Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2035202	08/29/2018
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	Noted deficiency and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Based upon the onsite survey conducted 08/29/2018, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. Condition 493.1487 Laboratory Testing Personnel (High Complexity) 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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's records from 2016 and 2017 and staff interview, it was revealed the laboratory failed have documentation of performing twice annual accuracy assessment. Findings included: 1. Review of the laboratory's records from 2016 and 2017 revealed the laboratory the failed to have documentation of performing twice annual accuracy assessment for tissue grossing. 2. The laboratory was asked to provide documentation of twice annual accuracy assessment for 2016 and 2017. No documentation was provided. 3. An interview with laboratory staff on 08/29/2018 at 12:40 PM in the breakroom confirmed the above findings.

D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to have documentation that the laboratory provided written specimen handling instructions to outside clinics for specimens submitted to the laboratory for testing. Findings included: 1. Review of laboratory records revealed the laboratory failed to provide documentation of written specimen handing instructions (collection, preservation, storage, transport, etc.) for specimens submitted to the laboratory for testing from an outside clinic. 2. The laboratory was asked to provide documentation of written specimen handling for clinics. No documentation was provided. 3. An interview with laboratory staff on 08/29/2018 at 10:58 AM in the breakroom confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to provide documentation of a policy for the use of hair conditioner and Gelatine in the tissue processing procedures. Findings included: 1. A tour of the laboratory on 08/29/2018 at 1035 hours revealed the following three bottles of Moisturizing Hair Conditioner stored in a cabinet. a. White Rain Moisturizing Hair Conditioner b. VO5 Hair Conditioner c. VO5 Extra Body Hair Conditioner 2. A tour of the laboratory on 08/29/2018 at 1035 hours revealed one box of Knox Gelatine in a drawer. 3. Review of the laboratory's policies revealed the laboratory failed to have documentation of a tissue processing procedure that utilized hair moisturizer and gelatine. The laboratory was asked to provide documentation of a procedure. No documentation was provided. 4. In an interview on 08/29/2018 at 10:35 AM in the laboratory, the laboratory representative indicated that the laboratory used the chemicals for sample preparation. This confirmed the above findings.
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 review of manufacturer's instructions, laboratory records, and staff interview, it was revealed that the laboratory failed to monitor the correct temperature range as defined by the manufacturer for the water bath temperature for the Gomori Methenamine Silver (GMS) stain procedure. Findings included: 1. The StatLab SSK-GMS/Gomori (Rev. Date: Jan. 22,2010) Instruction for Use under the "Procedure (Standard)" section stated "Place working GMS solution in 60 centigrade water bath and allow temperature to equilibrate." 2. Review of the 2017 and 2018 laboratory record titled "Waterbath QC Log" stated, "Tolerance Limits: 46 +/- 4C." 3. The laboratory was asked to provide documentation that the water bath was monitored for a temperature of 60C. No documentation was provided. 4. An interview with laboratory staff on 08/29/2018 at 1136 in the breakroom confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and staff interview, the laboratory failed to ensure reagents had not exceeded their expiration date. Findings included: 1. A tour of the laboratory on 08/29/2018 at 1035 hours revealed the following expired reagents: a. One Bottle StatLab Reserve Eosin Multichrome Lot number 046414; Expiration date 05/2018 b. One pint StatLab Tissue Grip Lot number 42957; Expiration date 02/2018 c. One bottle Scotty Tab Water Bluing Solution Lot number D19524; Expiration date 07/24/2016 The laboratory failed to ensure reagents had not exceeded their expiration date. 2. An interview with laboratory staff on 08/29/2018 at 10:35 AM in the laboratory 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 patient test reports, form CMS-209, and staff interview, the General Supervisor failed to review within 24 hours all physical examinations /descriptions of tissue including color, weight, measurement and other characteristics of the tissue. Findings included: 1. A random review of patient test reports from 07/13 /2017 through 07/30/2018 revealed 5 of 5 test reports which did not document review of the grossing by the general supervisor (GS) within 24 hours. The following test reports were reviewed: a. TL17-001323; collected 06/20/2017; received 07/13/2017; electronically signed on 07/17/2017; elapsed time 4 days. b. TL17-002404; collected 11/28/2017; received 12/14/2017; electronically signed on 12/18/2017; elapsed time 4 days. c. TL18-000499; collected 03/19/2018; received 03/30/2918; electronically signed on 04/02/2018; elapsed time 3 days. d. TL18-000698; collected 04/12/2108; received 04/20/2018; electronically signed on 04/25/2018; elapsed time 5 days. e. TL18-001519; collected 07/30/2018; received 08/07/2018; electronically signed on 08 /10/2018; elapsed time 3 days. 2. Review of form CMS-209 revealed that the random sample of patient test reports from 07/13/2017 through 07/30/2018 revealed 5 of 5 test

	reports were not electronically signed by the general supervisor for this facility. 3. The above findings were confirmed in an interview with laboratory staff on 08/29/2018 at 11:36 AM in the breakroom.
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 review of the CMS-209 form and personnel records, it was revealed the laboratory failed to have documentation that 2 of 2 testing persons (TP#1 and TP #2) met the qualifications required to perform high complexity testing. (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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and

	storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 2 of 2 testing persons (TP#1 and TP#2) met the qualifications required to perform high complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 and Testing Person #2 listed to perform high complexity tissue grossing. 2. Review of personnel records revealed the laboratory failed to provide educational documents needed to qualify Testing Person #1 and Testing Person #2. 3. No other education documents were provided for Testing Person #1 and Testing Person #2. Findings were confirmed by laboratory staff in an interview on 08/29/2018 at 10:26 AM in the breakroom.