

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657056	(X3) Date Survey Completed 12/10/2025
Name of Provider or Supplier Pittsburgh Retrovirus Laboratory	Street Address, City, State 3550 Terrace St Room 5879 Scaife Hall, Pittsburgh, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 BD FACSCANTO II used to perform flow cytometry testing from 03/05/2024 to 12/10/2025. Findings include: 1. The manufacturers operating environment specifications stated the following: BD FACSCanto II Flow Cytometer: maximum 20-80 % relative humidity. 2. On the day of the survey, 12/10 /2025, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform flow cytometry (Immunology) testing from 03/05/2024 to 12/10/2025: - 1 of 1 BD FACSCanto II (s/n: V96100288) 3. The laboratory performed 240 Flow cytometry tests in 2024 (CMS 116, estimated annual volume, dated 12/09/2025). 4. The LM confirmed the above findings on 12/10/2025 at 09:30am.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p>

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the Laboratory Manager (LM), the laboratory failed to include the address of the location where flow cytometry testing was performed on 2 of 2 patient test reports reviewed from 03/05/2024 to the date of the survey. Findings include: 1. On the day of survey, 11/10/2025 at 9:45 am, review of 2 of 2 patient test reports revealed the laboratory failed to ensure the addition of the address of the laboratory where flow cytometry (Immunology) testing was performed from 03/05/2024 until 12/10/2025. 2. The laboratory performed 240 flow cytometry tests in 2024 (CMS 116, estimated annual volume, dated 12/09/2025). 3. The LM confirmed the above findings on 12/10/2025 at 09:35 am.