

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2206866	(X3) Date Survey Completed 02/01/2024
Name of Provider or Supplier Accelevir Diagnostics Llc	Street Address, City, State 701 E Pratt St Suite 4016, 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 competency procedure and interview with the general supervisor (GS), the laboratory's procedure did not describe the six procedures required for assessing competency of the testing personnel (TP) and did not include instructions for performing competency of the technical supervisors (TSs) and GS. Findings: 1. The competency procedure did not include the six procedures required for assessing competency of the TP: 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 TSs and one GS. There was no procedure for performing competency assessments of the TSs and GS in their regulatory roles as TS and GS. 3. During the survey on 02/01/2024 at 1:10 PM, the GS confirmed that the competency procedure did not include the six procedures required for assessing competency of the TP and did not include instructions for performing competency of the TSs and GS in their regulatory roles as TS and GS.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the written "Proficiency Testing" procedure manual and interview with the general supervisor (GS), the laboratory failed to include the identity of the proficiency testing (PT) agencies that the laboratory is enrolled with to provide blind samples for PT. Findings: 1. The "Proficiency Testing" procedures defined how to perform "Split-Sample Testing", enrollment in an "External Quality Assessment" program, and alternate PT assessments. When interviewed the GS stated that the laboratory does not perform "Split-Sample Testing" nor alternate PT assessments. The GS stated that the laboratory is enrolled with "Mirimus" and Viral Quality Assurance with the National Institute of Health for the PT samples. 2. During the survey on 02/01/2024 at 1:10 PM, the GS confirmed that the "Proficiency Testing" procedure failed to include the identity of the PT agencies that the laboratory was enrolled with to receive PT specimens.