Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0012006	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ephrata Community Hospital	169 Martin Avenue, Ephrata, 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
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 record review, lack of documentation, and interview with the pathology assistant (PA), the laboratory failed to ensure that the verification of accuracy for macroscopic histopathology examinations were performed at least twice annually, as required for tests not included in subpart I from 12/1/2021 to 10/27/2023. Findings include: 1. The laboratory's College of American Pathologists Laboratory Activity Menu notes "surgical pathology gross evaluation, pathologist and surgical pathology gross evaluation, non-pathologist as scope of service/analytic method. Activities noted as scope of service/analytical method do not require PT or alternative assessment." 2. On the day of the survey, 01/17/2024 at 03:30 pm, the laboratory could not provide documentation for the verification of accuracy for macroscopic (grossing and inking) histopathology examinations performed at least twice annually from 12/01/2021 to 10 /27/2023. 3. The laboratory could not provide a procedure for performing verification of accuracy for required tests not included in subpart I. 4. The PA (CMS 209, personnel #25) confirmed the findings above on 01/17/2024 at 04:00 pm.
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 record review, lack of documentation, and interview with technical supervisor #1 (TS), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for each specialty and subspecialty of testing performed from 12/01/2021 to 10/27/2023. Finding include: 1. The laboratory failed to evaluate the relationship between test results using different methodologies, and instruments. Refer to D5775. 2. The laboratory failed to establish performance specification when modifying an FDA-cleared or approved test system. Refer to D5423. 3. The laboratory failed to document positive and negative reactivity each time of use for immunohistochemical stains used for histopathology examinations. Refer to D5601.
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 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 white blood cell (WBC) and platelet (PLT) counts performed on the Sysmex XN-10 from 12/01/2021 to 10/27/2023 Findings include: 1. The laboratory's Problem Specimens on the Sysmex XN-10 procedure states," Collect a specimen from the patient in a sodium citrated tube (blue-top). Run the citrated tube and calculate the Hgb and Hct first to check for proper dilution in the citrate tube. If the corrected Hgb matches the original EDTA hgb value +/- 0.5 g/dL, the WBC and PLT values may be corrected (X 1.11) and used. The original EDTA values for all parameters, except WBC and PLT must be reported with the correct WBC and PLT values from the citrate tube." 2. Review of the Sysmex XN-10 manufacturer's instructions for use states, "Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant and, serous and synovial fluids in EDTA-2K anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended." 3. On the day of the survey, 01/18/2024 at 02:25 pm, the laboratory could not provide documentation for the performance specifications established when performing WBC and PLT counts using sodium citrate anticoagulant (blue top tube) for 2 of 2 Sysmex XN-10 analyzers from 12/01/2021 to 10/27/2023 4. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm.
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: Based on the review of the Wellspan Ephrata Community Hospital IHC/Molecular Requests form and interview with the pathology assistant (PA), the laboratory failed to document positive and negative staining reactivity each time of use for 50 of 50 immunohistochemical (IHC) stains used for histopathology examinations from 12/01 /2021 to the date of the survey. Findings include: 1. On the day of the survey, 01/18 /2024 at 12:00 pm, review of the Wellspan Ephrata Community Hospital IHC /Molecular Requests log revealed that a control for negative and positive reactivity was not documented each time of use for the following 50 of 50 IHC stains used for histopathology examinations from 12/01/2021 to 10/27/2023: - BerEp4 - Mart-1 - Calretinin - S-100 - CDX2 - SOX-10 - CK20 - Helicobacter pylori - CK 5/6 - CD34 - CK7 - Myosin Smooth Muscle - E-cadherin - CD56 - GCDFP-15 - Chromogranin - GATA-3 - Synaptophysin - HepPar1 - bcl-2 - Ki67 - bcl-6 - Mammaglobin - CD10 - Napsin A - CD138 - NKX3.1 - CD15 (Leu-M1) - PAX8 - CD20 - P120 Catenin - CD3 - P16 - CD23 - P40 - CD30 - P53 - CD45 - P63 - CD5 - Pankeratin (AE1/AE3) - Cyclin D1 - TTF-1 - PAX-5 - WT-1 - CD68 - ER - PR - KI67 - HER2 2. Further review of the provided manufacturer's instructions for use of Estrogen Receptor (ER) IHC staining (page 3) revealed, "A positive tissue control must be run with every staining procedure performed. A negative reagent control must be run for every specimen to aid in the interpretation of results." 3. The PA (CMS 209, personnel #25) confirmed the findings above on 01/18/2024 at 01:00 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 immunohematology, and hematology from 12/01/2021 to 10/27/2023. Findings included: 1. On the days of the survey, 01/17 /2024 and 01/18/2024, the laboratory failed to provide documentation of the biannual comparison studies for the following immunohematology and hematology tests performed from 12/01/2021 to 10/27/2023: - automated body fluid analysis performed on 2 of 2 Sysmex XN-10 - manual white blood cell differentials vs. automated white blood cell differentials (Sysmex XN-10) - manual body fluid cell counts (hemacytometer) vs. automated body fluid cell counts (Sysmex XN-10) - Ortho

