Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2299741	02/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Derbala Institute For Reproductive Immunology	20480 Vernier Road, Harper Woods, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review, observations, and interviews, the laboratory failed to establish procedures to include specimen transportation (refer to D5403 A), failed to establish control procedures to include the laboratory's process for assessing staining control reactivity for flow cytometry testing using the BD FACSLyric instrumentation (refer to D5403 B), failed to establish procedures to include reference intervals for its immunophenotyping and natural killer cells functional assays (D5403 C), failed to ensure blood collection tubes had not exceeded expiration dates (refer to D5417), failed to establish performance specifications for its flow cytometry testing to include reference intervals (refer to D5423 A), failed to establish performance specifications for its flow cytometry testing to include the use of the Countess 3 automated cell counting system (refer to D5423 B), failed to establish accuracy and precision performance specifications for its flow cytometry testing (refer to D5423 C), failed to establish flow cytometry testing analytical specificity performance specifications including interfering substances for antibody cross reactivity (refer to D5423 D), and failed to perform and document positive and negative reactivity for its flow cytometry testing each time of use (refer to D5475).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
. A. Based on record review and interviews with technical supervisors #1 and #2, the laboratory failed to establish procedures to include specimen transportation for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Quality Assurance Program Occurrence Report" completed on 2/21/25 revealed issues with delayed FedEx deliveries and testing for patients with specimens in the delayed shipment were canceled. Showing the laboratory accepts specimens via FedEx. 2. A review of the laboratory's policies and procedures revealed a lack of established specimen transportation policy for specimens collected at outside facilities requiring transport to the laboratory. 3. An interview on 2/24/25 at 2:15 pm with technical supervisors #1 and #2 confirmed the laboratory failed to establish policies and procedures to include specimen transportation. B. Based on record review and interviews with technical supervisor #2, the laboratory failed to establish control procedures to include the laboratory's process for assessing staining control reactivity for flow cytometry testing using the BD FACSLyric instrumentation for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Immunophenotyping" test procedure revealed a section titled, "Quality Control" stating, "The daily cleanse and Performance QC must be within the acceptable limits before antibody titrations can be run on the cytometer. Refer to BD FACSLyric Maintenance procedure (Document ID: XXXXXX) for more detailed instruction." The procedure did not include the laboratory's process for assessing staining controls for cell surface immunophenotyping. 2. A reivew of the laboratory's "Natural Killer Cells Functional Assay" test procedure revealed a section titled, "Quality Control" stating, "Perform daily cleaning and calibration on the flow cytometer. Regularly check reagents for expiration and proper storage conditions. Perform control assays with known standards to validate assay performance." 3. An interview on 2/24/25 at 1:18 pm with technical supervisor #2 revealed the laboratory's controls process for assessing control reactivity for flow cytometry testing was performed by assessing cells within the patient specimens each time of use and confirmed this process was not included in the laboratory's test procedures. C. Based on record review and interviews with technical supervisor #2, the laboratory failed to

	establish procedures to include reference intervals for its immunophenotyping and natural killer cells functional assays for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Immunophenotyping" and "Natural Killer Cells Function Assay" test procedures revealed a lack of reference intervals. 2. An interview on 2/24/25 at 10:52 am with technical supervisor #2 confirmed the laboratory had not established a procedure to include reference intervals.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interviews with technical supervisors #1 and #2, the laboratory failed to ensure blood collection tubes had not exceeded expiration dates for 500 K2EDTA BD Vacutainer tubes observed. Findings include: 1. The surveyor observed the specimen collection area on 2/24/25 at 9:51 am. There were five flats of 100 count K2EDTA BD Vacutainer tubes with the expiration date of 3/31/24. 2. An interview on 2/24/25 at 10:00 am with technical supervisors #1 and #2 confirmed the blood collection tubes listed above had exceeded expiration dates.
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: . A. Based on record review and interview with technical supervisors #1 and #2, the laboratory failed to establish performance specifications for its flow cytometry testing to include reference intervals for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Summary of Flow Cytometry Validation" revealed a section titled, "Reference Ranges" stating, "The flow cytometry assay performed at The Derbala Flow Cytometry Laboratory adopted the normal ranges established by the reference lab and will be verifying and updating the ranges as data is made available." 2. The surveyor requested laboratory data used to verify the reference intervals used by the reference laboratory on 2/24/25 at 11:55 am and it was not made available. 3. An interview on 2/24/25 at 11:55 am with technical supervisors #1 and #2 confirmed the laboratory had not verified the reference intervals used for its flow cytometry assays

