

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0963030	(X3) Date Survey Completed 10/28/2024
Name of Provider or Supplier Sarah Bush Lincoln - Effingham Lab	Street Address, City, State 905 N Maple - Lab Suite, Effingham, 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
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 records, laboratory policies and procedures, College of American Pathologists (CAP) proficiency testing (PT) kit instructions, CAP PT records, and interviews with technical supervisor #1 and the clinical consultant; Laboratory A referred a total of 26 PT sample images for two of six PT event image sets for the regulated hematology analyte, blood cell identification (0765), and two of four PT event image sets for the non-regulated microscopic urinalysis PT events to Laboratory B for analysis/interpretation in the years of 2023 and 2024. See D2013.</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>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</p>

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) kit instructions, CAP PT records, and interviews with technical supervisor (TS) #1 and the clinical consultant (CC); Laboratory A referred a total of 26 PT sample images for two of six PT event image sets for the regulated hematology analyte, blood cell identification (0765), and two of four PT event image sets for the non-regulated microscopic urinalysis PT events to Laboratory B for analysis/interpretation in the years of 2023 and 2024. Findings include: 1. Review of laboratory records revealed the laboratory participated in CAP PT for identification events for regulated (0765) "Hematology Automated Differential Blood Cell ID" photos (FM13) and non-regulated "Urinalysis ...Urine Sediment Photos" (CM) in the years 2023 and 2024. Event: Shipment Date: FM13-A 2023 01/23/2023 CM-A 2023 02/13/2023 FM13-B 2023 05/01/2023 CM-B 2023 09/05/2023 FM13-C 2023 09/18/2023 FM13-A 2024 01/22/2024 CM-A 2024 02/12/2024 FM13-B 2024 04/29/2024 CM-B 2024 09/03/2024 FM13-C 2024 09/16/2024 2. Review of laboratory policies and procedures revealed the policy, "Analysis of CAP Surveys", which stated, under "Procedure": "The technologist must not contact employees of any other laboratory regarding survey results, or, if contacted, must not divulge any information. Proficiency testing specimens must not be sent to an outside laboratory for testing." 3. Review of CAP PT kit instructions for both "Hematology Automated Differential Survey" and "Urinalysis and Clinical Microscopy Survey" revealed, under "Regulatory Information", "-If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number. "-Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number." 4. Review of the laboratory's CAP PT records revealed components of two of six Hematology PT events and two of four Urinalysis Microscopy PT events, resulting in 26 images total, were sent to Laboratory B for analysis/interpretation in the years of 2023 and 2024 prior to the submission deadline via courier within the inter-office mail system. Event: # of images: FM13-A 2023 Ten (BCP-01 - BCP-10) CM-A 2023 Three (CMP 04 - CMP-06) FM13-B 2023 Ten (BCP-11 - BCP-20) CM-A 2024 Three (CMP-04 - CMP-06) 5. Interview with TS #1 on 10/28/2024, at 09:34 am, on-site at Laboratory A, stated the identification components of above-mentioned PT events, resulting in 26 images total, were sent to the CC, on site at Laboratory B, via courier within the inter-office mail system prior to the CAP PT event submission deadlines. 6. Telephone interview with the CC on 10/28/2024, at 12:05 pm, stated the above-mentioned PT events, including the photo identification components, were sent to the CC, while located at Laboratory B, for interpretation via courier within the inter-office mail system.