis - July 24, 2025 at 3: 00 pm. - Olympus BX46 clinical microscope instructions, 9. Operating Environment, stated "Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C (99F), to 50% relative humidity at 40C (104F)". c. Hematology - July 24, 2025 at 3:45 pm. - Olympus BX46

clinical microscope instructions, 9. Operating Environment, stated "Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C (99F), to 50% relative humidity at 40C (104F)". d. Immunohematology (Blood bank) - July 25, 2025 at 11:00 am. - Helmer Scientific Ultra CW II, operator manual stated, "Relative humidity (maximum for ambient temperature): 80% for temperatures up to 31 C, decreasing linearly to 50% at 40 C." 3. The laboratory could not provide documented humidity conditions for the above testing area with instruments / equipment that have humidity requirements. 4. By interviews, TS#1 and TP#3 confirmed the above findings on July 25, 2025 at 3:00 pm. II. Based on observation of the microbiology laboratory, review of manufacture instructions, and interview with technical supervisor (TS) #2, the laboratory failed to monitor room temperature that is consistent with the manufacturer's instructions for one of one box of AFB check control slides. Findings Included: 1. Observation of the microbiology laboratory on July 23, 2025 at 2:30 pm revealed one box of Fisherbrand AFB check control slides kept at room temperature. 2. The box of Fisherbrand AFB check control slides, package insert stated a temperature requirement to be kept at room temperature (20C - 30C). 3. Review of the laboratory temperature records revealed, the laboratory room temperature range was 19 C to 25 C. 4. In 2024, the microbiology room temperature was lower than the manufacturers established temperature range from August to December. 5. By interview, TS#2 confirmed the findings above on July 23, 2025 at 2:45 pm. III. Based on observation of the blood bank laboratory, review of manufacture instructions, and interview with testing personnel (TP) #3, the laboratory failed to monitor room temperature that is consistent with the manufacturer's instructions when performing RPR tests during a sample of three of three months in 2025. Findings Included: 1. The BD Macro-vue RPR card test, reagents stated, "Therefore, upon removal from the refrigerator, allow the antigen to warm to room temperature (23C - 29C) before use. 2. Observation of the blood bank on July 25, 2025 at 2:30 pm revealed one box of BD Macro-vue RPR card test, reagents were stored at room temperature in the Blood bank laboratory. 3. Review of the blood bank laboratory temperature records revealed, the laboratory room temperature range was 19 C to 25 C. 4. Further review of blood bank room temperature records showed the following number of days temperature were below the manufacturers established ranges: a. February 2025 - 28 out of 28 days. b. June 2025 - 30 out of 30 days. c. July 2025 - 24 out of 25 days. 5. By interview with TP#3 on July 25, 2025 at 2:45 pm confirmed the laboratory room temperatures established acceptable ranges fell outside of the manufacturers range. Key: RPR = Rapid Plasma Reagin. AFB = Acid-fast bacilli. 47107 IV. Based on direct observation, manufacturer's instructions, humidity records, and interview with the Testing Personnel (TP)-4, according to the Centers for Medicare and Medicaid (CMS) Form 209, the laboratory failed to define, monitor and document the humidity in the laboratory for two of two rooms (hematology and coagulation) where analyzers with humidity requirements were in use. Findings Included: 1. In direct observation on 7/25 /2025 at 9:06 AM the following were seen in the hematology and coagulation sections: a. Hematology section - Two Sysmex XN "A" and Sysmex XN "B" analyzers (S/N #s 21720, 21721) were observed in use. b. Coagulation section - Two Sysmex CA 660 "A" and "B" analyzers (S/N #s 25099, 25090) were observed in use. 2. Review of the manufacturer's instructions for both analyzers stated the following: a. Sysmex XN 1000 manufacturer's instructions titled 'Sysmex XN 1000 product fact sheet': "Operative humidity 30-85%". b. Sysmex CA 660 manufacturer instructions titled 'Sysmex Product Fact Sheet CA-650/CA-660': "Technical Specifications, Humidity, 30% - 85%". 3. Review of the laboratory's humidity records revealed no humidity ranges defined, monitored or documented in the hematology and coagulation sections where the analyzers were in use. 4. In an interview on 7/25/2025 at 9:15 AM