	prior to reporting patient test results. B. Based on record review, observation, and interview with technical supervisors #1 and #2, the laboratory failed to establish performance specifications for its flow cytometry testing to include the use of the Countess 3 automated cell counting system for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. The surveyor observed the Countess 3 automated cell counter in the laboratory on 2/24/25 at 9:51 am. 2. A review of the laboratory's "Summary of Flow Cytometry Validation" revealed a section titled "Equipment" listing the equipment used during the validation process. The Countess 3 automated cell counter was not listed. 3. A review of the "Countess v. Hemocytometer Viability" documentation revealed the laboratory compared the accuracy of the Countess 3 automated cell counter to the manual hemocytometer method, however, there was a lack of precision specifications. 4. An interview on 2/24/25 at 12:16 pm with technical supervisors #1 and #2 revealed the Countess 3 automated cell counter is used in patient testing to determine viability prior to continuing with the testing process and confirmed it was not included in the validation summary. C. Based on record review and interview with technical supervisors #1 and #2, the laboratory failed to establish accuracy and precision performance specification acceptability criteria for its flow cytometry testing for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Summary of Flow Cytometry Validation" revealed a section titled "Accuracy" stating, "No significant differences should be observed in percentages and immunophenotyping of normal cell populations" and did not define what a significant difference would be. 2. A review of the laboratory "Summary of Flow Cytometry Validation" revealed a section titled "Precision" stating, "Intra assay precision was performed on peripheral blood samples. One sample was set-up and run 10 times. The mean, standard deviation (SD) and coefficient of variation (CV) were calculated. Data was summarized. Results were acceptable. Inter assay precision was also performed on peripheral blood (replicate measurements that are tested in multiple runs). One sample is separated into 10 aliquots and stained separately and run on flow cytometer. The mean, standard deviation (SD) and coefficient of variation (CV) were calculated. Data was summarized. Results were acceptable" and did not define acceptability criteria. 3. A review of the laboratory's precision data revealed the laboratory had a coefficient of variation (CV) value of 21.70427 for CD19's inter laboratory precision, showing imprecision. 4. An interview on 2/24/25 at 11:46 am with technical supervisors #1 and #2 confirmed the laboratory had not established accuracy and precision specification acceptability criteria. D. Based on record review and interview technical supervisors #1 and #2, the laboratory failed to establish performance specifications for its flow cytometry testing to include analytical specificity including interfering substances for antibody cross reactivity for four (October 2024 to February 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's "Summary of Flow Cytometry Validation" revealed a section titled "Analytical Sensitivity and Specificity" stating, "Flow cytometry panels at The Derbala Laboratory are semi quantitative assays. This was calculated using the same data used in accuracy. Data was extracted from 34 samples." and "Specificity was calculated using the same data used in accuracy. Data was extracted from 34 samples" and failed to include potential interfering substances or antibody cross reactivity. 2. The surveyor requested the laboratory's analytical specificity data including interfering substances for antibody cross reactivity on 2/24/25 at 11:51 am and it was not made available. 3. An interview on 2/24/25 at 11:51 am with technical supervisor #2 confirmed analytical specificity data including how the laboratory interferring substances for antibody cross reactivity was not present.

D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. This STANDARD is not met as evidenced by: . Based on record review and interview with technical supervisor #2, the laboratory failed to perform and document positive and negative reactivity for its flow cytometry testing each time of use for nine (Patients #1-#9) of nine patient testing records reviewed. Findings include: 1. An interview on 2/24/25 at 1:18 pm with technical supervisor #2 revealed the laboratory's controls process for assessing control reactivity for flow cytometry testing was performed by assessing cells within the patient specimens each time of use. 2. A review of the testing records for nine patients tested between October 2024 and February 2025 revealed a lack of documentation of positive and negative reactivity for each fluorescent stain: a. Patient #1, test report date 10/18/24, had CD3, CD4, CD56, CD107, CD19, and CD5. b. Patient #2, test report date 10/31/24, had CD56, CD107, CD3, CD19, and CD5. c. Patient #3, test report date 11/22/24, had CD56, CD107, CD3, CD4, CD19, and CD5. d. Patient #4, test report date 12/7/24, had CD56, CD3, CD5, CD45, CD19, and CD107a. e. Patient #5, test report date 12/9/23, had CD19, CD5, CD3, CD56, and CD107a f. Patient #6, test report date 1/14/25, had CD107, CD56, CD3, CD19, and CD5. h. Patient #7, test report date 1/30/25, had CD107, CD56, CD3, CD19, and CD5. i. Patient #8, test report date 2/2/25, had CD107, CD56, CD3, CD19, and CD5. j. Patient #9, test report date 2/18/25, had CD107, CD56, CD3, CD19, and CD5.
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, observations, and interviews, the laboratory director failed to ensure performance specifications were established for its flow cytometry testing to include reference intervals (refer to D6085 A), failed to ensure performance specifications were established for its flow cytometry testing to include the use of the Countess 3 automated cell counting system (refer to D6085 B), failed to ensure accuracy and precision performance specifications for its flow cytometry testing were established (refer to D6085 C), failed to ensure performance specifications for its flow cytometry testing to include analytical specificity including interfering substances for antibody cross reactivity were established (refer to D6085 D), failed to establish control procedures to include the laboratory's process for assessing staining control reactivity for flow cytometry testing using the BD FACSLyric instrumentation (refer to D6093 A), failed to ensure positive and negative reactivity for its flow cytometry testing was assessed and documented each time of use for nine (Patients #1-#9) of nine patient testing records reviewed (refer to D6093 B), failed to have a qualified technical supervisor overseeing its high complexity general immunology flow cytometry testing (refer to D6101 A), failed to ensure staff performing the duties of a general supervisor (refer to D6101 B), failed to establish procedures to include

