

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0193463	(X3) Date Survey Completed 09/27/2023
Name of Provider or Supplier Barnes-Kasson County Hospital	Street Address, City, State 2872 Turnpike Street, Susquehanna, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: A. Based on interview with general supervisor (GS) #1 and review of the Pennsylvania's Department of Health (PA DOH) proficiency testing (PT) records the laboratory failed to provide 3 of 4 attestation statements for chemistry testing events performed in 2021 and 2022. Findings Include: 1. On the days of the survey, 09/26 /2023 and 09/27/2023, the laboratory could not provide the following PA DOH attestation statements for 2021 and 2022: - 1 of 1 DOH attestation for Serum Ethanol 2021 (Event 3) - 2 of 3 DOH attestation for Serum Ethanol 2022 (event 2 and 3) 2. GS #1 confirmed the findings above on 09/27/2023 around 10:30 am. B. Based on review of the American Association of Bioanalysts Association and Medical Laboratory Evaluations (AAB-MLE), and College of American Pathologists (CAP) proficiency testing (PT) records, the laboratory director (LD)/designee and testing personnel (TP) failed to sign 2 of 2 PT agencies attestation statements from 2021, 2022, and 2023. Findings include: 1. On the days of the survey, 09/26/2023 and 09/27/2023, review of AAB-MLE and CAP PT records revealed, the following PT attestation statements were not signed by the LD/ designee and testing personnel in 2021, 2022, and 2023: -</p>

AAB-MLE Non Chem M1 2023 - AAB-MLE Non Chem Q1 2022 (immunohematology) - AAB-MLE Non Chem Q3 2021 (urinalysis, syphilis serology) - AAB-MLE Non Chem Q2 2022 (immunohematology, heme with differential) - AAB-MLE Non Chem Q3 2022 (immunohematology) - CAP IDR A 2023 - CAP IDR R 2022 - CAP IDR C 2022 - CAP IDR C 2021 - CAP GIP B 2023 - CAP GIP C 2023 - CAP GIP C 2022 - CAP GIP B 2022 - CAP GIB A 2022 2. GS #1 confirmed the findings above on 09/27/2023 at 10:30 am.

D3000

FACILITY ADMINISTRATION
CFR(s): 493.1100

Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on record review and interview with general supervisor (GS) #1, the laboratory failed to meet the requirements under 493.1101 through 493.1105. Findings include:
1. Failure to comply with the state of Pennsylvania code Chapter 5.23 for Supervisor Qualifications . Refer to D3009. 2. Failure to document all transfusion-related activities. Refer to D3015. 3. Failure to appropriately monitor temperature of blood products when power outages occurs. Refer to D3021. 4. Failure to document all appropriate transfusion reaction activities. Refer to D3025.

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:
A. Based on lack of documentation, record review and interview with testing personal (TP)#1, the laboratory director (LD) failed to be present in the laboratory for a reasonable period of each day of patient testing from 10/28/21 to the day of survey. Findings include: 1. The laboratory's staffing policy states, " A qualified pathologist is the director of the laboratory and responsible for the total operation of the department. The pathologist is available on call and is present in the laboratory a minimum of one day per month for consultation." 2. Review of the Application for Approval to Direct More Than Two Clinical Laboratories (Exception to 5.22) form signed by the LD on 02/21/2022 revealed the LD currently oversees 5 laboratories. 3. On the days of survey, 09/26/2023 and 09/27/2023. the laboratory could not provide evidence of monthly on site visits by the LD to the laboratory from 10/27/21 to the date of the survey. 4. TP #1 confirmed the findings above on 09/27/2023 at 10:30 am. B. Based on review of the application for Approval To Direct More Than Two Laboratories (Exception to Section 5.22(f)) form, personnel credentials and interview with testing

personnel (TP) #1, the Laboratory Director (LD)/owner failed to ensure a qualified supervisor was onsite every hour of patient testing from 10/28/2021 to 09/27/2023. Findings include: 1. On the days of survey, 09/26/2023 and 09/27/2023, review of personnel credentials revealed that 1 of 3 supervisors (state personnel form personnel #2) has an Associates of Applied Science degree in Medical Laboratory Technology (obtained in May 2003). 2. The application for Exception to Section 5.22(f) form signed by the LD on 02/21/2022 states the LD will "Appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. The laboratory could not provide the acceptable credentials needed for personnel #2 in order to perform the duties of a supervisor in the state of Pennsylvania. 4. During an interview on 09/27/2023, personnel # 2 confirmed that there was not a qualified supervisor on site all hours of patient testing.

