

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1045322	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Firstpath Laboratory Services Llc	Street Address, City, State 6750 N Andrews Ave Ste 200-2142, Fort Lauderdale, 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 unannounced complaint survey, #2022005200, was conducted on 04/27/2022 - 08/04/2022 at First Path Laboratory Services LLC. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Condition was cited: D6168- Testing Personnel 493.1487
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> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to have 1 out of 1 Cytotechnologist's competency signed by a qualified personnel for 1 (2021) out of 2 years (2020 and 2021) reviewed. Findings Included: Review of the Cytotechnologist's competency evaluations revealed that in 2021 it was signed off by the Laboratory Manager who is not licensed in the State of Florida as a Cytotechnologist or a Cytotechnologist Supervisor. Interview on 04/29/2022 at 5:00 PM the Laboratory Manager confirmed that he signed off on the Cytotechnologist competency evaluation and that he was not licensed in the State of Florida.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview the laboratory failed to store Biorad Liquichek Immunology Controls per the manufacturers' instructions since 02/2022. Findings Included: During a tour of the laboratory on 04/27/2022 at 11:00 AM freezer #5 was observed to be -17 degree Celsius. In freezer #5 there were 7 packages of Biorad Liquichek Immunology level 1 controls (Lot# 68971 expiration 10/31/22) and 7 packages of Biorad Liquichek Immunology level 3 controls (Lot# 68973 expiration 10/31/22). Both levels of control were required to be stored -20 to -70 degrees Celsius. Review of freezer #5 monthly temperature charts from 02/2022 to 04/2022 revealed that the acceptable range was -10 to -25 degrees Celsius (which did not meet the criteria of the Biorad Liquichek Immunology control 1 and 3 that were stored in it). The 3 months reviewed revealed that only on 02/21/2022 the temperature was -20 degrees Celsius. Every other day from 02/2022 - 04/2022 the temperature recorded was warmer than -20 degrees Celsius. Interview on 04/27/2022 at 11:00 AM the Laboratory Manager confirmed that freezer #5 was not cold enough for the reagents stored in it.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Laboratory Manager the laboratory failed to ensure the Testing Personnel had a license in the specialty that they were performing testing for 1 (#D) out of 13 (#A-#L) Testing Personnel (See D6170).

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Manager the laboratory failed to ensure the Testing Personnel had a license in the specialty that they were performing testing for 1 (#D) out of 13 (#A-#L) Testing Personnel. Findings Included: Review of Testing Personnel #D revealed that they had a license with the specialties of Hematology and Chemistry. Review of Testing Person #D's competency evaluation revealed that they were performing Diagnostic Immunology and Molecular testing in the 3 month competency dated 11/11/2021 and yearly competency dated 03/08/2022. Testing Person #D's date of hire was 08/23/2021. Interview on 04/29/2022 at 4:00 PM the Laboratory Manager confirmed that Testing Person was only licensed in Hematology and Chemistry and was testing outside of their scope of license.