

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0657056	<b>(X3) Date Survey Completed</b>  03/05/2024
<b>Name of Provider or Supplier</b>  Pittsburgh Retrovirus Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 lack of documentation and interview with the Laboratory Manager (LM), the laboratory failed to follow a procedure to assess the competency of 1 of 1 technical supervisor (TS) and 1 of 2 general supervisor (GS) for their supervisory responsibilities in 2023. Findings include: 1. On the day of survey, 3/5/2024 at 10:06 am, the laboratory failed to provide competency assessment records for 1 of 1 TS (CMS 209 personnel #2) and 1 of 2 GS (CMS 209 personnel #2) for their supervisory responsibilities in 2023. 2. LM confirmed the findings above on 3/5/2024 at 10:58am.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with testing personnel (TP) #2, the laboratory failed to ensure that reagents and supplies used for CD4/CD8 T cell flow cytometry examinations had not exceeded their expiration date from 02/23/2023 to the date of the survey. Findings Include: 1. On the date of the survey, 03/05/2024 at</p>

10:48 am, during the laboratory tour the surveyor observed that the following 3 of 3 boxes of reagents used for CD4/CD8 T cell flow cytometry examinations performed on the BD FACS Canto II were expired: - 1 box BD FacsClean (on instrument BD FACS Canto II) expired 2-23-2023 - 2 boxes BD FacsClean (in storage) expired 2-23-2023 2. TP #2 confirmed the findings above on 03/05/2024 at 10:48 am.