

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2117998	(X3) Date Survey Completed 06/07/2021
Name of Provider or Supplier Windber Research Institute Biorepository	Street Address, City, State 620 7th Street, Windber, 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
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 review of the laboratory's Employee Competency Assessment (CA) records and interview with the Laboratory Director (LD), the laboraotry failed to assess the competency of 2 of 5 Testing Personnel (TP) who analyzed the fluorescence in situ hybridization (FISH) for HER-2 Gene Amplification slide examinations from 12/12 /2018 to the day of survey. Findings Include: 1. On the day of survey, 06/07/2021 at 12:40 p.m. the laboratory could not provide CA documentation for 2 of 5 TP (CMS 209 TP#4 and TP#5) for the years 2019 and 2020 2. About 12 FISH for HER-2 Gene slides were analyzed in 2020 3. The LD confirmed the findings above on 06/07/2021 at 01:55 p.m.</p>