Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2177063	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
James Maher, Md Laboratory	19255 Park Row Drive # 104, Houston, TX	

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 unannounced complaint investigation was performed on March 20, 2025, for Intake #TX 00533429. The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The following IMMEDIATE JEOPARDY findings were: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F. R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor; D6134 - 42 C.F.R. 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant; D6141 - 42 C.F.R. 493.1459 Condition: Laboratories performing high complexity testing; general supervisor; D6168 - 42 C.F. R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; The IJ Template was provided to the laboratory at the exit conference and the immediate jeopardy conditions were abated on 3/20/25. And the following CONDITION LEVEL findings were: D5028 - 42 C.F.R. 493.1219 Condition: Histopathology;
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory failed to meet the requirements for the specialty of histopathology for the grossing of patient's tissue specimens from January to March 2025. Findings include: 1. The laboratory failed to have documentation of a written procedure for the laboratory personnel to follow for the grossing of patient specimens. (Refer to D5403) 2. The laboratory failed to include the name and address of the testing facility on patient's test reports reviewed. (Refer to D5805)

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: Based on surveyor observation and staff interview, the laboratory failed to have documentation of one of one written procedure for the laboratory personnel to follow for the grossing of patient specimens from January to March 2025. Findings include: 1. Surveyor observation of the laboratory on 3/20/25 at 9:10 a.m. revealed the laboratory failed to have documentation of a written procedure for the grossing of patient specimens that included the following: a) Specimen labeling, storage and preservation b) Step-by-step performance of the procedure c) Corrective action d) Entering results 2. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient's test reports from January to March 2025 and staff interview, the laboratory failed to include the name and address of the testing facility on 16 of 16 patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from January to March 2025 revealed the laboratory failed to include the name and address of the testing facility on the following 16

	patient's test reports: Accession #: JM25-5 Reported: 1/20/25 Accession #: JM25-7 Reported: 1/20/25 Accession #: JM25-12 Reported: 1/24/25 Accession #: JM25-17 Reported: 1/24/25 Accession #: JM25-10 Reported: 1/30/25 Accession #: JM25-41 Reported: 2/12/25 Accession #: JM25-26 Reported: 2/17/25 Accession #: JM25-49 Reported: 2/19/25 Accession #: JM25-61 Reported: 2/27/25 Accession #: JM25-77 Reported: 3/7/25 Accession #: JM25-90 Reported: 3/12/25 Accession #: JM25-93 Reported: 3/12/25 Accession #: JM25-84 Reported: 3/13/25 Accession #: JM25-85 Reported: 3/13/25 Accession #: JM25-87 Reported: 3/13/25 Accession #: JM25-100 Reported: 3/17/25 2. In an interview on 3/20/25 at 11:05 a.m. in the office, after review of the records, the office manager confirmed the above findings.
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 a review of the laboratory's records, personnel records, and staff interview, the laboratory failed employ a laboratory director to provide overall management of the laboratory for one of one high complexity test- grossing of patient's tissue specimens from January to March 2025. Findings include: 1. The laboratory failed to have a qualified laboratory director from January 1, 2025 to March 20, 2025. (Refer to D6078)
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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, a 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 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS 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 (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii)

	Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records, patient test records, and staff interview, the laboratory failed to employ a qualified laboratory director for 79 of 79 days from January 1, 2025 to March 20, 2025. Findings include: 1. In an interview on 3/20/25 at 9:35 a.m. in the laboratory, the office manager stated the laboratory began a contract with a histopathology laboratory, to perform the grossing of patient's tissue specimens, on 1/1/25. 2. A review of the laboratory's records revealed no documentation that a new laboratory director was appointed when the histopathology laboratory began their contract on 1/1/25. 3. A review of patient test records revealed the laboratory grossed 120 patient's tissue specimens from January 9, 2025 to March 18, 2025 with no laboratory director in place. 4. In an interview on 3/20/25 at 11:00 a. m. in the office, after review of the records, the office manager confirmed the above findings.
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 review of the laboratory's records, personnel records, and staff interview, the laboratory failed to employ a technical supervisor to provide technical supervision for one of one high complexity test- grossing of patient's tissue specimens from January to March 2025. Findings include: 1. The laboratory failed to employ a qualified technical supervisor from January 1, 2025 to March 20, 2025. (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 a review of the laboratory's records, patient test records, and staff interview, the laboratory failed to employ a qualified technical supervisor for 79 of 79 days from January 1, 2025 to March 20, 2025. Findings include: 1. In an interview on 3/20/25 at 9:35 a.m. in the laboratory, the office manager stated the laboratory began a contract with a histopathology laboratory, to perform the grossing of patient's tissue specimens, on 1/1/25. 2. A review of the laboratory's records revealed no documentation that a new technical supervisor was appointed when the histopathology laboratory began their contract on 1/1/25. 3. A review of patient test records revealed the laboratory grossed patient's tissue specimens from January 9, 2025 to March 18, 2025 with no technical supervisor in place. 4. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings.
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 a review of the laboratory's records, personnel records, and staff interview, the laboratory failed to employ a clinical consultant to provide clinical consultation for one of one high complexity test- grossing of patient's tissue specimens from January to March 2025. Findings include: 1. The laboratory failed to employ a qualified clinical consultant from January 1, 2025 to March 20, 2025 (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 a review of the laboratory's records, patient test records, and staff interview, the laboratory failed to employ a qualified clinical consultant for 79 of 79 days from January 1, 2025 to March 20, 2025. Findings include: 1. In an interview on 3/20/25 at 9:35 a.m. in the laboratory, the office manager stated the laboratory began a contract

