

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2121329	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Eco Health Care Center	Street Address, City, State 1253 Kemper Meadow #325, Cincinnati, OH	
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 direct observation and an interview with the General Supervisor (GS), the Laboratory failed to ensure molecular amplification procedures have a unidirectional flow which includes separate areas for specimen preparation, amplification, product detection, and reagent preparation to prevent contamination. This deficient practice had the potential to affect 121,000 patients tested under the subspecialties of Bacteriology, Mycology, Parasitology, and Virology from 08/21/2023 through 11/28/2023. Findings Include: 1. Direct observation of the laboratory on the date of inspection revealed samples received passed by the sample preparation room, then the reagent preparation area before reaching the sample accessioning area. Accessioned samples would then pass back through the reagent preparation area to the sample preparation room. 2. Direct observation also showed the sample preparation room was directly across from the kitchenette and did not have a negative airflow. 3. Further observation found the amplification area was next to the accessioning area, which were in the same room as the post-PCR disposal. 4. The GS stated the laboratory had recently discovered RNase contamination in the respiratory panel. The Inspector requested the laboratory's plan for a unidirectional flow to mitigate contamination, which includes separate areas for specimen preparation, amplification, product detection, and reagent preparation from the GS. The GS was unable to provide a laboratory plan. The interview occurred on 11/28/2023 at 12:45 PM. RNase; ribonuclease</p>