

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2324417	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Knucks Labs Llc	Street Address, City, State 639 E Ocean Ave Ste #208, Boynton Beach, 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 announced CLIA initial survey was conducted at Knucks Labs LLC on July 30, 2026 to August 5, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited is as follows:
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) 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. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the laboratory failed to have separate areas for specimen preparation, amplification, and product detection for urinary tract infection (UTI) Polymerase Chain Reaction (PCR) testing. Findings Include: 1. On 7/30/26 at 11:00 AM, a tour of the work-up extraction room displayed one PCR hood used for patient sample, primers and probes, negative and positive controls, and extraction of deoxyribonucleic acid (DNA) from urine in an incubator. 2. On 7/30/26 at 11:20 AM, a tour of the amplification room revealed a specimen processing fridge in the same area as the Quant Studio used for process 384 well plate for PCR reading which is a crossing area. 3. Review of Molecular Environmental Testing signed by the Laboratory Director on 7/13/26 read, "the laboratory staff will follow a unidirectional flow in performing molecular testing." 4. On 8/05/26 at 2:00 PM, the Lab Manager confirmed there were no separate areas for UTI testing.