Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2296681	03/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Resonance Laboratories, Llc	729 E Pass Rd Ste G, Gulfport, MS	

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	An initial/complaint survey was completed on 3/13/2026. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1447 Condition: Technical Supervisor 42 C.F.R. 493.1453 Condition: Clinical Consultant 42 C.F.R. 493.1459 Condition: General Supervisor 42 C.F.R. 493.1487 Condition: Testing Personnel
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 deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283, monitor and evaluate the overall quality of the analytic systems, ensure the establishment of performance specifications for five of five gene panels, and ensure that quality control was performed with every sequencing run. Refer to D5423. Refer to D5455.
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 review of patient test reports, the laboratory's standard operating procedure manual, and interview with the laboratory director, the laboratory failed to establish performance specifications for five of five gene panels, consisting of a total of 266 genes for immune-deficiency disorders, reported on 185 patients from 8/12/2024 through 11/16/2025. Findings include: 1. Review of patient test reports in the laboratory's information system revealed 185 patients' final test reports, dated from 8/12/2024 through 11/16/2025, each of which included results for the following five panels of genes associated with immune-deficiency disorders: (1) Autoinflammatory Gene Panel, consisting of 117 genes. (2) Atypical Hemolytic Uremic Syndrome (aHUS), Thrombotic Microangiopathy (TMA), Thrombotic Thrombocytopenic Purpura (TTP) Panel, consisting of 15 genes. (3) B-Cell and Antibody Deficiency Panel/Viral Susceptibility, Intrinsic and Innate Immunity Panel, consisting of 90 genes. (4) Autoimmune Lymphoproliferative Syndrome (ALPS) Panel, consisting of 26 genes. (5) Telomere Biology Disorders Panel, consisting of 18 genes. 2. The laboratory's standard operating procedure manual included the "Analytical Validation" for 115 genes, of 117 genes included in the Autoinflammatory Gene Panel. The results of the validation, dated 9/19/2025, stated that the accuracy of NGS (Next-Generation Sequencing) variant calling was 88% and that the acceptable accuracy was 90%. 3. In a telephone interview on 3/13/2026 at 12:17 p.m., the laboratory director stated that because the accuracy of NGS variant calling for the Autoinflammatory Gene Panel was below his acceptable cut-off of 90%, he did not approve this test for patient testing. 4. There was no documentation of establishment of performance specifications for the other four gene panels listed above (aHUS/TMA/TTP Panel; B-Cell and Antibody Deficiency Panel/Viral Susceptibility, Intrinsic and Innate Immunity Panel; ALPS Panel; Telomere Biology Disorders Panel) for which patient results were reported from 8/12/2024 through 11/16/2025.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports and the laboratory's standard operating procedure manual, the laboratory failed to include at least two control materials with each sequencing run, when a total of 185 patient samples were tested for five gene panels, consisting of a total of 266 genes for immune-deficiency disorders, from 8/12/2024 through 11/16/2025. Findings include: 1. Review of patient test reports in the laboratory's information system revealed 185 patients' final test reports, dated from 8/12/2024 through 11/16/2025, each of which included results for the following five panels of genes associated with immune-deficiency disorders: (1) Autoinflammatory

	Gene Panel, consisting of 117 genes. (2) Atypical Hemolytic Uremic Syndrome (aHUS), Thrombotic Microangiopathy (TMA), Thrombotic Thrombocytopenic Purpura (TTP) Panel, consisting of 15 genes. (3) B-Cell and Antibody Deficiency Panel/Viral Susceptibility, Intrinsic and Innate Immunity Panel, consisting of 90 genes. (4) Autoimmune Lymphoproliferative Syndrome (ALPS) Panel, consisting of 26 genes. (5) Telomere Biology Disorders Panel, consisting of 18 genes. 2. Review of the laboratory's standard operating procedure manual revealed Section 9, Control Requirements, stated, "Each sequencing run must include: One Positive Control (genomic DNA with known variants) and one No Template Control. Control performance must be reviewed and documented prior to release of patient results." 3. There was no documentation of controls performed with each sequencing run for the 185 patient samples tested and reported from 8/12/2024 through 11/16/2025.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel files, the laboratory failed to have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart for a laboratory performing high complexity testing. Findings include: Review of the laboratory's personnel files revealed that the individual listed on the CMS 209 personnel form as technical supervisor did not meet the qualification requirements for technical supervisor at 493.1449 of this subpart for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders. 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 review of the CMS 209 personnel form and personnel files, the laboratory failed to have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the laboratory's personnel files revealed that the individual listed on the CMS 209 personnel form as technical supervisor held a master's degree

