

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0042416	(X3) Date Survey Completed 02/26/2026
Name of Provider or Supplier Lutheran General Hospital Laboratory	Street Address, City, State 1775 W Dempster St, Park Ridge, 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 02/26/2026. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493) for the following condition 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>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 Representative; Laboratory B received, tested, and interpreted two of two PT samples, for CAP PT event CHY-B 2025 Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification, from Laboratory A in 2025 prior to the CAP PT event due date. See D2013.</p>
D2012	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage</p>

in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

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 Representative; Laboratory B received, tested, and interpreted two samples for CAP PT event CHY-B 2025 Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification, from Laboratory A in 2025 prior to the CAP PT event due date. Findings include: 1. Review of laboratory policies and procedures revealed the policy, "Proficiency Testing Procedure" which stated, under "General guidelines": "10. All inter or intra laboratory communication concerning PT specimens and results, including use for educational purposes is prohibited until after the deadline for submission of data to the proficiency testing provider. PT records must not be shared with other laboratories, including affiliated laboratories until after the deadline for submission of results. Personnel are strictly prohibited from accessing PT records from other laboratories. This includes accessing PT results in a shared laboratory information system. Personnel that work at multiple CLIA locations should not participate in the same PT program at multiple laboratories. In cases where this is not possible, all testing, data review, interpretation and submission of PT results must occur within the testing laboratory. PT records must show the results were obtained at the laboratory reporting the result to the PT provider. The laboratory must report only those PT results obtained by personnel within their own laboratory location, not an affiliate laboratory." 2. Review of laboratory investigation records dated 9/18/25 revealed that Laboratory B received two samples (slides CHY-03 and CHY-04) from Laboratory A associated with CAP event CHY-B 2025 on 07/16/25 and these slides were interpreted by TP A. The results of the interpretation and slides were then transported back to Laboratory A via courier within the inter-office logistics system. 3. Review of laboratory emails dated 07/16/25 with subject line: "HER2 CAP slides" confirmed that Laboratory B received the CAP PT HER2 slides CHY-03 and CHY-04 from Laboratory A 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 CAP PT records for Fluorescence in situ hybridization testing (FISH) ERBB2 (HER2) amplification event CHY-B 2025 revealed that the submission due date was 07/22/25. 5. Telephone interview with TP A on 2/25/26, at 2:25 pm, confirmed that PT slides were received by 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. The slides were interpreted by TP A on 07/17/25. 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 laboratory representative on 02/26/26, at 03:00 PM, on-site at Laboratory B, confirmed two slides were sent to TP A, on site at Laboratory B, via a courier within the inter-office logistics system on 07/16/25 prior to the CAP PT event submission deadline of 07/22/25. These slides were interpreted by TP A. The results and slides were shipped back to Laboratory A.

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 Representative; 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 Representative; the laboratory director failed to ensure that PT samples from another laboratory were not tested by the laboratory or results sent to another laboratory before the event due date for 2 of 2 samples for FISH ERBB2(HER2) amplification testing for event 2 in 2025 See D2013