Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2035202	05/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Podiatric Medical Partners Of Texas	1151 N Buckner Blvd Suite 305, Dallas, 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 entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: Based on Tissue-Tek VIP (Vacuum Infiltration Processor) operator's guide, review of the laboratory's environmental monitoring records, and staff interview, the laboratory failed to monitor and document temperature and ambient humidity operating

	conditions of the Tissue-Tek VIP for 12 of 12 months in 2021 and 4 of 4 months in 2022 (01/2022-04/2022). Findings Included: 1. Review of the Tissue-Tek VIP operator's guide revealed the following: "Environmental Factors: Environmental factors influence the selection of a proper location for the VIP instrument. As will all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature and humidity should be held relatively constant to obtain the highest degree of operating stability. The ambient temperature range for operating the instrument is 10 C to 40 C.. The ambient operating humidity range is 30% to 85% relative humidity." 2. Review of laboratory's environmental monitoring records revealed the laboratory failed to document the temperature and humidity for the Tissue-Tek VIP operating area for 12 of 12 months in 2021 and 4 of 4 months in 2022 (01/2022-04/2022). 3. During an interview with the laboratory director on 05/04/2022 at 01:49 p.m., the laboratory director, after review of records, confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policy, quality control (QC) records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for 9 of 9 testing days reviewed in April 2021. Findings Included: 1. Review of manufacturer's instructions for the Gill-Hematoxylin stated the following staining characteristics: "Results: Nuclei: Blue Cytoplasm: Pink 2. Review of laboratory policy, "Staining Procedure" revealed the following: "Other Test Systems: Routine Stains: Daily Q.C (quality control) slides are taken and stained with the routine slides each day. Supervisor or pathologist will alert the laboratory of a technical staining problem that will be corrected." The laboratory failed to specify the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics prior to patient testing. 3. Review of laboratory stain quality control (QC) records, "QC Stains" revealed the following: 04/01/2021; 04/06/2021; 04 /08/2021; 04/12/2021; 04/14/2021; 04/19/2021; 04/21/2021; 04/27/2021; 04/29/2021 "PMPT Laboratories: Stain QC results: 1. H&E stain: PASS Excellent H&E stain NOTES: Patient specimen slides reviewed; hematoxylin and eosin staining acceptable" The laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for 9 of 9 testing days reviewed in April 2021. 4. During an interview with the laboratory director on 05/04/2022 at 02: 15 p.m., the laboratory director, after review of records, confirmed the above findings. II. Based on review of the manufacturer's instructions, laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to document for each time of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for Periodic Acid-Schiff (PAS) and GMS stains for 9 of 9 testing days reviewed in April 2021. Findings Included: 1. Review of

	manufacturer's instructions for the PAS stain revealed the following: "Results: Basement membrane, fungi, glycogen, and mucin stain pink to red, other tissues green, and nuclei blue." Review of manufacturer's instructions for the GMS stain revealed the following: "Results: Fungi and Pneumocystis jirovecii stain gray to black and background green." 2. Review of laboratory policy, "Staining Procedure" revealed the following: "Special Stains: Control slides are run with all special stain procedures. Control slides are checked during and after the procedures are complete." The laboratory failed to specify the intended reactivity for PAS and GMS staining to ensure predictable staining characteristics prior to patient testing. 3. Review of laboratory stain quality control (QC) records, "QC Stains" revealed the following: 04 /01/2021; 04/06/2021; 04/08/2021; 04/12/2021; 04/14/2021; 04/19/2021; 04/21/2021; 04/27/2021; 04/29/2021 "PMPT Laboratories: Stain QC results: 2. PAS Stain: PASS Excellent Moderate to good fungal staining intensity Acceptable low-moderate keratin staining background Very good positive control background staining of bacteria and serum pools 3. GMS Stain: PASS Excellent Very strong fungal staining Excellent low keratin background" The laboratory failed to document for each time of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for Periodic Acid-Schiff (PAS) and GMS stains for 9 of 9 testing days reviewed in April 2021. 4. During an interview with the laboratory director on 05/04 /2022 at 02:15 p.m., the laboratory director, after review of records, confirmed the above findings.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Review of laboratory personnel records, competency assessment records and laboratory representative interview, it was revealed the laboratory's technical supervisor failed to evaluate the competency assessment for testing personnel for 2021. Findings Included: 1. Review of laboratory personnel records, revealed 1 Testing Person (TP-1) performing high complexity testing. 2. Review of TP-1 personnel records revealed no documentation of competency assessment performed by the Technical Supervisor in 2021. 3. During an interview with the laboratory representative on 05/04/2022 at 01:35 p.m., the representative confirmed TP-1 did not have a competency assessment performed in 2021. This confirmed the above findings.
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 paragraph (b)(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, physical, biological or clinical 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)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (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 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of laboratory policies, personnel records, pathology gross quality control worksheets, and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 14 of 14 reviewed specimens grossed in April 2022. Findings Included: 1. Review of laboratory policy, "24-Hour Gross Examination of Tissue Specimens" revealed the following: "Procedure: ..7. Grosser will fill grossing log with their initials, the date biopsy was done, log in the first and last batch requisition number that will be send that same day next day air to make the cut off time for the 24 hours grossing check point for the Pathologist/Lab Director to date and initial that the gross was checked before they go ahead and read the bx case. Log will

