Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2315196	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Med Ai Diagnostics Llc	3705 Medical Parkway Ste 430, Austin, 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	The Med AI Diagnostics LLC laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements for laboratories as a result of an initial validation survey on 10/08/2025. The condition not met was: D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on review of manufacturer specifications, observation, temperature logs, and interview, the laboratory failed to monitor room temperature for the Leica CM 1850 cryostats used to prepare slides for small fiber neuropathy testing for eight of eight months reviewed. Findings follow. A. Review of the Leica CM 1850 Instruction Manual, V2.2 12/2003, under 3. Technical Data stated, Operating temperature range (ambient temperature) 18 degrees Celsius (C) to 40 C. All specifications related to temperature are valid only up to an ambient temperature of 22 C and an air humidity lower than 60%!" B. During a tour of the laboratory on October 8, 2025 at 1440 hours surveyor observed no room thermometer in the room with the cryostats. C. Review of maintenance and temperature logs showed no documentation of room temperature. Room temperature logs were requested on October 8, 2025 at 1450 hours but not

	provided. D. Interview with the General Supervisor/Testing Personnel #1 (as listed on the CMS Form 209) on October 8, 2025 at 1450 verified room temperature was not monitored. II. Based on observation, review of manufacturer instructions, temperature logs, and interview, the laboratory failed to document room temperature for the reagents stored in the flammable cabinet used to prepare slides for small fiber neuropathy testing for eight of eight months reviewed. Findings follow. A. During a tour of the laboratory on October 8, 2025 at 1430 hours surveyor observed the following randomly selected chemicals and stains stored in the flammable cabinet in the room with the refrigerators and freezer with the following specifications on the label: 1. Fisher Finest Hematoxylin + 15-30 C 2. Eosin Y Alcoholic 15-30 C 3. Bluing Reagent 15-30 C 4. Clarifier 2 15-30 C B. Review of temperature logs showed no documentation of room temperature. Room temperature logs were requested on October 8, 2025 at 1450 hours but not provided. C. Interview with the General Supervisor/Testing Personnel #1 on October 8, 2025 at 1450 verified room temperature was not documented. III. Based on review of manufacturer specifications, observation, maintenance and temperature logs, and interview, the laboratory failed to monitor humidity for the Leica CM 1850 cryostats used to prepare slides for small fiber neuropathy testing for eight of eight months reviewed. Findings follow. A. Review of the Leica CM 1850 Instruction Manual, V2.2 12/2003, under 3. Technical Data stated, Operating temperature range (ambient temperature) 18 degrees Celsius (C) to 40 C. All specifications related to temperature are valid only up to an ambient temperature of 22 C and an air humidity lower than 60%!" B. During a tour of the laboratory on October 8, 2025 at 1440 hours surveyor observed no hygrometer in the room with the cryostats. C. Review of the maintenance and temperature logs showed no documentation of humidity. Humidity logs were requested on October 8, 2025 at 1450 hours but not provided. D. Interview with the General Supervisor/Testing Personnel #1 on October 8, 2025 at 1450 confirmed humidity was not monitored.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, quality control records, test reports, and interview, the laboratory failed to provide the pathologists' quality control records for the interpretation of the controls for the intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used to aid in the diagnostic interpretation of small fiber neuropathy testing for eight of eight months reviewed. Findings follow. A. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Program Worksheet showed small fiber neuropathy interpretations began 02/11/2025. B. Quality control records performed by the pathologist were requested on October 8, 2025 at 1510 hours but not provided. C. The following test reports/cases with the H&E stain were reviewed: Sample ID Date Reported 1. MD25-00018 04/13/2025 2. MD25-00039 05/22/2025 3. MD25-00073 07 /02/2025 4. MD25-00105 07/26/2025 5. MD25-00125 08/08/2025 6. MD25-00155 08 /22/2025 7. MD25-00176 09/02/2025 8. MD25-00180 not provided, on page 3 of report 9. MD25-00210 09/16/2025 10. MD25-00244 10/03/2025. D. Interview with the General Supervisor/Testing Personnel #1 (as listed on the CMS Form 209) on October 8, 2025 at 1450 hours confirmed there was no documentation of the quality

