

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2259538	<b>(X3) Date Survey Completed</b>  02/07/2023
<b>Name of Provider or Supplier</b>  Monarch Global Labs Llc	<b>Street Address, City, State</b>  1901 S Harbor City Blvd Suite 507, Melbourne, FL	
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>D0000</b>	An Initial Certification survey was conducted on February 7, 2023. Monarch Global Labs LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<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 observation, record review and interview, the laboratory failed to ensure uni-directional sample preparation, Reagent prep and amplification of Coronavirus Disease 2019 Polymerase Chain Reaction (COVID-19 PCR), Respiratory Syncytial Virus (RSV) PCR Panel, and Influenza A and B PCR panel testing since 08/19/2022. Findings: A tour of the laboratory on 02/07/2023 at 9:45 AM revealed the laboratory consisted of an accessioning room, aliquoting room, extraction room and a PCR room. Patient specimens entering the laboratory's accessioning room and delivered to the accessioning table located on the back wall. To the right of the accessioning table is the aliquoting room, where the patient specimens are prepared for testing under a biological safety hood, the 96 deep-well plates are prepared, and the master mix is made under a biological safety hood. The patient specimens and reagents are aliquoted into the 96 deep-well plates and then taken out of the aliquoting room into the accessioning room past the accessioning table and into the extraction room that is located to the left of the accessioning table. The RNA extraction is performed on the Thermo Fisher King Fisher. After the extraction is completed the master mix, that was made in the aliquoting room located past the specimen preparation hood, is added to the 96 deep-well plates with the patient specimens. The 96 deep-well plate with the patient specimen is then taken to the PCR room for analysis. Review of "CovidNow</p>

SARS-CoV-2 Assay" Instructions for Use (IFU) read, "Amplification technologies such as PCR are sensitive to accidental introduction of PCR product from previous amplification reactions. Incorrect results could occur if either the clinical specimen or the real-time reagents used in the amplification step become contaminated by accidental introduction of amplification products (amplicon). Workflow in the laboratory should proceed in a unidirectional manner." On 02/07/2023 at 10:12 AM, the Technical Supervisor acknowledged that the laboratory did not have unidirectional flow for their COVID-19 testing.