

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0183697	(X3) Date Survey Completed 10/10/2024
Name of Provider or Supplier Warren General Hospital	Street Address, City, State 2 Crescent Park, Warren, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing (PT) records and interview with Technical Supervisor #2 (CMS 209 TS #2), the laboratory failed to interpret histology slides by a pathologist (CMS 209 TP #1) who routinely interpret Histology slides for 2 of 2 CAP PT events in 2023 and 2 of 2 CAP PT events in 2024. Findings include: 1. The laboratory's procedure "Surgical Pathology Services" states the following "All specimens for microscopic examination shall be performed by a board eligible/board certified anatomic pathologist who is to employ professional skills to render a proper diagnosis." 2. Interview with Technical Supervisor #3 (CMS 209 TS #3) revealed that the routine patient testing for interpretation of histology slides is only performed by TP #1. 3. Interview with TP #1 revealed that for proficiency testing, unqualified testing personnel (CMS 209 TP #17, #16, #10, or #7) would interpret the slides and he would review the PT results. 4. On the day of survey, 10/09/2024, review of CAP PT records revealed that interpretation of histology slides was not performed by the pathologist for 2 of 2 events in 2023 and 2 of 2 events in 2024: - PM3-A 2023 CD20 Immunohistochemistry Tissue Microarray survey. - PM3-B 2023 CD20 Immunohistochemistry Tissue Microarray survey. - PM3-A 2024 CD20 Immunohistochemistry Tissue Microarray survey. - PM3-B 2024 CD20 Immunohistochemistry Tissue Microarray survey. 5. Laboratory director confirmed the above findings on 10/10/2024 at 11:30 AM.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on a lack of documentation and interview with the Technical Supervisor #2 (CMS 209 form TS#2), the laboratory failed to retain quality control (QC) documents for virology testing performed in 2023 and 2024. Findings include: 1. On the day of the survey, 10/09/2024 at 10:00 am, the laboratory failed to provide QC documentation for the Cepheid XPERT GC/NG tests performed in the laboratory for 1 out of 9 months (September) in 2024. 2. On the day of the survey, 10/09/2024 at 10:00 am, the laboratory failed to provide maintenance logs for the Cepheid GeneXpert for: - 12 out of 12 months of 2023 - 2 out of 9 months (August and September) of 2024 3. TS #2 confirmed the findings above on 10/10/2024 around 12:00 pm.

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 Technical Supervisor #2 (CMS 209 TS #2), the laboratory failed to establish and maintain the accuracy of its testing procedures twice annually for histology testing performed in 2024. Findings Include: 1. On the day of survey, 10/09/2024 review of the laboratory's College of American Pathologist records revealed the laboratory failed to verify grossing and inking testing in Histology twice annually in 2024: - HQIP-A 2024 Histology Quality Improvement Program not performed in 2024. 2. TS #2 confirmed these findings on 10/09/2024 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 interview with Technical Supervisor (TS) #2 (CMS 209 TS #2) the laboratory failed to provide a complete procedural manual for Urinalysis sediment performed from 01/11/2023 to the date of survey. 1. On the day of the survey, 10/09/2024, review of the laboratory's urinalysis procedure manual revealed, the laboratory failed to include the following applicable requirements under 493.1251 (b) for urine sediment examinations performed on 1 of 1 Iricell analyzer and microscopically (manual) from 01/11/2023 to 08/20/2024: - The reportable range for test results for the test system as established or verified in 493.1253. - Limitations in the test methodology, including interfering substances. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - Pertinent literature references. - 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. 2. TS #2 confirmed the findings above on 10/09/2024 at 01:00 pm.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with Technical Supervisor #2 (CMS 209 TS #2) the laboratory failed to provide bioMerieux BacTAlert blood culture temperature records for 4 of 4 drawers in 2023 and 2024. Findings include: 1. On the day of survey, 10/09/2024 at 9:00 am, the laboratory could not provide temperatures for bioMerieux BacTAlert blood culture for the following: - 22 out of 31 days in January 2023 - 1 out of 31 day in October 2023 - 31 out of 31 days in July 2024 2. TS#2 confirmed the findings above on 10/10/2024 around 12:00 pm

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

A. Based on observation of the laboratory, document review and interview with technical supervisor #2 (CMS 209 TS #2), the laboratory failed to label aliquoted