	in the laboratory, TP-4 confirmed the laboratory had not defined, monitored or documented humidity in the hematology and coagulation sections of the laboratory. V. Based on direct observation, manufacturer's instructions, review of the freezer temperature ranges, and interview with TP-6, according to the CMS Form 209, the laboratory failed to define freezer temperature ranges consistent with the manufacturer's instructions, for 4 of 4 Bio-Rad Liquicheck control reagent boxes. Findings Included: 1. In direct observation on 7/24/25 at 9:31 AM, the following reagent boxes were found stored in the freezer (Midea, #03706): a. 1 box Bio-Rad Liquicheck Pediatric Control, Lot #74922, Manufacturer storage temperature requirements: -70 to -20 degrees C. b. 1 box Bio-Rad Liquicheck Elevated CRP Level 1 Control, Lot #90911, Manufacturer storage temperature requirements: -70 to -20 degrees C. c. 1 box Bio-Rad Liquicheck Elevated CRP Level 2 Control, Lot #90912, Manufacturer storage temperature requirements: -70 to -20 degrees C. d. 1 box Bio-Rad Liquicheck Elevated CRP Level 3 Control, Lot #90913, Manufacturer storage temperature requirements: -70 to -20 degrees C. 2. Review of the Midea #03706 freezer settings in the chemistry section stated a range of -18 degrees C or colder. 3. In an interview on 7/24/25 at 9:35 AM, TP-6 confirmed that the freezer temperature ranges were not set and defined to follow manufacturer instructions of reagent controls stored within. Key: CRP = C-reactive protein.
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's instructions, lack of records, and interview with testing personnel (TP) #3, the laboratory failed to indicate the revised stability expiration date on one of one lot of BioRad Virotrol RPR Panel quality control (QC) when opened. Findings Included: 1. The manufacturer's instructions for the BioRad Virotrol RPR Panel QC stated, "60 day open-vial stability at 2-8C. 2. Direct observation of the laboratory on July 25, 2025 at 1:00 pm revealed one box of BioRad Virotrol RPR Panel QC in use did not include a new expiration date that matched the 60 day stability. 3. Review of RPR QC records revealed the previous lot of BioRad Virotrol RPR Panel QC (lot#127160) was in use from January 5, 2024 to August 30, 2024 (238 days). 4. Approximately 1387 RPR tests were performed from July 25, 2023 to July 25, 2025. 5. On July 25, 2025 at 2:00 pm, by interview TP#3 confirmed the laboratory used the BioRad Virotrol RPR Panel QC was used beyond the 60 day stability. Key: RPR = Rapid Plasma Reagin.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, interview with technical supervisor (TS) #1 and testing personnel (TP) #4, the laboratory failed to ensure a sampling of bacteriology media plate (8 of 56) and one of two containers of pH strips were not available for use after they exceed their expiration dates. Findings Included: 1. Observation of the microbiology laboratory on July 23, 2025 at 10:00 am, revealed the following expired media available for use for patient tesing: a. Two of three Remel HE agar plates. b. One of two Remel TM agar plates. c. Five of sixteen Remel CNA agar plates. 2. Observation of the hematology laboratory on July 23, 2025 at 3: 00 pm, revealed one container of LRS Universal Plastic pH strips expired October 15, 2023. 3. Interview with TS#1 and TP#4 , on July 23, 2025 at 3:30 pm confirmed the above media and pH strips were expired. Key: TM - Thayer Martin. HE - Hektoen enteric. pH - potential of hydrogen. CNA - Columbia Nalidixic Acid.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 observation of the laboratory, lack of documentation and interview with technical supervisor (TS) #1, the laboratory he laboratory failed to perform verification studies for six of six microbiology test systems after instrumentation relocation in May 2024. Findings Included: 1. During the introduction of the survey, on July 23, 2025 at 10:30 am, observation of the laboratory revealed the laboratory was under construction. 2. While observing the microbiology laboratory, TC#1 was asked if any test systems have been moved in the past two years, in which they replied "yes". 