Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1033727	02/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Acl Laboratories	5400 Pearl St, Rosemont, IL	

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
D0000	A complaint survey was completed on 02/25/26. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493) for the following level deficiencies. D2000 - 42 CFR 493.801 - Condition: Enrollment and testing of proficiency samples D6076 - 42 CFR 493.1441 - Condition: Laboratories performing high complexity testing; laboratory director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records, laboratory policies and procedures, College of American Pathologists (CAP) proficiency testing (PT) records, laboratory communication records and interviews with Testing Personnel (TP) A and Laboratory Director (LD); Laboratory A sent a total of 2 samples for the CAP 2025 2nd PT event CHY-B 2025 for Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification, to Laboratory B for analysis and received test reports with interpretations for two of two samples back from Laboratory B prior to the PT due date. See D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)

(b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, laboratory policies and procedures, College of American Pathologists (CAP) proficiency testing (PT) records, laboratory communication records and interviews with Testing Personnel (TP) A and Laboratory Director (LD); Laboratory A sent a total of 2 samples for CAP PT event CHY-B 2025 Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification, to Laboratory B for analysis and received test reports with interpretations for two of two samples back from Laboratory B prior to the PT due date. Findings include: 1. Review of laboratory records revealed the laboratory was enrolled in CAP PT for FISH HER2 amplification in 2025. Event: Due Date: Samples: CYH-A 2025 02/25/25 2 slides CYH-B 2025 07/22/25 2 slides 2. Review of laboratory policies and procedures revealed the policy, "Genetics Quality Assurance Program policy (IL Division)", which stated, under "External quality control/ proficiency testing": "H. There is to be no interlaboratory communication regarding proficiency testing data before results are submitted and result submission is closed by the testing agency. I. Referral of proficiency testing to an external reference lab is not permitted." 3. Review of laboratory emails dated 07/16/25 with subject line: "HER2 CAP slides" confirmed that Laboratory A sent two of two samples of CAP PT HER2 (slides CHY-03 and CHY-04) to Laboratory B on 07/16/25. The same email chain requested the return of slides CHY-03 and CHY-04 as well as signed test reports for the interpretation completed by TP A on 07/17/25. 4. Review of Laboratory A's CAP PT records found TP A signed and completed test reports for slides CHY-03 and CHY-04 on 07/17/25 on Laboratory A's test report forms titled "HER2/neu ENUMERATION 20 count report form". 5. Telephone interview with TP A on 2/25/26, at 2:25 pm, confirmed the following that two of two PT slides were sent to Laboratory B for CAP PT event CYH-B 2025. Laboratory B received two slides on 07/16/25 via courier within the inter-office logistics system, that the slides were interpreted by TP A at Laboratory B on 07/17/25, and that the results of the interpretation and slides were transported back to Laboratory A via the courier system prior to the CAP event due date of 07/22/25. TP A confirmed they test samples at Laboratory A and Laboratory B on a rotating schedule. 6. Interview with the LD on 02/25/26, at 03:09 PM, on-site at Laboratory A, confirmed that slides CHY-03 and CHY-04, were sent to TP A, on site at Laboratory B, via courier within the inter-office logistics system on 07/16/25 prior to the CAP PT event submission deadline of 07/22/25. The LD also confirmed the test reports with interpretations were received by Laboratory A prior to the submission

	deadline.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory investigation records, laboratory policies and procedures, laboratory communication records, College of American Pathologists (CAP) proficiency testing (PT) records and interviews with Testing Personnel A and Laboratory Director (LD); the laboratory director failed to ensure to ensure no inter-laboratory communications pertaining to PT samples took place for College of American Pathologists (CAP) PT event CHY-B 2025 Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification. See D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of laboratory investigation records, laboratory policies and procedures, laboratory communication records, College of American Pathologists (CAP) proficiency testing (PT) records and interviews with Testing Personnel A and Laboratory Director (LD); the laboratory director failed to ensure that PT samples were not sent to another laboratory before the event due date for two of two samples for FISH ERBB2(HER2) amplification testing for event 2 in 2025. See D2013