D3015

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures, review of immunohemtalogy records, and interview with general supervisor (GS) #1, the laboratory failed to document all transfusion related activities performed on 02/22/2023. Finding include: 1. The laboratory's procedure states: "Vital signs (temperature, pulse, respirations, blood pressure, oxygen saturations and site observations) and patient assessment should be measured and recorded" : - "At the start of each transfusion" - "15 minutes after commencement of each unit" - "30 minutes after commencement of each unit" - "60 minutes after commencement of each unit" - "Then every 60 minutes until conclusion" - "At completion of transfusion" 2. On the day of survey, 09/27/2023 at 9:00 am, review of the blood transfusion flow chart revealed the laboratory failed to document the following vitals for 1 of 1 patient reviewed that received a transfusion of red blood cells on 02/22/2023: - Patient's vital signs every 60 minutes until conclusion per laboratory procedure 3. GS #1 confirmed the findings above on 09/27/2023 at 10:30 am.

D3021

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(c)(1)

Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

This STANDARD is not met as evidenced by:
Based on review of temperature records, and interview with general supervisor #1 (GS), the laboratory failed to ensure that refrigerator temperatures for the storage of blood products were monitored and documented when power outages occurred for 3 of 24 hours on 03/23/2022. Findings include: 1. On the day of the survey, 09/26/2023 at 10:45 am, review of temperature records revealed that the laboratory failed to monitor and document the hourly temperature of the temporary refrigerator where

blood was stored for 3 of 24 hours (01:00 am-04:00 am) on 03/23/2023 when a power outage occurred. 2. The laboratory performs patient testing 24/7 per the information listed on the CMS-116 form. 3. During an interview on 09/26/2023 at 10:32 am, GS #1 stated that the laboratory did not have personnel onsite all hours of operation. Personnel are scheduled on an on-call basis from 01:30-05:30 am .

D3025

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(d)

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures, review of immunohematology records, and interview with general supervisor (GS) #1, the laboratory failed to properly investigate 1 of 1 transfusion reaction investigation performed on 06/30/2020. Finding include: 1. The laboratory's procedure for performing an extended investigation states: "Culture blood from pilots and administration tubing: bap, mac, choc, and incubate remaining media. Cultures are read at 24hrs, 48 hrs. and 7 days." 2. On the day of survey, 09/27/2023 at 9:00 am, review of a ransfusion reaction investigation records revealed the laboratory failed to properly investigate per the laboratory's policy for 1 of 1 transfusion reaction that was performed on 06/30/2020 for the following: - Cultures from pilots and administration tubing 3. GS #1 confirmed the findings above on 09/27/2023 at 10:30 am.

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 lack of documentation and interview with general supervisor (GS) #1, the laboratory failed to verify twice annually the accuracy of Direct Antiglobulin Test (DAT) and Serum Ketones performed from 10/28/2021 through the days of survey. Findings include: 1. On the days of survey, 09/26/2023 and 09/27/2023, the laboratory could not provide documentation of verification of accuracy for DAT and Serum Ketones performed from 10/28/2021 through the days of survey. 2. The laboratory performed 670 immunohematology examinations and 149,622 Chemistry examinations from 09/07/2022 to 09/07/2023. 3. GS #1 confirmed the findings above on 09/27/2023 at 10:30 am.

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 observation of the laboratory, review of laboratory records, and interview with general supervisor (GS) #1, the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 from 10/28/2021 to 09/27/2023. Finding include: 1. Failure to label aliquoted solutions with pertinent information and failure to ensure proper storage of acids and bases. Refer to D5415. 2. Failure to ensure appropriate International Normalized Ratio (INR) calculations for Prothrombin Time (PT) test. Refer to D5423. 3. Failure to perform comparison studies in hematology and chemistry. Refer to D5775.

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:

