

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2114963	(X3) Date Survey Completed 03/10/2022
Name of Provider or Supplier Boris Havkin Plc	Street Address, City, State 3021 W Eau Gallie Blvd Ste 103, Melbourne, FL	
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
D0000	An initial certification survey was conducted on March 10, 2022. Boris Havkin PLLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 observation, and interview, the laboratory failed to ensure uni-directional sample preparation and amplification of their Polymerase Chain Reaction testing for urine bacteriology and mycology since the first day of testing on 04/18/2021. Findings: On 03/10/2022 at 12:38 PM, the VWR Plate Centrifuge and the BioRad CFX96 Real-Time System Thermal Cycler was located in the receptionist office area. On 03/10/2022 at 12:40 PM, the Testing Personnel stated she takes the 96 well UTI (Urinary Tract Infection) tear-away plate from the laboratory to the VWR Plate Centrifuge located in the receptionist office area to spin for five minutes. She noted the plate is then returned to the laboratory to add the patient samples to the plate and then sealed. She said the plate is then returned to the centrifuge to spin for five minutes and then placed on thermal cycler.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the initial and sixth month competency assessment for one of one technical supervisor from 04/18/2021 to 03/10/2022, and the initial competency of one of one testing personnel for 2021. Findings: Review of the Laboratory Personnel Report dated and signed by the Laboratory Director on 03/10/2020 showed there was one technical supervisor and one testing personnel. Review of personnel folder for the Technical Supervisor revealed there was no initial or 6th month competency evaluations in the folder. Review of personnel folder for the Testing Personnel revealed there was no initial competency evaluations in the folder. On 03/10/2022 at 10:27 AM, Testing Personnel stated there was no competency evaluation for the Technical Supervisor. On 03/10/2022 at 10:35 AM, Testing Personnel stated there was no documentation of her initial competency evaluation.