reagents with the pertinent information required for proper use from 01/11/2023 to the day of survey. Findings Include: 1. On the day of survey, 10/10/2024, observation of reagents and stains in use, revealed the laboratory did not label the following aliquots: - 1 of 1 bottle of Boric Acid. - 1 of 1 bottle of Hydrochloric Acid (HCL). - 2 of 2 bottles of deionized water. 2. TS #2 confirmed the findings above on 10/10/2024 around 12:00 pm. B. Based on observation of the laboratory, document review and interview with technical supervisor #2 (CMS 209 TS #2), the laboratory failed to ensure the proper storage of acids and bases from 01/11/2023 to day of survey. 1. The laboratory provided MDS sheet for Xylene states the following under "Conditions for Safe storage, Including Any Incompatibilities": "Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Incompatible Materials: Strong acids, strong bases, strong oxidizers." 2. During the laboratory tour a cabinet labeled "Acid Storage Only" stated the following: "Supplies of acids and bases must be stored in separate cabinets near floor level." 3. During the laboratory tour it was observed that: - 2 bottles of Xylene were stored in the flammable cabinet with 8 bottles of Ethanol, 1 bottle of Hematoxylin, and 2 bottles of Eosin Y alcohol. - 1 of 1 bottle of acetone, 1 of 1 bottle of boric acid, and 1 of 1 bottle of Sodium Hydroxide 1 of 1 bottle of Sulfuric Acid, and 4. of 2 bottles of HCL were stored together in a wooden cabinet labeled "Acid Storage only." 5. TS #2 confirmed the findings above on 10/10/2024 around 12:00 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 lack of documentation, and interview with technical supervisor #3 (TS), the laboratory failed to establish performance specifications before reporting patient test results when modifying an FDA-cleared/approved test system for body fluid analysis examinations performed on the Unicel DxC chemistry analyzers from 1/11/2023 to 10/9/2024. Findings include: 1. On the day of survey, 10/9/2024, review of the Beckman UniCel DxC procedures revealed the laboratory performed the following chemistry tests on 2 of 2 Beckman UniCel DxC chemistry analyzers using body fluid specimens from 1/11/2023 to 10/9/2024. -Amylase (Amy) -Glucose (GLU) -Total protein (TP) -Lactate dehydrogenase (LDH) 2. Review of the Beckman DxC manufacturer's instructions for use stated the following: -TP: "Serum samples, free from hemolysis, are the recommended specimens. Plasma is not recommended since fibrinogen in the sample will add to the protein measured. If plasma must be used, the recommended anticoagulant is heparin." -Glu: "Fasting serum or plasma (EDTA, heparin or sodium fluoride) samples, free from hemolysis, are the recommended specimens. Fresh, random collections are recommended for urine specimens" - Amy: "Fasting serum or plasma (EDTA, heparin or sodium fluoride) samples, free from hemolysis, are the

recommended specimens. Fresh, random collections are recommended for urine specimens" -LDH: "Serum or heparinized plasma, free from hemolysis, are the recommended specimens. Citrate and oxalate anticoagulants interfere with the assay. "

3. The laboratory failed to provide documentation for the performance specifications established when performing body fluid chemistry examinations on 2 of 2 Beckman DxC analyzers from 01/11/2023 to 10/09/2024. 4. For the time frame, the laboratory reported the following results on body fluid samples: Body Fluid Glucose - 11 Body Fluid Total Protein - 13 Body Fluid Amylase - 5 Body Fluid LDH - 5 CSF LDH - 4 5. TS #3 confirmed the findings above on 10/9/2024 at 10:30 am.

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 review of maintenance records, observation of the Blood Bank microscope and interview with the Technical Supervisor (TS) #2, the laboratory failed to establish a maintenance procedure and document the maintenance activities for the microscope used in Blood Bank from 1/11/2023 to the date of survey. Findings Include: 1. On the date of survey, 10/9/2024, the technical supervisor (TS) #2 could not provide documentation for 1 of 5 microscopes in the laboratory. 2. While on tour of the lab and review of microscope maintenance records revealed preventative maintenance was not performed on microscope # 228029 in Blood Bank. 3. Laboratory procedure titled "Cord Blood" review revealed that DAT testing of cord blood requires a microscopic reading. 4. In 2024, 184 DAT procedures were performed. 5. On 10/10/2024 around 9:50 am, the TS#2 confirmed the findings above.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
A. Based on review of the laboratory's quality control (QC) staining records and interview with Technical Supervisor #2 (CMS 209 TS #2), the laboratory failed to check for negative staining reactivity each time of use for immunohistochemical (IHC) stains used for microscopic histopathology slide examinations performed from 01/11/2023 to the day of the survey. Findings Include: 1. On the day of the survey, 10/09/2024, review of the laboratory's QC records revealed the laboratory failed to

check for negative and positive staining reactivity each time of use for IHC stains used for microscopic histopathology slide examinations performed from 1/11/2023 to 10/09/2024. 2. The laboratory failed to identify the name, lot, and opening date of IHC stains on the QC log. 3. TS #2 confirmed the finding above on 10/09/2024 at 12:00 pm. B. Based on review of the laboratory's quality control (QC) log, Histology procedure manual and interview with Technical Supervisor #2 (CMS 209 TS #2) the laboratory failed to establish criteria for intended reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains and IHC stains used in Histopathology from 01/11/2023 to the date of survey. Findings include: 1. On the day of survey, 10/09/2024 a review of the laboratory's Quality Control Log for Slide Preparation and the Histology manual revealed the laboratory did not establish or document criteria for intended reactivity to ensure acceptable H&E staining characteristics and/or IHC staining characteristics when Histopathology slides were examined from 01/11/2023 to 10/09/2024. 2. TS #2 confirmed the findings above on 10/09/2024 at 11:30 am.

