Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0183623	04/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Titusville Area Hospital	406 West Oak St, Titusville, PA	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of personnel records, thePennsylvania State Laboratory Personnel Report (PA LPR) and interview with the laboratory director and technical supervisor (TS) #2 , the laboratory director/owner failed to ensure that 1 of 7 (PA LPR GS #5) supervisors met the qualifications specified in the Pennsylvania (PA) Clinical Lab Act from 09/15/2022 to the date of the survey. Findings include: 1. The PA regulations (5.23(a)(3) states: "He shall hold a B.S or A.B degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 6 years experiences acceptable to the department in one or more of the applicable categories in the clinical laboratory." 2. A review of personnel credentials offsite revealed that 1 of 7 supervisors (PA LPR GS #5) has a associate degree in specialized technology (major in medical laboratory technician). 3. The LD and TC #2 confirmed the findings above on 03/10/2024 at 3:30 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of documentation, and interview with technical consultant (TC) #2 (CMS 209 personnel # 2) and general supervisor (GS) # 4 (CMS 209 personnel # 8), the laboratory failed to establish a procedure for laboratory information system (LIS) and microscopic gram stain (GS) examinations performed from 09/15/2022 to the date of the survey. Findings Include: 1. On the day of survey, 04/09/2024 at 12:17 pm, the laboratory failed to provide a procedure for LIS and microscopic GS examinations performed from 09/15/2022 to the date of the survey. 2. The TC #2 and GS #4 confirmed the finding above on 04/10/2024 at 03:30 pm.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Technical Supervisor #1 (TS), the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for hematology and chemistry testing performed from 9/15/2022 to the day of the survey. Findings include: 1. The laboratory's Platelet Clumping procedure states, "D. Clumps/Fibrin Strands present and an un-spun Sodium Citrate tube available: a. Citrated blood can be used to perform the WBC and PLT counts if the clumping is caused by the EDTA anticoagulant. b. Run a CBCAuto on the unspun sodium Citrate tube c. Multiply the PLT and WBC counts by 1.1 (this corrects for the 9:1 ratio in the sodium citrate tube). Enter the recalculated WBC and PLT results into Meditech. Change the MPV result from the EDTA result to the result obatained from the Sodium citrate tube. DO NOT perform a 1.1 calculation on this result. " 2. The laboratory's Body Fluid Analysis procedure states, "The following tests will be offered for body fluid analysis: BF ALB, BF AMYL, BF CREAT, BF GLUC, BF LDH, BF TP, BF