	control performed by the pathologist who was responsible for reporting the diagnostic interpretation of the slides. E. Review of the CMS Form 116 showed an estimated test volume of 5,000 blocks, special stains, and Immunohistochemical stains per year.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: I. Based on review of pre-survey paperwork, quality control records, test reports, and interview, the laboratory failed to provide the pathologists' quality control records for the interpretation of the controls for positive and negative reactivity each time of use for the Protein Gene Product (PGP) 9.5 Antibody stain used to aid in the diagnostic interpretation of Epidermal Nerve Fiber Density (ENFD) testing for eight of eight months reviewed. Findings follow. A. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Program Worksheet showed small fiber neuropathy interpretations began 02/11/2025. B. Quality control records performed by the pathologist were requested on October 8, 2025 at 1510 hours but not provided. C. The following test reports/cases with the PGP 9.5 stain were reviewed: Sample ID Date Reported 1. MD25-00018 04/13/2025 2. MD25-00039 05/22/2025 3. MD25-00073 07/02/2025 4. MD25-00105 07/26/2025 5. MD25-00125 08/08/2025 6. MD25-00155 08/22/2025 7. MD25-00176 09/02/2025 8. MD25-00180 not provided, on page 3 of report 9. MD25-00210 09/16/2025 10. MD25-00244 10/03/2025. D. Interview with the General Supervisor/Testing Personnel #1 (as listed on the CMS Form 209) on October 8, 2025 at 1450 hours confirmed there was no documentation of the quality control performed by the pathologist who was responsible for reporting the diagnostic interpretation of the slide. E. Review of the CMS Form 116 showed an estimated test volume of 5,000 blocks, special stains, and Immunohistochemical stains per year. II. Based on review of pre-survey paperwork, quality control records, test reports, and interview, the laboratory failed to provide the pathologists' quality control records for the interpretation of the controls for positive and negative reactivity for the Congo Red stain used to aid in the diagnostic interpretation of small fiber neuropathy for eight of eight months reviewed. Findings follow. A. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Program Worksheet showed small fiber neuropathy interpretations began 02/11/2025. B. Quality control records performed by the pathologist were requested on October 8, 2025 at 1510 hours but not provided. C. The following test reports/cases with the Congo Red stain were reviewed: Sample ID Date Reported 1. MD25-00018 04/13/2025 2. MD25-00039 05/22/2025 3. MD25-00073 07/02/2025 4. MD25-00105 07/26/2025 5. MD25-00125 08/08/2025 6. MD25-00155 08/22/2025 7. MD25-00176 09/02/2025 8. MD25-00180 not provided, on page 3 of report 9. MD25-00210 09/16/2025 10. MD25-00244 10/03/2025. D. Interview with the General Supervisor/Testing Personnel #1 on October 8, 2025 at 1450 hours confirmed there was no documentation of the quality control performed by the pathologist who was responsible for reporting the diagnostic interpretation of the slide. E. Review of the CMS Form 116 showed an estimated test volume of 5,000 blocks, special stains, and Immunohistochemical stains per year.

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 review of the test reports and interview, the laboratory failed to include the name and address of the facility where the small fiber neuropathy diagnostic interpretations were performed on the test reports for 10 of 10 cases reviewed. Findings follow. A. Review of the test reports did not show the name and address of the facility where the diagnostic interpretations were performed. The following test reports were reviewed as listed by sample ID and date reported: Sample ID Date Reported 1. MD25-00018 04/13/2025 2. MD25-00039 05/22/2025 3. MD25-00073 07 /02/2025 4. MD25-00105 07/26/2025 5. MD25-00125 08/08/2025 6. MD25-00155 08 /22/2025 7. MD25-00176 09/02/2025 8. MD25-00180 not provided, on page 3 of report 9. MD25-00210 09/16/2025 10. MD25-00244 10/03/2025 B. Interview with the General Supervisor/Testing Personnel #1 (as listed on the CMS Form 209) on October 8, 2025 at 1105 hours acknowledged all the pathologists had microscopes in their homes and glass slides were shipped to their home where the pathologists performed the interpretation. Follow-up interview with the General Supervisor/Testing Personnel #1 on October 8, 2025 at 1600 hours confirmed the name and address of the facility where the interpretations were performed was not on the test reports and the pathologists did not have CLIA certificates at those locations.
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 educational credentials and interview, the Technical Supervisors failed to meet the qualification requirements for Technical Supervisor for two of four Technical Supervisors for small fiber neuropathy diagnostic interpretations (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 educational credentials and interview, the laboratory failed to ensure the Technical Supervisors possessed a current Texas physician license where the laboratory was located for the high complexity small fiber neuropathy diagnostic interpretations performed by two of four Technical Supervisors. Findings follow. A. Review of educational credentials for Technical Supervisors #2 and 3 showed they held Medical Doctorates with board certifications in Anatomic and Clinical Pathology but did not have Texas physician licenses. B. Interview with the General Supervisor /Testing Personnel #1 (as listed on the CMS Form 209) on October 8, 2025 at 1005 hours confirmed Technical Supervisors #2 and 3 did not possess Texas physician licenses.