

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2201015	(X3) Date Survey Completed 04/20/2021
Name of Provider or Supplier Shield T3, Llc	Street Address, City, State 2115 Observatory Dr, Madison, WI	
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
D3005	<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 surveyor observation of the biological safety cabinet and interview with the laboratory manager, the master mix reagent preparation is not in a separate area different from the sample loading area to provide a uni-directional workflow. Findings include: 1. Observation of the biological safety cabinet on April 20, 2021 at 2:20 PM, showed sample loading of the plates for amplification. Further observation revealed the area where the master mix was prepared was the same area where the sample loading occurred. 2. Interview with the laboratory manager, Staff A, on April 20, 2021 at 2:20 PM confirmed the master mix reagent preparation is not in a separate area different from the sample loading area to provide a uni-directional workflow.</p>