

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0187054	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Fulton County Medical Center	Street Address, City, State 214 Peach Orchard Road, Mcconnellsburg, 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
D0000	A routine recertification survey was conducted by the Pennsylvania State Agency for Fulton County Medical Center on 06/24/2025 and 6/25/2025. The laboratory was found out of compliance with the following conditions: 493.1217 Condition: Immunohematology. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1447 Condition: Laboratories performing high complexity testing; laboratory technical supervisor.
D3035	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii)</p> <p>(a)(3)(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, record review, and interview with the Technical Supervisor (TS) #5, the laboratory failed to ensure that 2 of 4 immunohematology records related to the emergency release of blood products were retained for the appropriate period of time for testing performed from 8/15/2025 to 6/25/2025. Findings include: 1. On the day of survey 6/25/2025 at 10:30 am, review of the laboratory's policy titled Emergency Requisition of Uncrossmatched Blood revealed that "If time permits, do a quick ABO and RH using the tube method. Give type specific blood if possible and record results on the Blood Bank log and on the Blood Bank Slips." 2. The laboratory failed to provide documentation of the quick type performed for 2 of 4 (Spec #: 0727:BB0002S, Spec # 1128:BB0000S) emergency released transfusions that were issued type specific red blood cell units from 8/15/2025 to 6/25/2025. 3. TS #5 confirmed the above findings on 6/25/2025 at 2:30 pm.</p>
D5026	IMMUNOHEMATOLOGY

CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on record review, and interviews with Technical Supervisors (TS) #1 and #5, the laboratory failed to meet the requirements for the specialty of Immunohematology specified in 493.1230 through 493.1256 and 493.1281 through 493.1289 from 8/15 /2023 to the time of survey. Refer to: D3035, D5553, and D5555.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with Technical Supervisor #1 (TS), the laboratory failed to verify the accuracy of the PT results obtained for 3 of 3 API Microbiology testing events in 2024. Findings Include: 1. On the day of survey, 06/24/2024 at 11:00 am., review of the laboratory's API Microbiology PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the PT agency for 3 of 3 API Microbiology events in 2024: 1st event: - CSF Culture MIC /Zone Diameter Value - Gram Stain: nonconsensus - Urine Culture MIC/Zone Diameter Value 2nd event: - Blood Culture Susceptibility Interpretation - Urine Culture MIC/Zone Diameter Value 3rd event: - Additonal Antimicrobial Testing 2. The API Proficiency Testing performance Evaluation form states "Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded. 3. TS #1 confirmed the findings above on 06/25 /2025 at 1:00 pm.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(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 (TS) #1, 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 2 of 2 Siemens Vista chemistry analyzers from 8/15/2023 to 6/24/2025. Findings include: 1. On the day of survey, 6/24/2025 at 9:30 am, review of the Siemens Vista procedures revealed the laboratory performed the following chemistry tests on 2 of 2 Siemens Vista chemistry analyzers using body fluid specimens from 8/15/2023 to 6/24/2025. -Glucose (GLU) -Total protein (TP) -Lactate dehydrogenase (LDH) 2. Review of the Siemen's Vista manufacturer's instructions for use stated the following: -TP: "Serum or plasma samples are the recommended specimens." -Glu: "Serum, plasma, urine, or cerebral spinal fluid samples are the recommended specimens. -LDH: "Serum or plasma samples are the recommended specimens. 3. The laboratory failed to provide documentation for the performance specifications established when performing body fluid chemistry examinations on 2 of 2 Siemens Vista analyzers from 8/15/2023 to 6/24/2025. 4. TS #1 confirmed during interview on 6/24/2025 at 10:30 am, the laboratory performed 30 body fluid analysis (TP, GLU, LDH) from 8/15/2023 to 6/24/2025.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on review of procedures, maintenance records, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 5 of 5 instruments used in the laboratory from 8/15/2023 to 6/25/2025. Findings include: 1. The laboratory failed to perform and document manufacturer recommended maintenance/functions checks for the following 5 of 5 instruments from 8/15/2023 to 6/25/2025: - ACL TOPS - required monthly maintenance not performed 12 of 12 months in 2024 (Replace air filters) - Diasorin MDX - required monthly maintenance not performed 3 of 3 months (2/2025, 3/2025, 4/2025) - Bactec - required daily maintenance not performed 1 of 90 days (1/10/2025) - Gene Expert- required monthly maintenance not performed 1 of 3 months - Hematek - required monthly maintenance not performed 23 of 23 months 2. The TS#1 confirmed the findings above on 6/25/2025 at 2:00 pm.

