

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1024948	(X3) Date Survey Completed 10/28/2025
Name of Provider or Supplier Dplm At Iu Health West Hospital	Street Address, City, State 1111 Ronald Reagan Pkwy A1200, Avon, IN	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to test one of five proficiency testing (PT) samples (VM6-06) submitted for event 2 of 2025 for the analyte Alere Determine Human Immunodeficiency Virus (HIV) 1 / 2 antigens (Ag) and antibodies (Ab) combo in the same manner as a patient specimen by having two testing personnel (E5 and E11) run the same sample. Findings include: 1. Review of proficiency testing work sheet for event 2 of 2025 for Alere Determine HIV-1 / 2 Ag /Ab Combo indicated E5's initials were listed for sample VM6 with a question mark and one line through their initial. E11's initials and the date 5/27/2025 were underneath. 2. Review of an email sent on 5/27/25 at 11:08 am from E4 (Laboratory Supervisor) to E5 (testing personnel), indicated E5 did perform the test (for event 2 of 2025 for Alere Determine HIV-1 / 2 Ag/Ab Combo), but did not record their proficiency testing results on the log, and that the sample would have to be repeated by another testing personnel. 3. Review of policy titled, "Proficiency Testing and Alternative Assessments", last approved 8/28/24, on page 6, under "D. Analyzing PT samples 1. The laboratory shall examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens." 4. Review of policy titled, "Procedure: Alere Determine Rapid</p>

HIV-1/2 Ag/AB Combo", last approved 5/12/2025, indicated the procedure did not require two testing personnel to run patient samples. 5. In interview on 10/28/2025 at 11:30 am, E4 (Laboratory Supervisor) acknowledged that an email had been sent to E5 explaining that E5 had not documented their test performed on the log so the proficiency testing sample VM6-06 would be reassigned.