

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2185042	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier Foot And Ankle Specialists Of Arizona	Street Address, City, State 18301 N 79th Ave Bldg F, #168, Glendale, AZ	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's recorded temperature logs, including measurements for the cryostat and ambient humidity, and interview with the testing personnel, the laboratory failed to 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. Findings include: 1. The laboratory began patient testing on September 14, 2020 under the sub-specialties of Mycology and Histopathology. The laboratory performs a laboratory-developed PCR test for fungal organisms on the QuantStudio3 PCR analyzer with an approximate annual test volume of 2,000. The laboratory performs grossing and microscopic interpretation on histopathology specimens with an approximate annual test volume of 4,000. 2. During the survey performed on January 24, 2023, the laboratory presented monthly temperature logs for review. The temperature logs reviewed contained recorded temperatures for a refrigerator, two freezers, cryostat, room temperature and ambient humidity. 3. The laboratory failed to define criteria for the equipment, instruments and temperature-controlled spaces indicated above when those conditions are necessary for accurate test performance, and proper operation of reagents, instruments, and equipment. 4. At 12:35pm on 01/24/23, the testing personnel interviewed confirmed</p>

that the temperature logs indicated above failed to include acceptable ranges for the refrigerator, two freezers, cryostat, room temperature and ambient humidity.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on lack of documentation of a semi-annual competency evaluation for two testing personnel and interview with the laboratory director, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for two out of two testing personnel who began grossing patient specimens in August 2020 and November 2020, respectively. 2. No semi-annual competency evaluation documentation was presented for review for two out of two testing personnel who began PCR testing on the QuantStudio3 analyzer in August 2020 and November 2020, respectively. 3. The laboratory director interviewed on January 24, 2023 at 10:15am confirmed that the technical supervisor failed to document a semi-annual competency evaluation for each test performed by the two testing personnel indicated above.