Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0036143	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
University Health Service	207 Fletcher Street, Ann Arbor, MI	

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 recertification survey was performed on February 4, 2026, by the Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Technical Supervisor #1 (TS1), the laboratory failed to ensure that competency assessments for staff performing Provider-Performed Microscopy (PPM) testing were conducted per policy for 4 (TP5, TP19, TP20, and TP26) of 29 testing personnel (TP) reviewed. Findings include: 1. Review of laboratory's Form CMS-209 form identified testing personnel #24 (TP24) as moderate complexity testing personnel. 2. A review of the laboratory's personnel competency assessment documentation revealed TP24 conducted competency assessments for the following PPM testing personnel: a. A competency assessment for TP26 was performed on 8/5/2025. b. A competency assessment for TP5 was performed on 5/6/2025. c. A competency assessment for TP19 was performed on 11 /12/2025. d. A competency assessment for TP20 was performed on 11/12/2025. 3. A review of the laboratory policy titled "PPM Competency Assessment," page 1, item 1, stated, " ...a designated observer will observe each PPM provider perform testing." 4. On 2/4/2026 at 11:00 am, a request was made to the TS for delegation of duties documentation for PPM for TP24. A document titled "Delegation of CLIA Lab

	Director Duties" was provided; however, designation to TP24 was not indicated. 5. On 2/4/2026 at 11:05 am, an interview with TS1 confirmed that TP24 was not designated to perform competency assessments for PPM testing. B. Based on record review and interview with Technical Supervisor #1 (TS1), the laboratory failed to ensure that competency was assessed annually for 1 (TP16) of 29 Provider-Performed Microscopy (PPM) testing personnel (TP). Findings include: 1. A review of competency assessment documentation for TP16 revealed the annual compentency assessment was not completed for 2024. 2. A review of the laboratory policy titled "PPM Competency Assessment," page 1, item 1, stated, "...Annually, a designated observer will observe each PPM provider perform testing." 3. On 2/4/2026 at 11:05 am, an interview with TS1 confirmed the annual competency assessment for 2024 was not completed.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with techical supervisor #1, the laboratory failed to evaluate the effectiveness of its preanalytic quality assessment plan as part of the laboratory's Individualized Quality Control Plans (IQCP) for four (Commercially prepared media, Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact, Vitek identification system, and the Vitek yeast identification system) of five test systems since they were last reviewed on 6/15/23. Findings include: 1. A review of each of the IQCP's "Quality Assessment: Ongoing Monitoring for [Quality Control Plan] Effectiveness" includes a section requiring an "annual review" 2. A review of the laboratory's IQCPs revealed the most recent recorded date the effectiveness was reviewed was on 6/15/23 for the following IQCPs: a. Commercially prepared media b. Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact c. Vitek identification system d. Vitek yeast identification system 3. An interview on 2/4/26 at 1:51 pm with technical supervisor #1 confirmed evaluations of effectiveness were not performed and documented since 6/15/23 for the IQCPs listed above.
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 and interview with technical supervisor #1, the laboratory failed to evaluate the relationship between its two methods of performing peripheral white blood cell differentials for two (February 2024 to February 2026) of two years

	reviewed. Findings include: 1. A review of the laboratory's test menu revealed it used two methods for performing peripheral white blood cell differentials: automated via the Sysmex XN-550 and manually. 2. The surveyor requested the laboratory's automated to manual differential method evaluations performed between February 2024 and February 2026 on 2/4/26 at 2:45 pm and the documentation was not made available. 3. An interview on 2/4/26 at 2:45 pm with technical supervisor #1 confirmed the laboratory had not evaluated the relationship between the two methods of performing peripheral white blood cell differentials.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with techical supervisor #1, the laboratory failed to evaluate the effectiveness of its analytic quality assessment plan as part of the laboratory's Individualized Quality Control Plans (IQCP) for four (Commercially prepared media, Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact, Vitek identification system, and the Vitek yeast identification system) of five test systems since they were last reviewed on 6/15/23. Findings include: 1. A review of each of the IQCP's "Quality Assessment: Ongoing Monitoring for [Quality Control Plan] Effectiveness" includes a section requiring an "annual review" 2. A review of the laboratory's IQCPs revealed the most recent recorded date the effectiveness was reviewed was on 6/15/23 for the following IQCPs: a. Commercially prepared media b. Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact c. Vitek identification system d. Vitek yeast identification system 3. An interview on 2/4/26 at 1:51 pm with technical supervisor #1 confirmed evaluations of effectiveness were not performed and documented since 6/15/23 for the IQCPs listed above.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with techical supervisor #1, the laboratory failed to evaluate the effectiveness of its postanalytic quality assessment plan as part of the laboratory's Individualized Quality Control Plans (IQCP) for four (Commercially prepared media, Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact, Vitek identification system, and the Vitek yeast identification system) of five test systems since they were last reviewed on 6/15/23.