D5543

HEMATOLOGY
 CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate.

This STANDARD is not met as evidenced by:
 Based on record review and interview with Testing Personnel (TP) #3, the laboratory failed to perform quality control (QC) for manual cells counts using a hemocytometer in duplicate for 6 of 6 manual body fluid cell counts performed from 8/15/2023 to 6/25

/2025. Findings Include: 1. On the day of the survey, 6/25/2025 at 11:30 am, the laboratory failed to provide documentation of the QC performed in duplicate for 6 of 6 manual body fluid cell counts performed using a hemocytometer from 8/15/2023 to 6/25/2025. 2. TP #3 confirmed the findings above on 6/25/2025 at 2:30 pm.

D5553

IMMUNOHEMATOLOGY
CFR(s): 493.1271(b)(f)

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

This STANDARD is not met as evidenced by:
Based on record review and interview with Technical Supervisor (TS) #5, the laboratory failed to establish and maintain a policy that ensured compliance with testing and distribution records for emergency release of blood (606.160(b)(3)(v)) for 2 of 15 emergency requisitions from 8/15/2023 to 6/25/2025. Findings include: 1. The laboratory's Emergency Requisition of Uncrossmatched Blood Procedure states, "When requested, complete the Emergency Request form -number of units, name of patient and medical record number, signature from physician or authorized representative, and date, time and tech initials". 2. On the day of the survey, 6/25/2025 at 11:00 am, review of the laboratory's Emergency Requisition of Uncrossmatched Blood Procedure revealed the laboratory failed to establish and maintain a policy that ensured compliance with blood and blood product distribution for emergency release, including signature of requesting physician obtained before or after release (606.160(b)(3)(v)) from 8/15/2023 to 6/25/2025. 3. Further review of the laboratory's Emergency Release forms revealed the laboratory allowed for a Registered Nurse (RN) to sign in lieu of the requesting physician 2 of 15 emergency release of blood from 8/15/2023 to 6/25/2025. 4. The TS #5 confirmed the above findings on 6/25/2025 at 3:00 pm.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory Blood Bank Procedures, lack of documentation, and interview with Technical Supervisor (TS) #5, the laboratory failed to perform and document alarm system checks as required for 3 of 3 automated temperature graphs used to monitor storage of blood products from 8/15/2023 to 6/25/2025. Findings Include: 1. On the day of the survey, 6/25/2025 at 1:00 pm, the laboratory failed to establish and maintain a procedure for documentation of alarm checks for 3 of 3 automated temperature graphs used to monitor storage of red blood cells, platelets and fresh frozen plasma from 8/15/2023 to 6/25/2025. 2. The laboratory could not provide documentation of alarm checks performed for the alarm system used for the storage of platelets and fresh frozen plasma from 8/15/2023 to 6/25/2025. 3. TS#5 confirmed the

