

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2004577	<b>(X3) Date Survey Completed</b>  01/21/2026
<b>Name of Provider or Supplier</b>  Johns Hopkins Biological Repository	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3011</b>	<p>FACILITIES 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 record review and observation, the laboratory did not ensure that recommended repairs be performed on centrifuge A to prevent potential injury to users. Findings: 1. On 2/3/2025 and in 2024 the company performing preventive maintenance for the centrifuges (used to process patient samples for testing), reported that the hinges on centrifuge A were poor and did not keep the centrifuge lid from closing unexpectedly. 2. It was observed by the surveyor on 1/21/2026 at 12:00 pm that the centrifuge lid would not stay open, because the hinges no longer functioned as designed.</p>
<b>D6079</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p>

This STANDARD is not met as evidenced by:

Based on review of staff credentials, the laboratory director did not ensure that the technical supervisor (listed on the laboratory personnel report) had their foreign medical degree transcripts evaluated by a CLIA approved credentialing agency (for example the Educational Commission for Foreign Medical Graduates, ECFMG) to show the US equivalency for their degree, to credential for the position of technical supervisor. Findings: 1. Review of credentialing records for the technical supervisor showed that they had a foreign medical degree that would be appropriate for the position of technical supervisor, but did not have an evaluation of that foreign degree to show its equivalency in the US. The technical supervisor also stated during interview on 1/21/26 at 12:00 pm that they had received written approval to take state medical board examinations in the US. 2. The laboratory did not provide an evaluation of the technical supervisors foreign medical degree at the time of the survey.