

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2294662	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Foot And Ankle Center Of North Houston, Pa	Street Address, City, State 17215 Red Oak Drive, Suite 102, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, surveyor observation, the laboratory's records, and staff interview, the laboratory failed to follow their policy for shipping patient samples and ensuring the temperature of patient's nail and wound specimens were maintained during transport to the laboratory for testing for seven of seven months from February to August 2024. Findings include: 1. A review of the laboratory's policy titled 'SOP Nail Fungal Specimen Collection Handling' revealed the following: "Specimen Shipping and Storage Conditions: - Specimen can be stored and shipped at room temperature (18 - 25C) immediately upon collection." 2. A review of the laboratory's policy titled 'Wound Specimen Collection Handling' revealed the following: "Specimen Shipping and Storage Conditions: - The specimen is stored refrigerated and shipped on ice." 3. In an interview on 8/15/24 at 10:50 a.m. in the conference room, testing person #1 (as indicated on the CMS 209 form) confirmed that patient's nail and wound samples were shipped to the laboratory in bags, no ice packs or coolers were used. 4. Surveyor observation of the laboratory's accessioning area on 8/15/24 at 10:00 a.m. revealed the laboratory personnel did not</p>

have a mechanism in place for determining the temperature of the nail and wound specimens that were being received into the laboratory for testing. 5. A review of the laboratory's records revealed the laboratory had tested 376 nail specimens and 286 wound specimens from February to August 2024. 6. In an interview on 8/15/24 at 10:50 a.m. in the conference room, after review of the records, testing person # 1 and the laboratory's quality consultant confirmed the above findings. Key: C = Degrees Celsius