3. The laboratory was asked to provide documentation of verification studies after the relocation. No documentation was provided. 4. The following microbiology test systems were moved in May of 2024: a. Two Cepheid GeneXpert system with four modules. b. One Cepheid GeneXpert system with sixteen modules. c. Two BioMerieux Vitek2. d. One BioMerieux Biofire Torch. 5. TS#1 on July 23, 2025 at 2: 00 pm confirmed the above findings. 6. Per form CMS 116, signed by the laboratory director on July 23, 2025, there were 9,100 microbiology tests performed annually. 47107 II. Based on observation of the laboratory, lack of documentation and interview with the Laboratory Director (LD), and test records, the laboratory failed to perform performance verification studies for two of two Hematology analyzers and two of two Coagulation analyzers after instrument relocation in April of 2024. Findings Included: 1. During the introduction of the survey, on July 23, 2025 at 10:30 AM, observation of the laboratory revealed the laboratory was under construction; the following analyzers were seen in use: a. Hematology - Two Sysmex XN 'A' & 'B' analyzers (S /Ns # 21720, 21721) b. Coagulation - Two Sysmex CA-600 Series 'A' & 'B' analyzers (S/Ns # 25099, 25090) 2. Review of the laboratory's procedures and documentation of accuracy verification yielded no findings of either documentation of performance verification being performed or a policy/procedure. 3. Review of the laboratory's test records revealed an annual total patient test volume of 30,541 for the specialty of

	hematology. 4. The LD on July 25, 2025 at 12:59 PM confirmed the laboratory did not perform verification of performance specifications (accuracy and precision) after relocation.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 instrument preventative maintenance records (random review May-December 2024), calibration records, test records, and confirmed in interview, the laboratory failed to perform calibration verification to ensure the accuracy of the Siemens Dimension EXL analyzer after there was a major preventative maintenance and/or replacement of critical parts that may influence test performance for 3 of 3 Integrated Multi-Sensor (IMT) analytes that used single point calibration. Findings Included: 1. Review of the laboratory instrument preventative maintenance records revealed the following dates when a major preventative maintenance and/or replacement of critical parts occurred by Siemens Healthineers (service technicians): a. 5/6/2024 - Contract #0450096718 - Employee #196995 - Corrective Action/Service Performed: Replace PM parts, Clean surface. Run System check Passed. Run QC's passed. The PM was performed with the protocol DCIN-A03.331.11.13.02 b. 11/13 /2024 - 11/13/2024 - Contract #04500096718 - Employee #196995 - Synptoms Reported/Reason for Service: Photometer Source Lamp Problem - Corrective Action /Service Performed: Reviewed error logs, replaced photometer board (used) still encounter error. Replace lamp, detected broken filter motor and replaced it by old and used motor, run system check run QC's (passed). Still having intermittent error with the photometer, need to replace photometer board and photometer assay. c. 11/22 /2024 - Contract #04500096718 - Employee #196995 - Symptoms Reported/Reason for Service: Photometer source lamp problem - Corrective Action/Service Performed: Install photometer and photometer board, calibrate photometer. Initialized machine, Run system check (passed), Run QC's (passed) monitor patient running. 2. Review of the laboratory calibration records for the Integrated Multi-Sensor (IMT) analytes (NA, K, CL) revealed only a single point calibration, and not three levels of calibration material. The laboratory performed the following tests after a major preventative maintenance and/or replacement of critical parts before a calibration verification of at least three levels of separate concentrations were performed on the electrolytes: a. 5/6

