

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2154506	<b>(X3) Date Survey Completed</b>  11/14/2024
<b>Name of Provider or Supplier</b>  Florida Bladder Institute	<b>Street Address, City, State</b>  1890 Sw Health Pkwy, Ste 202, Naples, 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 November 14, 2024. Florida Bladder Institute 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, procedure manual review and interview with Testing Person (TP) the laboratory failed to have a uni-directional workflow while performing PCR (Polymerase Chain Reaction) Urinary Tract Infection (UTI) Panel since 07/18/2024. Findings included: 1-During the laboratory tour on 11/14/2024 at 9:00 AM the surveyor observed that the laboratory had one room, with 4 work areas: accession, extraction, PCR mix preparation and amplification. The laboratory had one mini centrifuge located in the PCR mix preparation area. 2-Review of the sample preparation procedure effective on 07/15/2024 revealed that the steps for the direct extraction of urinary samples require to transfer 1 ml of the sample to a microfuge tube and centrifuge at 5000 rpm for 10 minutes, remove supernatant and prepare the cel lysis. Review of BPX Duo Direct Detection Kit read, "set up lysis at -55 Celsius (C) -8mins, 95(C) spin down the sample and prepare PCR reaction mix. Where possible a unidirectional workflow is preferable, where this is not possible the separation of pre and post amplification areas is key to preventing contamination." 3-The laboratory is using the same centrifuge for urine sample preparation for direct extraction and for the step of the sample preparation mix for PCR reaction. During an interview on 11/14/2024 at 9:30 AM, the TP confirmed that the PCR test for UTI was not set up for uni-directional workflow.</p>