Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0181633	08/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Punxsutawney Area Hospital	81 Hillcrest Drive, Punxsutawney, 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
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 competency assessment records and interview with Technical Supervisor (TS) #2, the laboratory failed to perform the competency assessment of 1 of 6 general supervisor (GS) #2 and 1 of 14 testing personnel (TP) #2 for their responsibilities performed in 2023. Findings include: 1. On the day of survey, 08/20 /2024 at 9:03 am, review of competency assessment records revealed the laboratory failed to assess the competency of GS #2 (CMS 209 personnel #2) for their supervisory responsibilities in 2023. 2. Review of records on 08/20/2024 at 9:45 am revealed the laboratory failed to assess the annual competency of TP #2 (CMS 209 personnel #2) who performed testing in microbiology, chemistry, hematology, immunohematology and immunology in 2023. 3. On the days of survey, 08/20/2024 and 08/21/2024, the laboratory could not provide competency assessment records for GS #2 and TP #2 for their responsibilities performed in the laboratory in 2023. 4. TS #2 confirmed the findings above on 08/21/2024 at 11:22am.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) records and interview with General Supervisor (GS) #3 (CMS 209 personnel #3), the laboratory failed to establish and maintain the accuracy of its testing procedures twice annually for chemistry and hematology testing performed in 2023 and 2024. Findings Include: 1. On the day of survey, 08/20/2024, review of the laboratory's American Proficiency Institute (API) PT records revealed the laboratory failed to verify the accuracy twice annually for the following tests performed in 2023 and 2024: -Prostate specific antigen (PSA) - Body fluid pH - Sperm morphology - Sperm motility 2. GS #3 confirmed these findings on 8 /20/2024 at 10:00 am.
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's procedure manual, and interviews with Technical Supervisor (TS) #2 (CMS 209 personnel #2) and TS #3 (CMS 209 personnel #3), the laboratory failed to provide a complete procedural manual for hematology testing performed from 02/09/2023 to the date of survey. 1. On the day of the survey, 08/20 /2024, review of the laboratory's hematology procedure manual revealed, the laboratory failed to include the following applicable requirements under 493.1251 (b) for the manual differentials and body fluid tests performed from 02/09/2023 to 08/21 /2024: - Body Fluid Crystal Analysis - Control procedures - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - Manual Differentials (WBC) - Control procedures - Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. - Automated Body Fluid Analysis performed on 1 of 1 Sysmex XN 1000 - Step-by-step performance of the procedure, including test calculations and interpretation of results when performing dilutions. 2. TS #2 and TS #3 confirmed the findings above on 08/20/2024 at 11:30 am.
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 lack of documentation, record review, and interview with general supervisor (GS) #3 (CMS 209 personnel #3), the laboratory failed to establish and verify performance specifications for 2 of 2 Ortho Vitros 5600 chemistry analyzers before reporting patient test results for body fluid analysis examinations performed from 02 /09/2023 to 08/20/2024. Findings include: 1. On the day of survey, 8/20/2024, review of the Ortho Vitros 5600 chemistry analyzer procedures revealed the laboratory performed the following chemistry tests on 2 of 2 Vitros 5600 analyzers using body fluid specimens from 02/09/2023 to 08/20/2024: -Albumin -Amylase -Cholesterol -Creatinine -Glucose -Total protein -Triglycerides -Urea Nitrogen -Lactate dehydrogenase 2. The laboratory failed to provide documentation for the accuracy, precision, reportable range, and reference interval/range for the laboratory's patient population performed on the 2 of 2 Vitros 5600 analyzers used for body fluid analysis examinations performed from 2/9/2023 to 8/20/2024. 3. GS #3 confirmed the findings above on 8/20/2024 at 10:30 am.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the Laboratory Information System (LIS) policy, lack of documentation and interview with general supervisor (GS) #3 (CMS 209 personnel #3), the laboratory failed to follow written policies for an ongoing mechanism to monitor and verify calculations for postanalytic systems specified in 493.1291(a)(1). from 02/09/2023 to the day of survey. Findings include: 1. On the date of the survey, 8 /21/2024 at 2:15pm, review of the laboratory's LIS policy revealed that the laboratory failed to follow written procedures to periodically ensure the accuracy of calculated results performed by the LIS from 02/09/2023 to 08/21/2024. 2. The laboratory failed to provide documentation of the periodic verification of accuracy for the LIS calculated results. 3. GS #3 confirmed the findings above on 8/21/2024 at 2:30 pm.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with Technical Supervisor #2 (TS) and TS #3, the TS failed to assess test performance using previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 11 of 14 testing personnel (TP) that performed hematology/coagulation testing from 02/09/2023 to the day of survey. Findings include: 1.Review of the laboratory's American Proficiency Institute (API) Hematology/Coagulation proficiency testing (PT) records revealed TP #5 (CMS 209 TP #5) performed and signed the attestation statements for all coagulation PT samples tested for 5 of 5 API testing events reviewed in 2023 and 2024. 2. On the day of the survey, 08/20/2024, the laboratory failed to provide documentation for the assessment of test performance using previously analyzed specimens, internal blind testing samples, or external PT samples for 11 of 14 TP (CMS 209 TP #2,#3,#4,#6,#7,#8,#9, #10,#11,#12, and #13) that routinely performed coagulation testing in 2023 and 2024. 3.TS #2 and TS #3 confirmed the findings above on 8/20/2024 at 10:00 AM.