	/24 - 5/7/24: 167 test volume (Electrolytes - Na, K, CL) b. 11/13/24 - 11/15/24: 265 test volume (Electrolytes - Na, K, CL) c. 11/22/24 - 11/23/24: 148 test volume (Electrolytes - Na, K, CL) 3. Review of the laboratory's test records revealed an annual patient test volume of 84,944 for the speciality of Chemistry. 4. In an interview on 7/24/25 at 9:05 AM, TP-6 confirmed that he did not perform a calibration verification after a major preventative maintenance and/or replacement of critical parts on the aforementioned analytes that utilize single point calibration. Key: K = Potassium. NA = Sodium. CL = Chloride. QC = Quality control.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: I. Based on review of microbiology records, lack of an individualized quality control plans (IQCP), and interview with technical supervisor (TS) #1 and the laboratory director (LD), the laboratory failed to perform quality control (QC) at least once each day of patient testing for three of three microbiology test systems in use. Findings Included: 1. The microbiology laboratory used the following test systems and test kits: a. Cepheid GeneXpert system. I. SARS CoV-2, Flu, RSV cartridge. II. CT/NG cartridge. III. MTB/RIF cartridge. IV. C. Diff cartridge . b. BioMerieux Vitek2. I. ID testing. II AST testing. c. BioMerieux Biofire Torch. I. GI panel. II. BCID2 panel. III. ME panel. IV. Respiratory panel. V. Pnemo panel. 2. Review of the above test system procedure manuals on June 23, 3035 at 9:24 am revealed the above test procedures stated, QC is performed every 30 days. 3. The laboratory failed to have complete IQCPs for the following: a. Cepheid GeneXpert system. I. CT/NG cartridge - QC plan. II. MTB/RIF cartridge - QC plan. III. BioMerieux Vitek2 - AST testing - QA plan. 4. The laboratory could not provide IQCPs for the following tests: a. Cepheid GeneXpert system. I. SARS CoV-2, Flu, RSV cartridge. II. C. Diff cartridge. b. BioMerieux Vitek2. I. ID testing. c. BioMerieux Biofire Torch. I. GI panel. II. BCID2 panel. III. ME panel. IV. Respiratory panel. V. Pnemo panel. 5. The following number of tests for each system were performed from July 1, 2023 to July 25, 2025: a. Cepheid GeneXpert system. I. SARS CoV-2, Flu, RSV cartridge - 541. II. CT/NG cartridge - 2893. III. MTB/RIF cartridge - 81. IV. C. Diff cartridge - 30. b. BioMerieux Vitek2. I. ID testing - 7549. II AST testing - 7549. c. BioMerieux Biofire Torch. I. GI panel - 262. II. BCID2 panel - 14. III. ME panel - 19. IV. Respiratory panel - 605. V. Pnemo panel - 228. 6. The LD confirmed the findings above on July 25, 2025 at 3:00 pm. Key: RSV = Respiratory Syncytial Virus. CT/NG cartridge = Clamydia/Gonorrohea. MTB/RIF cartridge = Mycobacterium tuberculosis / rifampicin resistance. C. Diff = Clostridioides difficile. GI = gastrointestinal.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on observation of the microbiology laboratory records, lack of documentation and interview with technical supervisor (TS) #1, the laboratory failed to monitor and evaluate the relationship between three of three Cepheid GeneXpert analyzers were used to run the SAR-CoV2 tests twice a year. Finding Included: 1. Observation of the laboratory on July 23, 2025 at 10:30 am, revealed the microbiology laboratory used three Cepheid GeneXpert analyzers (A - S/N8048201, B - S/N836416, and C - S /N836408). 2. The laboratory was unable to provide documentation evaluating the relationship between three of three Cepheid GeneXpert analyzers used to run the SAR-CoV2 tests. 3. TS#1 confirmed the above findings on July 23, 2025 at 11:00 am Key: S/N = Serial Number
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: Based on direct observation, review of the laboratory quality control records, laboratory policies and procedures, test records, and confirmed in interview with the Testing Personnel (TP)-6, 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 three of three unacceptable quality control (QC) failures, requiring recalibration or new lot, from June 1, 2025 to July 25, 2025 (random review). Findings Included: 1. In direct observation on 6/24/2025 at 9:03 AM, 2 Siemens EXL analyzers were in use in the Chemistry section of the laboratory. 