	Provue vs. manual gel vs. manual tube method (blood typing, antibody screen and identification, antigen typing, direct and indirect antiglobulin testing). - Ortho Vision vs. manual gel vs. manual tube method (blood typing, antibody screen and identification, antigen typing, direct and indirect antiglobulin testing). 2. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with technical supervisor #1 (TS), the laboratory director (LD) failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 12/01/2021 to 10/27/2023. Findings include: 1. The LD failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory 's performance and to identify any problems that require corrective action. Refer to D6091. 2. The LD failed to ensure a quality control program was established and maintained. Refer to D6093. 3. The LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D6095. 4. The LD failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing to assure they were competent. Refer to D6103.
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 the American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records, and interview with technical supervisor #1 (TS) , the laboratory director (LD) failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for chemistry, immunology, immunohematology, microbiology and hematology PT results in 2022 and 2023. Findings Include: 1. On the day of the survey, 01/17/2024 at 08:50 am, the laboratory could not provide documentation that the following API and CAP PT results were reviewed and assessed by the LD/designee: - 2023 API Immunology/Immunohematology Event #1 - 2023 API Immunology/Immunohematology Event #2 - 2023 API 2023 Core Chemistry Event #2 - 2023 API Hematology/Coagulation Event #1 2. Further review of the laboratory's API and CAP PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the proficiency testing agency: - 2022 API Event 1 Immunohematology: Compatibility Ser-05 not graded - 2022 API Event #1 Microbiology: Gram stain GS-05, not graded - 2022 CAP Automated Urine Microscopic UAA-1B: casts, code 26. - 2022 CAP Automated

	Urine Microscopic UAA-1A: casts, code 26. 3. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, lack of documentation, and interview with technical supervisor #1 (TS), the laboratory director (LD) failed to ensure that QC programs were established and maintained to ensure the quality of services provided and to identify failures in quality as they occur for testing performed in immunohematology, hematology, and microbiology from 12/01/2021 to 10/27/2023. Findings Include: 1. On the days of the survey, 01/17/2024 and 01/18 /2024, review of QC records revealed that the LD failed to ensure that QC programs were established and maintained to ensure the quality of services provided and to identify failures as they occur for the following immunohematology, hematology, and microbiology testing performed from 12/01/2021 to 10/27/2023: - The corrective action taken was not documented when QC did not meet the laboratory's established criteria for direct antiglobulin testing (DAT) performed on 01/04/2023. - Immunohematology QC (MBC QC History Report:ABSC) was not reviewed by the LD or TS that met the qualifications of 493.1449 for immunohematology in January and September 2023. - The laboratory could not provide documentation of the monthly review performed for the Xm QC graph from the Sysmex XN-10 for shift and trends from 12/01/2021 to 10/27/2023. - The laboratory could not provide documentation of the periodic annual review in 2022 for the Individualized Quality Control Plans (IQCP) performed for the Biofire Film Array, BD Bactec FX, Cepheid Genxpert, and the DiaSorin Liaison MDX. 2. TS # 1 confirmed the findings above on 01/18/2024 at 06:45 pm.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records, and interview with technical supervisor #1 (TS), the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for chemistry testing performed in 2023. Findings include: 1. On the date of the survey, 01 /18/2024 at 01:00 pm, review of the laboratory's calibration verification records revealed the laboratory failed to provide documentation of the review by appropriate personnel to ensure the accuracy of the test system met the laboratory's established acceptable limits for calibration verifications performed for the following analytes in 2023: - Calibration verification performed on 03/8/2023 for 2 of 2 Beckman Coulter AU 680 (Instrument ID #: 1490 and 1492) - Glucose, Potassium, Lactic Acid, Magnesium, Sodium, Phosphorous, Total Protein, Triglycerides, Albumin, Blood

	Urea Nitrogen, Calcium, Cholesterol, Chloride, Creatinine, Lithium. 2. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and interview with technical supervisor #1 (TS), the laboratory director (LD) failed to ensure that procedures were established and maintained to assure individuals who conduct preanalytical, analytical, and postanalytical phases of testing were competent and maintained their competency from 12/01/2021 to 10/27/2023. Findings Include: 1. On the days of the survey, 01/17/2024 and 01/18/2024, review of the laboratory's personnel competency assesment records revealed the LD failed to ensure that procedures were established and maintained to assure individuals who conduct preanlytical, analytical, and postanalytical phases of testing were competent and maintained their competency for the following from 12/01/2021 to 10/27/2023: - The laboratory failed to assess personnel that performed immunohematology testing (ProVue, Manual Gel, and Tube Method) in 2022 for problem solving skills. - The laboratory failed to assess personnel that performed the following immunohematology testing in 2022 for their minimal regulatory requirements (6 CLIA required procedures): - Antibody Elutions - Antibody Identification - Fetal-maternal bleed screen (rosette) - The laboratory failed to assess the competency of 1 of 2 technical consultants (TC), 1 of 2 technical supervisors (TS), and 1 of 7 general supervisors for their delegated supervisory responsibilities in 2022: - TC #1, (CMS 209) - TS #1 (CMS 209) - GS #1 (CMS 209) - The laboratory failed to assess personnel that performed macroscopic/microscopic histopathology and cytology examinations in 2022 and 2023 for the following: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing - Monitoring the recording and reporting of test results - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records - Direct observations of performance of instrument maintenance and function checks - Assessment of problem solving skills - The laboratory failed to perform direct observations of performance of instrument maintenance and function checks on the Biofire FilmArray Torch23 for testing personnel # 8 and #16 (CMS 209) in 2023. - 2. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