	in Medical Sciences. 2. There was no evidence that the individual possessed at least two years of laboratory training or experience, or both, in high complexity testing in the specialty of diagnostic immunology, in order to qualify as technical supervisor for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel files, the laboratory failed to have a clinical consultant who meets the qualification requirements of 493.1455 of this subpart for a laboratory performing high complexity testing. Findings include: Review of the laboratory's personnel files revealed that the individual listed on the CMS 209 personnel form as clinical consultant did not meet the qualification requirements for clinical consultant at 493.1455 of this subpart for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders. Refer to D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form and personnel files, the laboratory failed to have a clinical consultant who meets the qualification requirements of 493.1455 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the laboratory's personnel files revealed that the individual listed on the CMS 209 personnel form as clinical consultant held a master's degree in Medical Sciences. 2. There was no evidence that the individual met the clinical consultant education requirements as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine, licensed to practice in the state in which the laboratory is located , or held an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, in order to qualify as clinical consultant for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders.
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 review of the CMS 209 personnel form and personnel files, the laboratory failed to have a general supervisor who meets the qualification requirements of 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. Findings include: Review of the laboratory's documentation of personnel qualifications revealed that the individual listed on the CMS 209 personnel form as general supervisor did not meet the qualification requirements for general supervisor at 493.1461 of this subpart for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders. 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 review of the CMS 209 personnel form and personnel files, the laboratory failed to have a general supervisor who meets the qualification requirements of 493.1461 of this subpart for a laboratory performing high complexity testing. Findings include: 1. Review of the laboratory's personnel files revealed that the individual listed on the CMS 209 personnel form as general supervisor held a master's degree in Medical Sciences. 2. There was no evidence that the individual possessed at least one year of laboratory training or experience, or both, in high complexity testing, in order to quality as general supervisor for a laboratory performing gene panels, consisting of a total of 266 genes for immune-deficiency disorders.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on an interview with the laboratory's owner and review of patient test reports and personnel files, the laboratory failed to ensure that the individuals performing and reporting high complexity tests from 8/12/2024 through 11/16/2025 met qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. Findings include: A telephone interview with the laboratory's owner on 3/13/2026 at 1: 00 p.m., review of patient test reports in the laboratory information system from 8/12 /2024 through 11/16/2025, and review of the laboratory's personnel files revealed no documentation of education or training for the individual performing high complexity testing from 8/12/2024 until May 2025 or for the individual interpreting the results for the final reports from 8/12/2024 through the day of the survey, 3/13/2026, in order for these two individuals to meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) 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; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have

	laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on an interview with the laboratory's owner and review of patient test reports and personnel files, the laboratory failed to ensure that the individuals performing and reporting high complexity tests from 8/12/2024 through 11/16/2025 met qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. Findings include: 1. In a telephone interview with the laboratory's owner on 3/13/2026 at 1:00 p.m., he stated that one individual performed gene testing from August 2024 until May 2025 (TP#1), and a second individual performed gene testing from May 2025 until February 2026 (TP#2). He also stated that a third individual (TP#3) interpreted the gene testing results for the final reports from August 2024 until the day of the survey, 3/13/2026. 2. Review of patient test reports in the laboratory information system (LIS) from 8/12/2024, the first test reports available in the LIS, through 11/16/2025, the last test reports available in the LIS, revealed test results for five panels of genes, with a total of 266 genes associated with immune-deficiency disorders, were reported for 118 patients from 8/12/2024 until May 2025, the time frame during which the first individual (TP#1) performed high-complexity testing. 3. Review of patient test reports in the laboratory information system from 8/12/2024 through 11/16/2025 revealed test results for the five panels of genes were reported for 185 patients from 8/12/2024 through 11/16/2025, the time frame during which the third individual (TP#3) interpreted the results for the final reports. 4. Review of the laboratory's personnel files revealed there was no documentation of education or training for the individual (TP#1)performing high complexity testing from 8/12/2024 until May 2025 or for the individual (TP#3) interpreting the results for the final reports from 8/12/2024 through the day of the survey, 3/13/2026.