	go back and forth from us to them and visa-versa." 2. Review of laboratory personnel records revealed 1 Testing Person performing grossing of the patient specimens requiring 24-hour grossing review by the General Supervisor. 3. Random review of laboratory, "Pathology Gross Quality Control Worksheets" revealed the following: a. Date Received: 04/23/2022 Accession Numbers: 514-540 b. Date Received: 04/25 /2022 Accession Numbers: 541-542 c. Date Received: 04/26/2022 Accession Numbers: 543-554 4. Random review of patient final reports, revealed the following 14 of 14 patients not reviewed by the General Supervisor within 24-hours of grossing: a. Lab Received Date: 04/23/2022 Patient Account Number: 540059 Resulted: 05/03 /2022 Days elapsed: 10 b. Lab Received Date: 04/25/2022 Patient Account Number: 540299 Resulted: 05/03/2022 Days elapsed: 8 c. Lab Received Date: 04/25/2022 Patient Account Number: 540510 Resulted: 05/03/2022 Days elapsed: 8 d. Lab Received Date: 04/26/2022 Patient Account Number: 528022 Resulted: 05/03/2022 Days elapsed: 7 e. Lab Received Date: 04/26/2022 Patient Account Number: 528720 Resulted: 05/03/2022 Days elapsed: 7 f. Lab Received Date: 04/26/2022 Patient Account Number: 528720 Resulted: 05/03/2022 Days elapsed: 7 g. Lab Received Date: 04/26/2022 Patient Account Number: 508942 Resulted: 05/03/2022 Days elapsed: 7 h. Lab Received Date: 04/26/2022 Patient Account Number: 540026 Resulted: 05/03/2022 Days elapsed: 7 i. Lab Received Date: 04/26/2022 Patient Account Number: 540392 Resulted: 05/03/2022 Days elapsed: 7 j. Lab Received Date: 04/26/2022 Patient Account Number: 483837 Resulted: 05/03/2022 Days elapsed: 7 k. Lab Received Date: 04/26/2022 Patient Account Number: 524996 Resulted: 05/03/2022 Days elapsed: 7 l. Lab Received Date: 04/26/2022 Patient Account Number: 540060 Resulted: 05/03/2022 Days elapsed: 7 m. Lab Received Date: 04/26/2022 Patient Account Number: 367567 Resulted: 05/03/2022 Days elapsed: 7 n. Lab Received Date: 04/26/2022 Patient Account Number: 540197 Resulted: 05/03/2022 Days elapsed: 7 The general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 14 of 14 reviewed specimens grossed in April 2022. 5. During an interview with the laboratory director on 05/04/2022 at 02:15 p.m., the laboratory director, after review of records, confirmed the above findings.