	This STANDARD is not met as evidenced by: Based on the lack of documentation and interview with the pathology assistant (PA), the technical supervisor (TS) failed to reassess the workload limit every 6 months for testing personnel (TP) that performed cytology slide examinations from 12/01/2021 to 10/27/2023. Findings include: 1. On the days of the survey, 01/17/2024 and 01/18 /2024, the inspector requested for documentation for the workload limits established and reassessed at least every 6 months by the TS for each individual that examined cytology slides from 12/01/2021 to 10/27/2023. 2. The laboratory could not provide documentation for the reassessment of workload limits for the following TP personnel that performed cytology slide examinations from 12/01/2021 to 10/27/2023: - 2 of 2 current TP: CMS 209 personnel # 9 (listed as the laboratory director/TS) and personnel #23. - 3 of 3 previously employed TP from 12/01/2021 to 10/27/2023 3. During an interview on 01/18/2024 at 12:37 pm, the PA (CMS 209, personnel # 25) confirmed the findings above.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), personnel qualification records, and interview with technical supervisor #1 (TS), the laboratory failed to ensure that each individual performing high complexity testing (1 of 22) were qualified. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the

	individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CLIA laboratory personnel report, personnel credentials, and interview with technical supervisor #1 (TS), the laboratory failed to provide the requested educational credentials for 1 of 22 testing personnel (TP) who performed high complexity testing from 12/01/2021 to 10/27/2023. Findings Include: 1. On the days of the survey, 01/17/2024 and 01/18/2024, the laboratory was unable to provide documentation for the evaluation of credentials for 1 of 22 TP (CMS 209 high complexity TP# 13) that received their degree from a foreign institution to determine the equivalency of their education to an education obtained in the United States (U. S.). - TP # 13 received a Bachelors of Biomedical Laboratory Science from Konyang University (Republic of Korea) in 2019. 2. The laboratory was asked to provide the requested personnel documents by 01/25/2024. 3. TS #1 confirmed the findings above on 01/18/2024 at 06:45 pm. 4. The laboratory was contacted by email on 01/27/2024 as personnel records for TP#13 were still not provided by the laboratory.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent

may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:
Based on lack of documentation, and interviews with technical supervisor #1 (TS), the system laboratory quality manager, and the Team Lead POC/QA, the laboratory failed to (b)(5) provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires, ensure (c) all records and data are accessible and retrievable within a reasonable time frame during the course of the inspection, and (d) provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part during the validation inspection performed on 01/17/2024 and 01/18/2024. Findings include: 1. On the days of the survey, 01/17/2024 and 01/18/2024, the laboratory could not provide the following records upon numerous requests throughout the validation inspection: - Quality control records each day of patient testing for December 2021, May 2022, January 2023, and September 2023 for the following instruments: - 2 of 2 Beckman Coulter AU 680's - 1 of 1 Beckman Coulter DXI - 1 of 1 Beckman Coulter Access 2 - Background checks performed for December 2021, May 2022, January 2023, and September 2023 for the following instruments: - 2 of 2 Sysmex XN-10 - Proficiency testing Event B 2023 for DNA mismatch repair MMRA. - Documentation of the laboratory's acceptable criteria for performance specifications for precision, accuracy, reportable ranges, and reference intervals/range (normal values) for the following analyzers/analytes introduced into the laboratory: - 2 of 2 Gem 5000 blood gas analyzers (approved for testing 11/2022) - Advanced Micro Osmometer approved for testing (5/2022) - High sensitivity Troponin (Beckman Coulter Unicel DxI, Access 2) (approved for testing 5/2022) - Documentation of the reference intervals/range (normal values) study performed for the laboratory ' s patient population when introducing new analyzers/analytes into the laboratory: - 2 of 2 Gem 5000 blood gas analyzers - Advanced Micro Osmometer - High sensitivity Troponin (Beckman Coulter Unicel DxI, Access 2) - 2022 competency assessment records for TP # 12 (CMS 209). Annual competency assessment for microbiology testing performed on 2/7/2023. 2. While reviewing laboratory records the inspectors requested copies of documents on 01/17/2024, the system laboratory quality manager then stated, "the hospital's accreditation department would not allow for copies of any information to leave the premises." 3. TS #1, the system laboratory quality manager, and the Team Lead POC/QA confirmed the findings above on 01/18/2024 at 06:45 pm.