Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D0667363	**(X3) Date Survey Completed** 11/06/2024
Name of Provider or Supplier Sarah Bush Lincoln - Health Center Lab	**Street Address, City, State** 1000 Health Center Drive, Mattoon, 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	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) kit instructions, CAP PT records from Laboratory A, and interviews with technical supervisor (TS) #1 of Laboratory A and the laboratory director (LD) of Laboratory B; Laboratory B failed to notify Center for Medicare and Medicaid Services (CMS) of the receipt of 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 testing from Laboratory A and the subsequent analysis/interpretation and return of the PT event images by Laboratory B in the years of 2023 and 2024. See D2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) 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) kit instructions, CAP PT records from Laboratory A, and interviews with technical supervisor (TS) #1 of Laboratory A and the laboratory director (LD) of Laboratory B; Laboratory B failed to notify Center for Medicare and Medicaid Services (CMS) of the receipt of PT samples 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 testing from Laboratory A and the subsequent analysis/interpretation and return of the PT event images by Laboratory B in the years of 2023 and 2024. Findings include: 1. Review of laboratory records revealed both Laboratory A and Laboratory B participated in CAP PT 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, "Proficiency Testing", which stated, under "Statement of Policy": "[Laboratory A] performs all proficiency testing on-site. Survey specimens are not sent to a reference laboratory and the laboratory does not confer with other laboratories concerning the survey results." 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 Laboratory A'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 16 images total, were sent to the LD of Laboratory B, on site at Laboratory B, via courier within the inter-office mail system prior to the CAP PT

	event submission deadlines. 6. Interview with the LD of Laboratory B on 11/06/2024, at 2:26 pm, confirmed the receipt of two of six regulated hematology PT events and two of four non-regulated microscopic urinalysis PT events from Laboratory A for analysis/interpretation prior to the CAP PT event submission deadlines and that the LD analyzed and returned the interpretations to Laboratory A.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, laboratory records, lack of documentation, test volume worksheet, and interview with technical supervisor (TS) #5; the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between three of three Film Array molecular platforms used for the identification of 100 molecular organisms/analytes in the years of 2023 through the survey date, 11/06/2024. Findings include: 1. During a tour of the laboratory on 11/06 /2024, at 1:20 pm, three Film Array molecular platforms used for the identification of 100 molecular organisms/analytes were observed: Instrument: Serial Number: 1) Film Array 2FAC832F 2) Film Array 2FA32AF9 3) Film Array Torch TB05200 2. Review of the laboratory's test volume worksheet revealed the following four molecular assays performed: a) Blood Culture Identification 2 (BCID2) Panel Testing 1. Enterococcus faecalis 2. Enterococcus faecium 3. Listeria monocytogenes 4. Staphylococcus aureus 5. Staphylococcus epidermidis 6. Staphylococcus lugdunensis 7. Streptococcus agalactiae (Group B) 8. Streptococcus pneumonia 9. Streptococcus pyogenes (Group A) 10. Acinetobacter calcoaceticus-baumannii complex 11. Bacteroides fragilis 12. Haemophilus influenzae 13. Neisseria menigitidis (encapsulated) 14. Pseudomonas aeruginosa 15. Stenotrophomonas maltophilia 16. Enterobacter cloacae complex 17. Escherichia coli 18. Klebsiella aerogenes 19. Klebsiella oxytoca 20. Klebsiella pneumonia group 21. Proteus species (spp.) 22. Salmonella spp. 23. Serratia marcescens 24. Candida albicans 25. Candida auris 26. Candida glabrata 27. Candida krusei 28. Candida parapsilosis 29. Candida tropicalis 30. Cryptococcus neoformans/gattii 31. mecA/C [genes] 32. mecA/C and MREJ [mec gene right-extremity junction] 33. vanA/B [genes] 34. KPC [Klebsiella pneumoniae carbapenemase] 35. CTX-M [cefotaximase] 36. IMP [imipenemase] 37. mcr-1 [genes] 38. VIM [Verona Intergron Encoded Metallo-Beta-Lactamase producing] 39. NDM [New Delhi metallo beta lactamase-1] 40. OXA-48-like [enzymes] b) Pneumonia Panel Testing 1. Acinetobacter calcoaceticus-baumannii complex 2. Klebsiella oxytoca 3. Serratia marcescens 4. Enterobacter cloacae complex 5. Klebsiella pneumoniae group 6. Staphylococcus aureus 7. Escherichia coli 8. Moraxella catarrhalis 9. Streptococcus agalactiae 10. Haemophilus influenzae 11. Proteus spp. 12. Streptococcus pneumoniae 13. Klebsiella aerogenes 14. Pseudomonas aeruginosa 15. Streptococcus pyogenes 16. Chlamydia pneumoniae 17. Legionella pneumophila 18. Mycoplasma pneumoniae 19. Adenovirus 20. Human Rhinovirus/Enterovirus 21. Parainfluenza Virus 22. Coronavirus 23. Influenza A 24. Influenza B 25. Respiratory Syncytial Virus (RSV) 26. Human Metapneumovirus 27. CTX-M 28. NDM 29. mecA /C and MREJ 30. IMP 31. OXA-48-like 32. KPC 33. VIM c) Meningitis/Encephalitis

	Panel Testing 1. Escherichia coli K1 2. Haemophilus influenzae 3. Listeria monocytogenes 4. Neisseria meningitidis (encapsulated) 5. Streptococcus agalactiae 6. Streptococcus pneumoniae 7. Cytomegalovirus 8. Enterovirus 9. Herpes simplex virus 1 10. Herpes simplex virus 2 11. Human herpesvirus 6 12. Human parechovirus 13. Varicella zoster virus 14. Crytococcus neoformans/gattii d) Respiratory Panel Testing 1. Adenovirus (Adv) 2. Coronavirus (CoV) 3. Enterovirus (EV) 4. Human rhinovirus (hMPV) 5. Influenza A (subtypes H1, H 2009, H3) 6. Influenza B 7. Parainfluenza Virus (PIV) 1, 2, 3 and 4 8. RSV 9. Bordetella pertussis 10. Chlamydia pneumoniae 11. Mycoplasma pneumoiae 12. Bordetella parapertussis 13. SARS [Severe acute respiratory syndrome]-CoV2 3. Review of laboratory records found the laboratory lacked documentation for instrument-to-instrument test result comparison for three of three Film Array molecular platforms used for the identification of 100 molecular organisms/analytes. 4. An interview with TS #5 on 11/06/2024, at 1:32 pm, confirmed that no documents/results of instrument-to-instrument test result comparison were available nor had been performed.