

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2176577	(X3) Date Survey Completed 06/04/2021
Name of Provider or Supplier Md Foot And Ankle Specialist Llc	Street Address, City, State 1010 Liberty Rd Suite 100, Eldersburg, MD	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on standard operating procedure manual (SOPM) and proficiency testing (PT) record review and interview with the laboratory consultant, the laboratory did not ensure that the procedure for performing PT accurately reflected the current practice in the laboratory. Findings: 1. The procedure "Quality Assurance", "ANALYTIC MONITORS" in the SOPM states, "Twice a year, five random cases for each test will be submitted, along with cover letter to Broward Medical Lab to submit to a different Board Certified Pathologist." 2. PT record review showed that the laboratory performed PT on 9/18/2020 and 3/18/2021. The laboratory sent 3 random cases out for each PT event. 3. The procedure "Proficiency Testing" states, "Twice a year 3 biopsy cases and 3 cytology cases will be reviewed by an outside pathologist." During a phone interview on the day of the survey the laboratory consultant stated that the laboratory had not performed any cytology cases and that the laboratory had submitted paperwork to remove cytology from the laboratory's license. 4. During an interview on 6/4/2021 at 1:00 PM, the laboratory consultant confirmed that the written procedures for performing PT in the SOPM were not consistent, and that the "Quality Assurance" procedure did not accurately reflect the actual practice of the laboratory.</p> <p>II. Based on standard operating procedure manual (SOPM) and quality assurance (QA) record review and interview with the laboratory consultant, the laboratory did not ensure that the procedure for performing QA accurately reflected the current practice in the laboratory. Findings: 1. The procedure "Quality Assurance", "POST-ANALYTIC MONITORS", "A. Monitoring of Turnaround Times" in the SOPM</p>

states, "On a monthly basis, the finalized reports will be reviewed for reporting turnaround times." 2. QA record review showed that the "Specimen Transport /Reporting Timeliness Worksheet" documented an average of the turnaround times for specimens collected from January through December, 2020. There were no monthly turnaround time reports available at the time of the survey. 3. During an interview on 6/4/2021 at 1:00 PM, the laboratory consultant stated "the laboratory is not looking at turnaround times monthly, but the computer system is capable of doing so." III. Based on standard operating procedure manual (SOPM) and quality control (QC) record review and interview with the laboratory consultant, the laboratory did not follow written procedures for documenting daily slide QC for histopathology testing.

Findings: 1. The procedure, "Quality Control" in the SOPM states, "All Quality Control procedures pertinent to the technical component are done at Broward Medical Lab." "Slides are transported to Maryland Foot and Ankle Specialists with the appropriate controls for H&E, Immunoperoxidase, PAS, and GMS stains. This will be documented on the appropriate Quality Control Worksheet." 2. The daily QC log for Hematoxylin and Eosin (H&E) stained slides has columns for "Date," "Case #," "Stain," "Doctor," and "Comment." The evaluation of adequate slide stain quality was not documented on 16 of 16 days of testing from March through May, 2020. 3. The "Daily Quality Control For Special Stains" log records daily stain quality for "PAS," "GMS," "PAS-ALCIAN BLUE," and "ALCIAN BLUE" and has a column for "ADEQUATE (SAT/UNSAT)" and "ADEQUATE CONTROLS IMMUNO." The evaluation of adequate slide stain quality was not documented on 39 of 42 days of testing from 5/8/2020 through 10/22/2020. 4. The "Daily Quality Control For Special Stains" log has a space at the bottom of the log which states, "REVIEWED BY" AND "DATE." There was no review of stain QC logs documented for 11 out of 42 days of testing. 5. During an interview on 6/4/2021 at 1:00 PM, the laboratory consultant confirmed that the testing personnel did not follow the written procedure for performing histopathology slide QC.