

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2093505	<b>(X3) Date Survey Completed</b>  04/05/2023
<b>Name of Provider or Supplier</b>  Integrated Regional Laboratories Pathology Llc	<b>Street Address, City, State</b>  4000 Burns Rd, Palm Beach Gardens, 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 announced CLIA recertification survey was conducted at Integrated Regional Laboratories Pathology on 04/05/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Histology Supervisor, the laboratory failed to follow manufacturer's instructions to store flammable chemicals in a flammable area for two out of two years (2021 - 2023). Findings Included: A tour of the laboratory on 04/05/2023 at 9:50 AM revealed the following items were stored in a cabinet over the sink: two containers of 100% Reagent Alcohol, one container of Bluing Agent, two containers of Xylene, one container of Methanol, three containers of Eosin-Y Alcoholic, and a jug labeled flammable liquid, which was used for chemical waste. Review of the Material Safety Data Sheets revealed that 100% Reagent Alcohol was a Category 2 flammable liquid, Bluing Agent, Xylene, Methanol, and the Eosin - Y Alcoholic were flammable and should be stored in well ventilated areas. "Flammable area" or "in approved areas for flammables." On 04/05 /23 at 10:00 AM the Histology Supervisor confirmed the 100% Reagent Alcohol, Bluing Agent, Xylene, Methanol, and Eosin - Y Alcoholic reagents were not stored appropriately.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</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 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 review of the cryostat user manuals, lack of documentation, and interview with the Histology Supervisor, the laboratory failed to document the room temperature and humidity where the cryostat was located for two out of two years (2021 - 2023). Findings Included: Review of the cryostat user manual revealed the Operating Environment (room) temperature had to be 15 to 28 degrees Celsius or 59 - 82.4 degree Fahrenheit and the room humidity had to be 15- 85%. Record review revealed a lack of documentation for room temperature and humidity for two out of two years (2021 - 2023) On 04/05/23 at 10:50 AM, the Histology Supervisor confirmed that room temperature and humidity were not being documented in the laboratory.