Based on observation of the laboratory and interview with general supervisor (GS) #1, the laboratory failed to label 3 of 3 aliquoted reagents with the pertinent information required for proper use and failed to ensure the proper storage of 4 of 4 bottles of acids and 3 of 3 bottles of bases from 10/28/2021 to 09/27/2023. Findings Include: 1. On the day of survey, 09/27/2023, observation of reagents and stains in use, revealed the laboratory did not label pertinent information regarding 3 of 3 unlabeled aliquoted solutions, thought to be Hema3 Quik stains. 2. During the laboratory tour it was observed that 3 of 3 bottles of methyl alcohol (fixative) solution, 3 of 3 bottles of bleach, and 1 of 1 bottle of isopropyl alcohol were stored together under a sink. 3. Flammable reagents were not stored in a flammable cabinet. 4. The flammable cabinet in the laboratory was empty. 5. GS #1 confirmed the findings above on 09/27/2023 around 10:30 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) #1, the laboratory failed to establish and verify each new thromboplastin lot used for 1 of 1 Sysmex CA-600 coagulation analyzer before reporting patient test results from 10/28/2021 to 09/27/2023. Findings include: 1. On the days of survey, 09/26/2023 and 09/27/2023, review of the laboratory's hemostasis reagent new lot number roll over verification data revealed the laboratory failed to establish and verify the following for each new lot of thromboplastin reagent used on 1 of 1 Sysmex CA-600 analyzer from 10/28/2021 to 09/27/2021: - Establish a normal patient Prothrombin time mean with each new thromboplastin lot number. - Verify that the normal patient Prothrombin time mean study has been performed according to the manufacturer's instructions. - Incorporate the current and pertinent normal patient Prothrombin time mean for each lot of thromboplastins. - Document the manual check of the INR calculation for each new lot number. - Periodically verify, for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean, and the International Sensitivity Index (ISI) value are being used for calculating the INR value. - Periodically verify the accuracy of the INR calculation. - Periodically verify centrifuge for platelet poor plasma. 2. The laboratory could not provide records of the new lot number roll over verification studies performed per the laboratory's procedure for the Sysmex CA-600 coagulation analyzer. 3. GS #1 confirmed the findings above on 09/27/2023 at 10:30 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 general supervisor #1 (GS), the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different methodologies and instrumentation for examinations performed in hematology and chemistry from 10/28/2021 to the date of the survey. Findings include: 1. On the days of the survey, 09/26/2023 and 09/27/2023, the laboratory failed to provide documentation of the biannual comparison of test results for the following 2 of 2 tests performed in chemistry and hematology from 10/28/2021 to 09/27/2023: -White blood cell differentials: manual microscopic vs. automated (Sysmex XS-1000i) - Serum Human Chorionic Gonadotropin (hCG): Fisher Healthcare SureVue Serum hCG test kit vs. Siemens Dimension EXL w/LM analyzer 2. The laboratory performed 82,739 hematology tests and 149,622 chemistry test in 2022 (CMS 116 annual volume from 09/22/2022 to 09/22/2023). 3. GS #1 confirmed the findings above on 09/27/2023 at 10:00 am.

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 observation of the laboratory, record review, and interview with general supervisor (GS) #1, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 10/28/2021 to 09/27/2023. Findings include: 1. The laboratory director failed to ensure that verification procedures were adequate for new test/methodologies that were introduced to the laboratory. Refer to D6086. 2. The laboratory director failed to ensure an approved corrective action plan was followed when any proficiency testing result was found to be unacceptable or unsatisfactory. Refer to D6092. 3. The laboratory director failed to ensure a quality control program was established and maintained. Refer to D6093. 4. The laboratory director failed to ensure quality assessment activities were documented and maintained by the appropriate staff. Refer to D6094.

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 lack of documentation and interview with general supervisor #1 (GS), the laboratory director (LD) failed to ensure performance verification specification procedures were established and followed to determine the accuracy, precision, and other pertinent performance characteristics when a new test or methodology is introduced into the laboratory from 12/01/2021 to 09/27/2023. Findings Include: 1. On the day of the survey, 09/26/2023 at 11:57 am, the laboratory could not provide documentation for the establishment and verification of performance specifications performed for 1 of 1 Diesse MINI-CUBE analyzer before reporting erythrocyte sedimentation rate (ESR) results on patients from 12/01/2021 to 09/27/2023. 2. The laboratory could not provide a procedure for the establishment and verification of performance characteristics when a new test or methodology is introduced into the laboratory. 3 The laboratory performed 405 ESR examinations from 09/07/2022 to 09/07/2023. 4. GS #1 confirmed the findings above on 09/27/2023 at 10:30 am.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) and College of American Pathologists (CAP) proficiency testing (PT) reports and interview with general supervisor (GS) #1, the Laboratory Director (LD) failed to ensure that approved and effective corrective actions were established for unacceptable or unsatisfactory PT results in 2022 and 2023. Findings include: 1. On the days of the survey, 09/26/2023 and 09/27/2023, review of the AAB-MLE PT records revealed the following PT reports did not have an approved and