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 (TS) #3, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments in chemistry from 1/11/2023 to the date of the survey. Findings include: 1. Laboratory procedure titled " Calibration and Standards" defined the schedule for comparisons to be performed in April and October of each year. 2. On the dates of the survey, 10/9/2024 at 11:17 am and 10/10/2024 at 08:57 am, the laboratory provided documentation for 3 of 4 comparison studies for Chemistry Testing and Blood Gas testing from 1/11/2023 to 10/10/2024. Beckman Unicel DxC comparison were performed: May 2023, Dec 2023, and Oct 2024. Blood Gas comparisons were performed: April 2023, October 2023, and October 2024 3. The laboratory performed 766,618 chemistry examinations in 2023 (CMS 116 annual volume). 4. TS # 3 confirmed the findings above on 10/10/2024 around 11:00 am.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Manual Microbiology QC log, maintenance records and interview with Technical Supervisors #2 and #3 (TS) (CMS 209 form

TS#2 and TS#3), the TS failed to perform and document the review of quality control (QC) logs and maintenance records from 01/11/2023 to 10/09/2024. Findings include: 1. On the day of survey, 10/09/2024 a review of the laboratory's Manual Microbiology QC log, revealed the TS failed to review logs from May 2024 to September 2024 for following tests: - Occult Blood - Rapid Strep - Gastrocult - India Ink 2. Further review of the laboratory's maintenance records revealed the TS failed to review temperature logs for May and June 2024 for the BacTAlert. 3. TS #2 and TS #3 (CMS-209) confirmed the above findings on 10/10/2024 at 12:00 pm.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(6)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
A. Based on review of the records and interview with the technical supervisor (TS#3), the laboratory failed to ensure acceptable levels of performance for the Drug of Abuse testing every six months as defined by policy for 2 of 2 Beckman Unicel DxC analyzers from 1/11/2023 to the day of survey. Findings include: 1. The laboratory's Qualitative Results Based on Quantitative Measurement Using a Threshold Value procedures states, "The laboratory must verify the cut-off value every six months" in August and February. 2. On the date of the survey, 10/10/2024 at 9:30 am, the laboratory provided documentation for the verification of the cut-off values for 3 of 4 instances from 1/11/2023 to 10/10/2024. - Verifications were performed: 2/2023, 8 /2023, and 3/2024 3. The TS#3 confirmed the findings above on 10/10/2024 at 11:30 am. B. Based on record review and interview with the technical supervisor (TS) #3, the laboratory director (LD) failed to ensure acceptable levels of performance for Glycosylated Hemoglobin performed on the Beckman Unicel DxC analyzer from May 2024 to the date of the survey. Findings include: 1. On the date of the survey, 10/10 /2024 at 10:30 am, review of the laboratory's verification records for Glycosylated Hemoglobin revealed the laboratory performed the initial performance verification studies in May 2021. 2. Patient testing for Glycosylated Hemoglobin began in May 2024. 3. The laboratory failed to provide documentation that reverification of accuracy, precision, and other pertinent performance characteristics was performed prior to patient testing. 4. The TS #3 confirmed the findings above on 10/10/2024 at 12:00 pm.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of College of American Pathologists (CAP) proficiency testing (PT)

records and interview with the Technical Supervisor #2 (CMS 209 TS #2) the laboratory failed to ensure review and evaluation of the results obtained for 3 of 4 CAP PT events in 2023 in Histology. Findings: 1. On the day of survey 10/09/2024 at 9:55 am review of CAP PT records revealed the Laboratory Director's (LD) review signature for PT score reports was missing for the following CAP PT events: - PM3-B 2023 IHC Tissue Microarray - CD20. - HQIP-B 2023 Histology Quality Imprv Prg. - HQIP-A 2023 Histology Quality Imprv Prg. 2. TS #2 confirmed the findings above on 10/09/2024 at 10:00 AM.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CMS-209), personnel credentials, competency assessment (CA) records and interview with Technical Supervisor (TS) #2, the TS failed to evaluate the competency of 3 of 16 testing personnel (TP) that performed histopathology testing in 2023 and 2024. Findings include: 1. On the day of survey, 10/09/2024 at 9:00 am, review of the laboratory's CA records revealed the TS failed to perform competency assessment on the following TP that performed macroscopic examination of slides in histopathology: - 2023: TP #6 and TP #8 (CMS 209 personnel #7 and #9) - 2024: TP# 16 (CMS 209 personnel #17) 2. Further review of CA records revealed TP #15 (CMS 209 personnel #16) performed the competency assessment of TP # 6 and TP #8 in 2023 and TP #16 in 2024. 3. Review of personnel credentials provided on 10/03/2024 revealed TP# 15 has an Associates of Applied Science degree (Histotechnician) conferred on April 1998 4. TS#2 confirmed the findings above on 10/10/2024 at 12:20pm.