

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2209160	<b>(X3) Date Survey Completed</b>  11/30/2021
<b>Name of Provider or Supplier</b>  Foot And Ankle Specialists Of Western	<b>Street Address, City, State</b>  6050 Northland Drive Ne Suite 180, Rockford, MI	
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>D3005</b>	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to follow its policy to perform weekly contamination checks for 8 (March 2021 to November 2021) of 8 months reviewed. Findings include: 1. A review of the laboratory's "Quality Control Monitoring" policy revealed a section titled "Weekly Environmental Controls" stating, "On a weekly basis, environmental checks will be performed by swabbing equipment and surfaces in the laboratory with a sterile swab to check for contamination." 2. A review of the laboratory's documentation revealed a lack of environmental contamination checks performed weekly. 3. An interview on 11/30/21 at 1:50 pm with the LD confirmed the laboratory had not performed weekly environmental contamination checks according to their policy.</p>