above findings on 06/25/2025 at 10:45 am. B. Based on record review and interview with technical supervisor (TS) #5, the laboratory failed to ensure blood and blood products were stored under appropriate conditions for 6 of 6 months from 1/1/2025 to 6/25/2025. Findings Include: 1. The laboratory's Blood Bank Refrigeration Temperature Out of Acceptable Range policy stated, "The automated temperature graph on the blood bank refrigerator will be reviewed each day, to ensure temperature has been continuously maintained in the blood bank refrigerator." 2. Further review of the laboratory's Fresh Frozen Plasma policy stated, "FFP is stored at -18 to - 30 degrees Celsius." 3. On the day of survey, 6/25/2025 at 01:00 pm, review of the laboratory's temperature charts revealed the laboratory failed to ensure the refrigerator and freezers used for the storage of fresh frozen plasma (FFP) and red blood cells (RBC) were maintained at appropriate temperatures for 6 of 6 from 1/1/2025 to 6/25/2025: - RBC products temperature charts reading at 12 degrees Celsius from 1/1/2025 to 06/25/2025. - FFP products temperature charts reading at - 14 degrees Celsius from 1/1/2025 to 6/25/2025. 4. During interview 6/25/2025 at 02:00pm, TS #5 confirmed the temperature charts were not checked daily and the laboratory did not ensure the temperature monitoring system was working appropriately when blood products were stored.

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.

This STANDARD is not met as evidenced by:
 Based on record review, lack of documentation, and interview with technical supervisor (TS) #1, the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instruments for 4 of 4 comparison studies from 8/15/2023 to 6/25/2025. Findings include: 1. On the day of the survey, 6/24/2025 at 11:30 am, review of laboratory procedure titled " Instrument and Method Comparison" defined the the comparisons between instruments or method to be performed as follows: - Nova POC glucose - iSED and mini iSED - Vista 1 and Vista 2 - Cepheid and MDX SARS - Tops 1 and Tops 2 - Manual and automated body fluid - Manual and automated differential -Vision, manual gel, and tube typing - Sysmex XN1000 and XS450 2. The laboratory failed to provide documentation for the following 4 of 4 comparison studies performed from 8/13/2023 to 6/25/2025: -Manual and automated body fluid 1 of 4 comparisons . -Vision, manual gel, and tube testing in Blood Bank- 3 of 4 comparisons did not include crossmatch and 2 of 4 comparisons did not include DAT testing. 3. The laboratory failed to establish a policy or perform comparisons for different specimen types for hematology testing for platelet clumping (Sodium Citrate versus EDTA tubes) from 8/15/2023 to 6/24/ 2025. 4. The laboratory performed 30 body fluid, 819 immunohematology, and 81,894 hematology examinations in 2024 (CMS 116 estimated annual volume). 5. TS # 1 confirmed the findings above on 6/24/2025 at 1:00 pm. ****REPEAT DEFICIENCY****

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 2 of 2 years from 08/15/2023 to the day of survey. Findings include: 1. On the day of survey, 6/24/2025 at 12:00 pm, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correction of problems found in the postanalytic system specified in 493.1291 for 2 of 2 years from 8/15/2023 to 6/24/2025. 2. The laboratory failed to provide records for the periodic calculation checks performed to verify that calculated patient results were accurately transmitted between the laboratory instrumentation and the Laboratory Information System (LIS) from 8/15/2023 to 6/24/2025. 3. Further review of patient test reports and laboratory procedures revealed the following: - Patient test report for drugs of abuse testing did not include the detection limits established for each analyte resulted. - Patient test report for prothrombin (PT) listed normal range as: 9.5-12.5 seconds - Laboratory's Prothrombin Time ACL Top Family procedure listed PT normal range as: 9.8-12.5 seconds. 4. TS #1 confirmed during interview on 6/24/2025 at 12:50 pm, the laboratory did not have a process in place to monitor and evaluate the accuracy of information provided to clients.