	specimen transportation (refer to D6106 A), and failed to establish procedures to include to include reference intervals for its immunophenotyping assay and natural killer cells functional assay (refer to D6106 B).
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) (e)(3) Ensure that-- (e)(3)(i) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: . A. Based on record review and interview with technical supervisors #1 and #2, the laboratory director failed to ensure performance specifications were established for its flow cytometry testing to include reference intervals. Refer to D5423 A. B. Based on record review and interview with technical supervisors #1 and #2, the laboratory director failed to ensure performance specifications were established for its flow cytometry testing to include the use of the Countess 3 automated cell counting system. Refer to D5423 B. C. Based on record review and interview with technical supervisors #1 and #2, the laboratory director failed to ensure accuracy and precision acceptability criteria for its flow cytometry testing were established. Refer to D5423 C. D. Based on record review and interview technical supervisors #1 and #2, the laboratory director failed to ensure performance specifications for its flow cytometry testing to include analytical specificity including interfering substances for antibody cross reactivity were established. Refer to D5423 D.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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: . A. Based on record review and interviews with technical supervisor #2, the laboratory director failed to establish control procedures to include the laboratory's process for assessing staining control reactivity for flow cytometry testing using the BD FACSLyric instrumentation. Refer to D5403 B. B. Based on record review and interview with technical supervisor #2, the laboratory director failed to ensure positive and negative reactivity for its flow cytometry testing was assessed and documented each time of use. Refer to D5475.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by:

	. A. Based on record review and a lack of documentation, the laboratory director failed to have a qualified technical supervisor overseeing its high complexity general immunology flow cytometry testing. Refer to D6111. B. Based on record review, lack of documentation, and interview with technical supervisor #1, the laboratory director failed to ensure staff performing the duties of a general supervisor. Refer to D6143.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: . A. Based on record review and interviews with technical supervisors #1 and #2, the laboratory director failed to establish procedures to include specimen transportation. Refer to D5403 A. B. Based on record review and interviews with technical supervisor #2, the laboratory failed to establish procedures to include to include reference intervals for its immunophenotyping and natural killer cells functional assays. Refer to D5403 C.
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 record review and a lack of documentation, the laboratory failed to have a qualified technical supervisor overseeing its high complexity general immunology flow cytometry testing. 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 a lack of documentation, the laboratory failed to have a qualified technical supervisor overseeing its high complexity general immunology

	flow cytometry testing for one (technical supervisor #1) of two technical supervisors listed on Form CMS-209. Findings include: 1. A review of technical supervisor #1's qualification records revealed a lack of testing training or experience documentation to meet the one year minimum for physicians holding a state license. 2. The laboratory was provided seven days after the survey to submit the additional documentation and it was not received.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: . Based on record review, lack of documentation, and interview with technical supervisor #1, the laboratory failed to ensure staff performing the duties of a general supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who

	is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g). This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with technical supervisor #1, the laboratory failed to ensure staff performing the duties of a general supervisor for two (technical supervisor #1 and testing personnel #3) of six laboratory personnel listed on Form CMS-209. Findings include: 1. A review of the personnel competency assessment records revealed both technical supervisor #1 and testing personnel #3 were performing competency assessments for testing personnel, a general supervisor duty. 2. A review of technical supervisor #1's qualification records revealed a lack of testing training or experience documentation to meet the one year minimum for physicians holding a state license. 3. A review of testing personnel #3's qualification records revealed a Bachelor of Science degree in Biotechnology and a lack of at least two years' of training or experience in high complexity testing. 4. An interview on 2/24/25 at 10:16 am with technical supervisor #1 confirmed testing personnel #3 had not met qualification requirements to serve as a general supervisor. 5. The laboratory was provided seven days after the survey to submit additional documentation, and it was not received.