2. A review of the laboratory's QC records on the Siemens EXL (S/N #12252291) revealed the laboratory failed to evaluate patient test results since the last acceptable QC run after recalibration and/or usage of different lot after QC failure for the following dates: a. 6 /3/25 Analytes: Urine CA Action Taken/Tech Comments: "Repeat QC, QC out. Recon new QC, QC out. Remove old CA reagent and run the new reagent lot - QC OK." b. 6/16/25 Analytes: Albumin, Cholesterol, Urine Potassium Action Taken/Tech Comments: "Rerun Urine K QC, QC is in. Rerun Albumin, QC is in in. Rerun Tbl and Cholesterol, QC is out. Cholesterol to recalibrate - QC is in." Patient Tests Run: 37 Albumin, 2 Cholesterol, 0 Urine Potassium tests run on 6/15/25 to last acceptable QC. c. 7/6/25 Analytes: MMB Action Taken/Tech Comments: "Repeat QC 2, twice. Still out. Thawed new lot of Cardiac QC 1 and 2. Then reran QC2. Used different lot of for MMB, QC OK." 3. Review of the laboratory's Chemistry section policy titled 'Commonwealth Health Center Laboratory Standard Operating Procedures, Category:

	Chemistry' did not contain information regarding patient evaluations after QC failures requiring recalibration and/or usage of new lot, nor define what was considered a QC failure, and stated a QC failure or "deviation" would be at the discretion of a laboratory technician. 4. Review of the laboratory's test records revealed an annual patient test volume of 84,944 for the specialty of chemistry. 5. In an interview on 7/24 /25 at 9:05 AM, TP-6 confirmed that in the event of deviation/QC failures, recalibration and/or usage of new lots, the laboratory failed to establish corrective action policy with instruction to perform a patient evaluation of tests run to the last acceptable QC to determine if patients test results had been adversely affected, nor performed this.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, review of laboratory records, and interview with testing personnel (TP) #3 and the laboratory director (LD), the laboratory failed to review the effectiveness of corrective actions (CA) taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems and document corrective actions for a sampling of three of three blood bank blood product refrigerator alarms in 2024. Findings Include: 1. The Clinical laboratory Quality Assessment/improvement procedure stated, "the laboratory measure quality indicators of concern/interest to the hospital CEO and QI office". 2. Review of laboratory records revealed the laboratories Clinical laboratory quality Assessment/improvement procedure on July 25, 2025 at 11:00 am revealed the procedure does not include the review for the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems and document corrective actions. 3. For example, in the blood bank laboratory area, three instances below were found where temperatures were outside of the refrigerator (1-6 degrees Celsius) and freezer acceptable range (-18 degrees Celsius): a. June 20, 2024 - refrigerator - 24 degrees Celsius. b. November 22, 2024 - freezer - -14 degrees Celsius. c. March 23, 2025 - refrigerator - 20 degrees Celsius. d. April 18, 2025 - freezer - temperature spiked off the chart (greater than 0 degrees Celsius). 4. The laboratory could not provide a procedure on how to handle blood bank refrigerator / freezer alarms, nor were documented CA provided on July 25, 2025 by 3:00 pm. 5. The LD and TP#3 confirmed the above findings on July 25, 2025 at 2:50 pm.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required

	prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Form 209, personnel records, and staff interview, the Laboratory Director (LD) failed to specify, in writing, the responsibilities and duties, for one of one General Supervisor (GS) for high complexity testing. Findings Included: 1. Review of the CMS-209 form submitted by the laboratory at the time of survey revealed one General Supervisor (GS) of high complexity testing. 2. Review of the laboratory personnel records revealed the Laboratory Director failed to specify GS responsibilities and duties in writing, for high complexity testing. 3. The laboratory's position description titled 'Lead Clinical Laboratory Technician' did not contain the duties and responsibilities to meeting the requirements of the General Supervisor level. 4. In an interview on 7/25 /2025 at 2:00 PM, the LD confirmed the laboratory's position description of 'Lab Manager' contained roles and responsibilities to meet the requirements of the Technical Supervisor level, but the 'Lead Clinical Laboratory Technician' position description did not suffice to meet the requirements of the General Supervisor responsibilities.