	with a histopathology laboratory, to perform the grossing of patient's tissue specimens, on 1/1/25. 2. A review of the laboratory's records revealed no documentation that a new clinical consultant was appointed when the histopathology laboratory began their contract on 1/1/25. 3. A review of patient test records revealed the laboratory grossed patient's tissue specimens from January 9, 2025 to March 18, 2025 with no clinical consultant in place. 4. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings.
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 a review of the laboratory's records, personnel records, and staff interview, the laboratory failed to employ a general supervisor to provide general supervision for one of one high complexity test- grossing of patient's tissue specimens from January to March 2025. Findings include: 1. The laboratory failed to employ a qualified general supervisor from January 1, 2025 to March 20, 2025. (Refer to D6143A)
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: A. Based on a review of the laboratory's records, patient test records, and staff interview, the laboratory failed to employ a qualified general supervisor for 79 of 79 days from January 1, 2025 to March 20, 2025. Findings include: 1. In an interview on 3/20/25 at 9:35 a.m. in the laboratory, the office manager stated the laboratory began a contract with a histopathology laboratory, to perform the grossing of patient's tissue specimens, on 1/1/25. 2. A review of the laboratory's records revealed no documentation that a new general supervisor was appointed when the histopathology laboratory began their contract on 1/1/25. 3. A review of patient test records revealed the laboratory grossed patient's tissue specimens from January 9, 2025 to March 18, 2025 with no general supervisor in place. 4. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings. B. Based on a random review of the laboratory's Grossing Logs from January to March 2025, personnel records, and staff interview, the laboratory failed to have documentation of the technical supervisor reviewing the gross examination of patient's tissue specimens within 24 hours for 16 of 16 patient's records reviewed. Findings include: 1. A review of the laboratory's Grossing Logs from January to March 2025 revealed three testing personnel performing gross examinations of patient's tissue specimens. 2. A review of the laboratory's personnel records for all 3 testing personnel found no documentation to qualify them as a technical supervisor for high complexity testing in the specialty of histopathology. Therefore, grossing must be reviewed by the technical supervisor within 24 hours. 3. Further review of the laboratory's Grossing Logs revealed the following 16 patient's specimens were grossed by the three testing personnel and the laboratory failed to have documentation of the technical supervisor reviewing the grossing within 24 hours: Patient Accession number: JM25-5 Grossed on 1/9/25 Patient Accession number: JM25-6 Grossed on 1/9/25 Patient Accession number: JM25-10 Grossed on 1/16/25 Patient Accession number: JM25-12 Grossed on 1/16/25 Patient Accession number: JM25-17 Grossed on 1/16/25 Patient Accession number: JM25-26 Grossed on 1/30/25 Patient Accession number: JM25-41 Grossed on 2/6/25 Patient Accession number: JM25-49 Grossed on 2/13/25 Patient Accession number: JM25-61 Grossed on 2/20/25 Patient Accession number: JM25-77 Grossed on 2/27/25 Patient Accession number: JM25-100 Grossed on 3/1/25 Patient Accession number: JM25-84 Grossed on 3/5/25 Patient Accession number: JM25-85 Grossed on 3/5/25 Patient Accession number: JM25-87 Grossed on 3/5/25 Patient Accession number: JM25-90 Grossed on 3/5/25 Patient Accession number: JM25-93 Grossed on 3/5/25 4. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings.
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 a review of the laboratory's personnel records and staff interview, the laboratory failed to ensure three of three testing personnel qualified to perform high complexity testing- grossing of patient's tissue specimens from January to March 2025. (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 a review of the laboratory's Grossing Logs from January to March 2025, the laboratory's personnel records, and staff interview, the laboratory failed to ensure the following: a) one of three testing personnel met the qualifications to perform high complexity testing- grossing of patient's tissue specimens b) two of three testing personnel had sufficient documentation available to qualify them to perform high complexity testing- grossing of patient's tissue specimens. Findings include: 1. A

	review of the laboratory's Grossing Logs from January to March 2025 revealed 3 testing personnel performing high complexity testing- grossing of patient's tissue specimens. 2. A review of the laboratory's personnel records revealed the laboratory failed to ensure: a) Testing person, that grossed specimens JM25-01 - JM25-06 on 1/9 /25, was qualified to perform grossing b) - Testing person, that grossed specimens JM25-18 - JM25-24 on 1/30/25, had sufficient documentation available to qualify them to perform grossing - Testing person, that grossed specimens JM25-90 - JM25-95 on 3/6/25, had sufficient documentation available to qualify them to perform grossing * No additional documentation was provided by the time of the exit conference on March 20, 2025. 3. In an interview on 3/20/25 at 11:00 a.m. in the office, after review of the records, the office manager confirmed the above findings.