

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2004577	(X3) Date Survey Completed 02/02/2024
Name of Provider or Supplier Johns Hopkins Biological Repository	Street Address, City, State 615 N Wolfe St, Rm W6704, Baltimore, MD	
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 standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the SOPM did not include instructions for evaluating the competency of the testing personnel (TP) using the six required procedures or for evaluating the competency of the TC. Findings: 1. The laboratory's SOPM did not include instructions for assessing the competency of the TP semiannually during the first year and annually thereafter using the six procedures: a. Direct observation of routine patient test performance, b. Monitoring the recording and reporting of test results, c. Review of intermediate test results or worksheets, quality control records, proficiency testing (PT) results, and preventive maintenance records, d. Direct observations of performance of instrument maintenance and function checks, e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples, and f. Assessment of problem solving skills. 2. The Laboratory Personnel Report (form CMS-209) listed two TCs. There was no procedure for performing competency assessments of the TCs in their regulatory roles as TC. 3. During the survey on 02/02/2024 at 1:55 PM, the TC confirmed that the SOPM did not include a procedure to assess the competency of the TP using the six procedures and did not include instructions for performing competency of the TCs in their regulatory roles as TC.</p>