

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2285792	<b>(X3) Date Survey Completed</b> 05/09/2024
<b>Name of Provider or Supplier</b> North Texas Podiatry Associates	<b>Street Address, City, State</b> 401 Westpark Way, Euless, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5213</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records in 2024, and confirmed in interview, the laboratory failed to document evaluation of all analytes not scored by the proficiency testing program for one of one event in 2024. Findings Included: 1. Review of API PT results for the first event in 2024 revealed the following randomly selected analytes failing to receive a grade by the proficiency testing program: Microbiology 1st Event 2024 Analyte/Sample a. Nannizzia nana/ NAF-01 Result: Not Graded b. AmpC (AmpC beta)/UTI-02; UTI-03; UTI-04 Result: Not Graded c. CTX-M Group 1 (plasmid-mediated cefotaximases)/ UTI-02; UTI-03 Result: Not Graded d. CTX-M Group 2/UTI-02; UTI-03 Result: Not Graded e. ErmA (erythromycin ribosome methylase)/ UTI-02; UTI-04; UTI-05 Result: Not Graded f. ErmB (erythromycin ribosome methylase)/ UTI-02; UTI-04; UTI-05 Result: Not Graded h. SHV (sulfhydryl reagent variable)/ UTI-02; UTI-03 Result: Not Graded i. Tet B (tetracycline efflux protein)/ UTI-02; UTI-03 Result: Not Graded j. VIM (Verona Intergron Encoded Metallo-Beta-Lactamase producing)/ UTI-02; UTI-03 Result: Not Graded The surveyor requested documentation of review of the above analytes failing to receive a grade by the PT program. No documentation was provided. 3. In an interview on 05/07/2024 at 12:02 PM, Testing Person 1 (TP-1) confirmed the laboratory failed to document evaluation of all analytes not scored by the proficiency testing program for one of one event in 2024.</p>

**D5311****SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, method validation documentation, environmental logs, patient sample volumes, and confirmed in interview, the laboratory failed to test patient samples within their proven stability for 7 of 20 days reviewed in 2024 (January-March). Findings Included: 1. Review of laboratory policy, "Temperature Audit" (Reviewed by the Laboratory Director on 08/31/2023) revealed the following laboratory temperature range: 20-25 C (Celsius) 2. Review of method validation for laboratory developed PCR nail and wound testing revealed the following acceptable laboratory temperature range to ensure specimen stability: 20-25 C 3. Review of laboratory environmental logs in 2024 (January-March) revealed the following laboratory temperature range: 15-30 C The surveyor requested documentation of the nail and wound sample stability validations in the updated temperature range. No documentation was provided. Further random review of logs revealed the following 7 of 20 days temperatures were recorded beyond the proven sample stability in 2024 with no corrective actions documented: February 2024 a. 02/23/2024 Laboratory Temperature: 25.5 C Beyond proven sample stability: 0.5 C March 2024 e. 03/06/2024 Laboratory Temperature: 25.3 C Beyond proven sample stability: 0.3 C f. 03/07/2024 Laboratory Temperature: 25.7 C Beyond proven sample stability: 0.7 C g. 03/12/2024 Laboratory Temperature: 25.1 C Beyond proven sample stability: 0.1 C h. 03/13/2024 Laboratory Temperature: 26.2 C Beyond proven sample stability: 1.2 C i. 03/21/2024 Laboratory Temperature: 26.2 C Beyond proven sample stability: 1.2 C j. 03/25/2024 Laboratory Temperature: 25.7 C Beyond proven sample stability: 0.7 C 4. Review of laboratory sample volumes in 2024 (January-March) revealed the following patient sample volumes stored prior to analysis beyond the validated sample stability laboratory temperature range: February 2024 a. Patient Sample Volumes 02/23/2024 Nail: 6 Wound: 4 March 2024 b. Patient Sample Volumes 03/06/2024; 03/07/2024 Nail: 26 Wound: 1 c. Patient Sample Volumes 03/12/2024; 03/13/2024 Nail: 5 Wound: 1 d. Patient Sample Volumes 03/21/2024 Nail: 24 Wound: 0 e. Patient Sample Volumes 03/25/2024 Nail: 20 Wound: 1 5. In an interview on 05/07/2024 at 12:02 PM, Testing Person 1 (TP-1) confirmed the laboratory failed to test patient samples within their proven stability for 7 of 20 days reviewed in 2024 (January-March). Word Key PCR- Polymerase Chain Reaction