	CHOL, and BF TRIG. There is no QC for body fluids. Body fluids are run on the Cobas 6000 and are run the same as serum/plasma. Specimens should be spun before analyzing. There are no reference ranges for body fluids. We will provide the serum /plasma range for comparison reasons. There will be a comment with each test stating that these are not body fluid reference ranges, but are serum/plasma ranges that are provided for the physician to see." 3. On the day of the survey, 04/09/2024 at 03:00 pm, the laboratory failed to provide documentation for the establishment of performance specifications for the following 8 of 8 chemistry tests performed on the Cobas 600, and the following 3 of 3 hematology tests perfomed on the Sysmex XN 450 and 1000 form 09/15/2022 to the date of the survey: Chemistry - Body Fluid albumin - Body Fluid amylase - Body Fluid creatinine - Body Fluid glucose - Body Fluid LDH - Body Fluid total protein - Body Fluid cholesterol - Body Fluid triglycerides Hematology - WBC count - Platelet Count - MPV 4. TS #1 confirmed the findings above on 04/09/2024 at approximately 3:00 pm.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record review, and interview with the technical consultant (TC) #2 (CMS 209 personnel # 2), the laboratory failed to maintain a maintenance protocol that ensures equipment performance for 1 of 1 thermometer used for Room Temperature (RT) and humidity monitoring for microbiology, chemistry, hematology, urinalysis, and histopathology testing performed from 09/15/2022 to the day of the survey. Findings include: 1. At the time of survey, 04/09/2024 at 02:00 pm, the laboratory failed to provide documentation of calibration for 1 of 1 thermometer (LA CROSSE) used for RT and humidity monitoring for microbiology, chemistry, hematology, urinalysis, and histopathology testing performed from 09/15/2022 to the day of survey. 2. The laboratory's temperature and humidity recording procedure states, "All equipment must be calibrated once a year to make sure that the equipment is accurate." 3. TC #2 confirmed the findings above on 04/10/2024 at 03:30 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on lack of documentation and interview with the technical supervisor #1 (TS), the laboratory failed to include two control materials of different concentrations at least once each day of patient testing for body fluid chemistry analysis performed on the Cobas 6000 from 9/15/2022 to the day of survey. Findings include: 1. The laboratory's Body Fluid Analysis procedure states, "The following tests will be offered for body fluid analysis: BF ALB, BF AMYL, BF CREAT, BF GLUC, BF LDH, BF TP, BF CHOL, and BF TRIG. There is no QC for body fluids." 2. On the day of survey, 04/09/2024 at approximately 1:55 pm, the laboratory failed to provide documentation of the QC performed at least once each day of patient testing for the following 8 of 8 chemistry body fluid analytes performed on the COBAS 6000 from 09/15/2022 to the date of the survey:: - Amylase - Glucose - Total Protein - Albumin - LDH - Triglyceride - Creatinine - Cholesterol. 3. The TS confirmed the findings above on 04/09/2024 at approximately 1:55 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with general supervisor (GS) # 4 (CMS 209 personnel #8), the laboratory failed to establish and document a negative and positive control each day of patient testing for microscopic pinwarm preparation examinations performed from 09/15/2022 to the day of survey. Findings Include: 1. On the day of the survey, 04/09/2024 at 01:46 pm, the laboratory failed to provide documentation of QC each day of patient testing for microscopic pinwarm preparation examination performed in mycology from 09/15/2022 to the day of survey. 2. GS #4 confirmed the findings above on 04/10/2024 at 03:30 pm.
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. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical supervisor #1 (TS), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instrumentation in hematology and serology from 09/15 /2022 to the date of the survey. Findings included: 1. The laboratory's procedure Test Method Validation states the following, "Comparability of Instruments and Methods If the laboratory uses more than one non-waived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results. Procedures and acceptance criteria are included in

	the specific department." 2. On the date of the survey, 04/10/2024 at approximately 2: 00 pm, the laboratory failed to provide documentation of the biannual comparison studies for the following 4 of 4 tests performed from 09/15/2022 to 04/09/2024: - CBC with automated differential (Sysmex XNL450) vs. CBC with automated differential (Sysmex XNL1000) - manual cell counts (body fluids and CSF) vs. automated cell counts (Sysmex) (body fluids and CSF) - manual differential vs. automated differential (Symex XN) - Qualitative Serum HCG (Cardinal Health Rapid Test hCG combo rapid test) v. Quantitative HCG (Roche Cobas 6000 analyzer series) 2. TS #1 confirmed the findings above on 04/10/2024 at approximately 2:30 PM.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the laboratory director (LD) the laboratory failed to include the location where Dermatopathology microscopic examinations were performed on the patient test report from 09/15/2022 to the day of survey. Findings include: 1. On the day of survey, 04/09/2024 at 04:30 pm, review of 1 of 1 patient test report (07/07/2022) revealed documentation of dermatopathology microscopic examination test result that did not include the address of where the microscopic examination was performed. 2. The LD confirmed the above findings on 04/10/2024 at 03:30 pm.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the Roche cobas 6000 analyzer series validation records, procedural manual document review, and interview with the Technical Supervisor #1 (TS), the Laboratory Director (LD) failed to approve the performance specification procedures used to determine the accuracy and precision for the High Sensivitiviy Troponin (HS Trop) testing performed on the Roche cobas 6000 analyzer before reporting patient test results from September 2023 to the date of survey. Findings Include: 1. The laboratory's Test Method Validation procedure states the following "2. The laboratory must verify outside data, or establish datay, on accuracy precision, sensitivity, interferences, and reportable range. Reference intervals must also be verified or established. This verification must be reviewed by the Laboratory Director, and found to be acceptable before any patient tests can be reported. A summary

	statement, signed by the Laboratory Director, documenting review of validation studies and approval for each test for clinical use must be completed." 2. On the day of the survey, 04/09/2024 at 02:30 pm, review of the Roche Cobas 6000 validation records revealed the LD failed to review and approve the validation studies performed on 12/20/2022 for HS Trop testing before patient tests are reported. 3. During an interview on 04/09/2024 at 02:20 pm, TS #1 confirmed that patient testing was performed and reported for HS Trop from September 2023 to the day of the survey.