	Findings include: 1. A review of each of the IQCP's "Quality Assessment: Ongoing Monitoring for [Quality Control Plan] Effectiveness" includes a section requiring an "annual review" 2. A review of the laboratory's IQCPs revealed the most recent recorded date the effectiveness was reviewed was on 6/15/23 for the following IQCPs: a. Commercially prepared media b. Commercial antimicrobial susceptibility testing (AST) on Vitek II Compact c. Vitek identification system d. Vitek yeast identification system 3. An interview on 2/4/26 at 1:51 pm with technical supervisor #1 confirmed evaluations of effectiveness were not performed and documented since 6/15/23 for the IQCPs listed above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on a record review and interview with technical supervisor #1 (TS1), the laboratory failed to provide the required training and experience documentation for 1 (TC1) of 5 technical consultants. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(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 (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(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 (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in

	nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate 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 a record review and interview with the technical supervisor #1(TS1), the laboratory failed to provide the required training and experience documentation for 1 (TC1) of 5 technical consultant personnel. Findings include: 1. A review Form CMS-209 revealed 5 (TC1, TC2, TC3, TC4 and TC5) personnel listed as serving in the technical consultant role. 2. A review of personnel documentation for technical consultants revealed lack of documentation for TC1. 3. An interview with TS1 on 2/4/2026 at 11:00 am revealed documentation for TC1's education, training and experience was not available. The laboratory was provided with a 7-day extension to submit the requested documentation. 4. On 2/17/2026 at 4:00 pm, a review of personnel documentation submitted on 2/11/2026 for TC1 revealed that TC1 did not have the required laboratory training and experience in the specialties of hematology, microbiology, diagnostic immunology and chemistry for moderate complexity testing at 493.1411.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: . Based on record review and interview with technical supervisor #1, the laboratory director failed to be onsite at least once every six months for one (January 2025 to January 2026) of one year reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation showing the laboratory director had been present in the laboratory at least once every six months between January 2025 and January 2026. 2. The surveyor requested documentation of laboratory director visits performed between January 2025 and January 2026 on 2/4/26 at 11:14 am and it was not made available. 3. An interview on 2/4/26 at 2:57 pm with technical supervisor #1 confirmed no documentation was available for laboratory director onsite visits between January 2025 and January 2026.
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 a record review and interview with technical supervisor #1 (TS1), the laboratory failed to provide the required training and experience documentation for 1 (TS1) of 5 technical supervisor personnel. 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. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not 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; (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 #1 (TS1), the laboratory failed to provide the required training and experience documentation for 1 (TS1) of 5 technical supervisor personnel. Findings include: 1. A review Form CMS-209 revealed 5 (TS1, TS2, TS3, TS4 and TS5) personnel listed as serving in the technical supervisor role. 2. A review of personnel documentation for technical supervisors revealed lack of documentation for TS1. 3. An interview with TS1 on 2/4/2026 at 11:00 am revealed documentation for TS1's education, training and experience was not available. The laboratory was provided with a 7-day extension to submit the requested documentation. 4. On 2/17/2026 at 4:00 pm, a review of personnel documentation submitted on 2/11/2026 for TS1 revealed that TS1 did not have the required laboratory training and experience in the specialties of hematology and microbiology for high complexity testing at 493.1449.