effective corrective action: - 50% WBC diff abnormal/other: Event #1 and #2 for 2023, Event #1, #2, and #3 for 2022. - 40% Troponin: Event #1 2023 - 60% Troponin: Event #1, and #2 2022 - 20% Direct Bilirubin: Event #2 2023 - 0% Fecal Leukocytes: Event #2 2023, Event #2 2022 - 50% Urine Sediment: Event #1 2022 - 50% WBC differential lymphocyte %: Event # 1 2022, Event #2 2022 - 50 % WBC differential monocyte %: Event #2 and #3 2022. - 60% Human chorionic gonadotropin (HCG): Event # 2 2022 2. Further review of CAP PT records revealed the laboratory failed to determine and document their own evaluation criteria approved by their LD when evaluation criteria was not established by the PT agency for the following: - IDR-B 2023: Influenza A subtype, Parainfluenza subtype, Legionella pneumophila - IDR-B 2022: Coronavirus strain, RSV - IDR-A 2023: Influenza A subtype, Parainfluenza subtype, Coronavirus strain - IDR-A 2022: Influenza A subtype, Parainfluenza subtype - IDR-B 2022: Influenza A subtype, Parainfluenza subtype, Coronavirus strain - IDR-C 2022: Influenza A subtype, Parainfluenza subtype 3. GS # 1 confirmed the findings above on 09/27/2023 at 10:30 am.

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 a review of quality control (QC) records, lack of documentation and interview with general supervisor (GS) #1 , the laboratory director (LD) failed to ensure that a QC program was established and maintained to ensure the quality of services provided for testing performed in hematology from 10/28/2021 to the date of the survey. Findings Include: 1. The laboratory's Coagulation Quality Control procedure states, "One level should be tested every 4 hours." 2. On the days of the survey, 09/26/2023 and 09/27/2023, review of QC records revealed that the LD did not ensure that quality control programs were established and maintained for the following from 10/28/2021 to 09/27/2023: - The laboratory could not provide documentation of the laboratory's established acceptable ranges for complete blood counts (CBC), protime, and activated prothrombin time. - The laboratory could not provide documentain of quality control results every 4 hours for coagulation testing performed. - Quality control results were not reviewed periodically to identify quality issues and implement corrective action if needed for hematology, coagulation, chemistry, microbiology, and immunohematology testing. 3. The laboratory could not provide quality control documentation for the following: - Manual reticulocyte counts - Post vasectomy specimen 4. GS # 1 confirmed the findings above on 09/27/2023 around 10:30 am.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 assurance (QA) records, laboratory procedures, and interview with general supervisor (GS) #1, the Laboratory Director (LD) failed to ensure a QA program was maintained and documented to ensure the quality of services provided by the laboratory from 10/28/2021 to the date of survey. Findings include: 1. The laboratory's Quality Assurance Program-Laboratory procedure states, "the overall quality assurance program is reviewed and signed by the laboratory director every month or as needed". 2. On the days of the survey, 09/26/2023 and 09/27/2023, the laboratory could not provide documentation for the periodic QA evaluation reviewed and signed by the LD to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 10/28/2021 to 09/27/2023. 3. GS #2 confirmed the findings above on 09/27/2023 around 10:30 am. * Repeat Deficiency

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of personnel qualification records and interview with general supervisor (GS) #1, the laboratory failed to ensure that 2 of 2 Technical Supervisors (TS) who performed the responsibilities of a TS for immunohematology from 10/28/2021 to 09/27/2021 met the required TS qualifications under C.F.R 493.1449. Refer to D6111.

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) 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; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an

accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) 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; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) 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; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical,

physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) 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; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g) (2)(i) 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; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical,

physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) 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; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) 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; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a

chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) 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; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by

the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(2)(i)(B) (3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (1)(2)(ii) An individual qualified under 493.1449(b) or paragraph (1)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (1) (3) For tests in ophthalmic pathology, meet one of the following requirements: (1)(3)(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (1)(3)(i)(B) Must meet one of the following requirements: (1)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (1)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) 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; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science

or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) 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; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) 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; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) 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; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:

Based on review of personnel qualification records, and interview with general supervisor (GS) #1, the laboratory failed to ensure that 2 of 2 technical supervisors (TS) met the requirements under C.F.R 493.1447 to perform technical supervision for

immunohematology testing performed from 10/28/2021 to 09/27/2023. Findings include: 1. Review of the CMS-209 personnel form signed by the laboratory director on 09/14/23, lists personnel # 3 and #4 as the TS of immunohematology. 2. On the days of the survey, 09/26/2023 and 09/27/2023, review of personnel credentials revealed that 2 of 2 TS (CMS 209 personnel #3 and #4) did not meet the required education requirements to perform technical supervision of testing performed in immunohematology. 3. The laboratory provided the following personnel credentials: - TS #1 (CMS 209 personnel #3) Bachelors of Science degree in Biology - TS #2 (CMS 29 personnel #4) Masters degree in Biology 4. GS #1 confirmed the findings above on 09/27/2022 at 10:30 am.