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 (TS) #1, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 8/15/2023 to 6/24/2025. Refer to D6086 and D6106.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on review of the ALCOR iSED analyzer verification of performance specification records, lack of documentation, and interview with Technical Supervisor (TS) #1, the laboratory director (LD) failed to ensure performance verification specification procedures were established and followed to determine the reportable range for Erythrocyte Sedimentation Rate (ESR) testing performed on 1 of 1 ALCOR iSED before reporting patient test results from 4/18/2025 to 6/25/2025. Findings

	<p>Include: 1. On the day of survey, 6/25/2025 at 11:00 am, review of 1 of 1ALCOR iSED performance specification records revealed the laboratory failed to verify the manufacturers stated reportable range for ESR determinations prior to reporting patient results from 4/18/2025 to 6/25/2025. 2. TS# 1 confirmed the findings above on 6/25/2025 at 1:00 p.m.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with Technical Supervisor (TS) #1, the laboratory director (LD) failed to ensure an approved policy for 1 of 1 Hematek stainer was available to testing personnel that performed microscopic hematology examinations from 8/15/2023 to 6/25/2025. Findings Include: 1. On the day of survey, 6/25/2025 at 10:30 am, review of the laboratory's current procedure manual revealed the LD failed to ensure an approved policy for 1 of 1 Hematek Stainer was available to testing personnel that performed microscopic hematology examinations from 8/15/2023 to 6/25/25. 2. TS#1 confirmed the findings on 6/25/2025 at 11:00 am.</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel qualification and competency assessment records, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure 1 of 12 testing personnel (TP) (CMS 209 TP# 3, dated 6/15/2025) performing the responsibilities of a TS met the minimum regulatory qualification requirements (493.1449) for high complexity hematology testing performed from 8/15/2023 to 6/25/2025. Refer to D6111.</p>
<p>D6111</p>	<p>TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449</p> <p>(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. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not</p>

met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, 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
- (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 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or
- (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); 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)(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 of experience in high complexity testing within the applicable subspecialty; or
- (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and
- (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or
- (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and
- (c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; 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 of experience in high complexity testing within the applicable subspecialty; or
- (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or
- (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either-

 - (c)(5)(i)(B)(1) 48 semester hours of medical laboratory technology courses; or
 - (c)(5)(i)(B)(2) 48 semester hours of science courses that include-

 - (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; or
 - (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and
 - (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; 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 of experience in high complexity testing within the applicable subspecialty.

(d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must-

- (d)(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
- (d)(1)(ii) Be certified in clinical pathology by the

American Board of Pathology or the American Osteopathic Board of Pathology; 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 for the applicable specialty; or (d)(3)(i) (A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(3)(i) (B) Meet the education requirement at 493.1443(b)(3)(i)(B); and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(5)(i)(B) Meet the education requirement at paragraph (c) (5)(i)(B) of this section; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty. (e) Cytology- 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- (e)(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 (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (e) (2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met. (f) Histopathology - 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- (f)(1) Meet one of the following requirements: (f)(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 (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(1)(ii) An individual qualified under paragraph (b) or (f)(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 (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (f)(2) For tests in dermatopathology, meet one of the following requirements: (f)(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 (f) (2)(i)(B) Meet one of the following requirements: (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or (f) (2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f) (2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in

ophthalmic pathology, meet one of the following requirements: (f)(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 (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- 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: (g)(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 (g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(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 (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(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 (i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December

28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure 1 of 12 testing personnel (TP) (CMS 209 TP# 3, dated 6/15/2025) performing the responsibilities of a TS met the minimum regulatory qualification requirements (493.1449) for high complexity hematology testing performed from 8/15/2023 to 6/25/2025. Finding include: 1. On the day of survey, 6/24/2025 at 10:30 am, review of competency assessment (CA) records revealed CA for TP performing high complexity testing (hematology) were performed by TP #3 (CMS 209, dated 6/15/2025) from 8/15/2023 to 6/25/2025. 2. The laboratory failed to provide personnel qualification records that documented TP# 3 met the minimum regulatory qualification requirements to perform the duties of a TS from 8/15/2023 to 6/24/2025. 3. The TS#1 confirmed during interview, 6/24/2025 at 2:30 pm, TP #3 did not meet the minimum educational requirements (493.1449) to perform the duties of a TS. ****REPEAT DEFICIENCY****