

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0669515	(X3) Date Survey Completed 05/01/2025
Name of Provider or Supplier Illinois State University Student Health Service	Street Address, City, State 201 N University Street, Normal, 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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, Wisconsin State Laboratory Hygiene (WSLH) proficiency testing (PT) records, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to ensure accuracy of 89 of 89 analytes not evaluated by the PT provider for six of six PT events in the specialties of hematology and microbiology in 2023 through the date of survey, 05/01/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Proficiency Testing", which stated, under "Proficiency Processing:", "10. If results are not within limits, an investigation will be performed." 2. Review of WSLH comparative evaluation summaries for the following PT events of 2023 through 2025 revealed the following un-graded PT samples: PT Event: Analyte: Sample: 2023 Event 2 - Hematology RDW-CV %* AF5-6 2023 Event 2 - Hematology RDW-CV % AF5-7 2023 Event 2 - Hematology RDW-CV % AF5-8 2023 Event 2 - Hematology RDW-CV % AF5-9 2023 Event 2 - Hematology RDW-CV % AF5-10 2023 Event 3 - Hematology RDW-CV % AF5-11 2023 Event 3 - Hematology RDW-CV % AF5-12 2023 Event 3 - Hematology RDW-CV % AF5-13 2023 Event 3 - Hematology RDW-CV % AF5-14 2023 Event 3 - Hematology RDW-CV % AF5-15 2024 Event 1 - Hematology RDW-CV % AF5-1 2024 Event 1 - Hematology RDW-CV % AF5-2 2024 Event 1 - Hematology RDW-CV % AF5-3 2024 Event 1 - Hematology RDW-CV % AF5-4 2024 Event 1 - Hematology RDW-CV % AF5-5 2024 Event 1 - Hematology MPV AF5-1 2024 Event 1 - Hematology MPV AF5-2 2024 Event 1 - Hematology MPV AF5-3 2024 Event 1 - Hematology MPV AF5-4 2024 Event 1 - Hematology MPV AF5-5 2024 Event 2 - Hematology</p>

Leukocytes AF5-6 2024 Event 2 - Hematology Leukocytes AF5-7 2024 Event 2 - Hematology Leukocytes AF5-8 2024 Event 2 - Hematology Leukocytes AF5-9 2024 Event 2 - Hematology Leukocytes AF5-10 2024 Event 2 - Hematology MCH*** AF5-6 2024 Event 2 - Hematology MCH AF5-7 2024 Event 2 - Hematology MCH AF5-8 2024 Event 2 - Hematology MCH AF5-9 2024 Event 2 - Hematology MCH AF5-10 2024 Event 2 - Hematology RDW-CV AF5-6 2024 Event 2 - Hematology RDW-CV AF5-7 2024 Event 2 - Hematology RDW-CV AF5-8 2024 Event 2 - Hematology RDW-CV AF5-9 2024 Event 2 - Hematology RDW-CV AF5-10 2024 Event 2 - Hematology RDW-SD**** AF5-6 2024 Event 2 - Hematology RDW-SD AF5-7 2024 Event 2 - Hematology RDW-SD AF5-8 2024 Event 2 - Hematology RDW-SD AF5-9 2024 Event 2 - Hematology RDW-SD AF5-10 2024 Event 2 - Hematology MPV***** AF5-6 2024 Event 2 - Hematology MPV AF5-7 2024 Event 2 - Hematology MPV AF5-8 2024 Event 2 - Hematology MPV AF5-9 2024 Event 2 - Hematology MPV AF5-10 2024 Event 2 - Microbiology Sensitivity Ciprofloxacin 2024 Event 2 - Microbiology Sensitivity Gentamicin 2024 Event 2 - Microbiology Sensitivity Levofloxacin 2024 Event 3 - Hematology Leukocytes AF5-11 2024 Event 3 - Hematology Leukocytes AF5-12 2024 Event 3 - Hematology Leukocytes AF5-13 2024 Event 3 - Hematology Leukocytes AF5-14 2024 Event 3 - Hematology Leukocytes AF5-15 2024 Event 3 - Hematology MCHC***** AF5-11 2024 Event 3 - Hematology MCHC AF5-12 2024 Event 3 - Hematology MCHC AF5-13 2024 Event 3 - Hematology MCHC AF5-14 2024 Event 3 - Hematology MCHC AF5-15 2024 Event 3 - Hematology RDW-CV % AF5-11 2024 Event 3 - Hematology RDW-CV % AF5-12 2024 Event 3 - Hematology RDW-CV % AF5-13 2024 Event 3 - Hematology RDW-CV % AF5-14 2024 Event 3 - Hematology RDW-CV % AF5-15 2024 Event 3 - Hematology RDW-SD AF5-11 2024 Event 3 - Hematology RDW-SD AF5-12 2024 Event 3 - Hematology RDW-SD AF5-13 2024 Event 3 - Hematology RDW-SD AF5-14 2024 Event 3 - Hematology RDW-SD AF5-15 2024 Event 3 - Hematology MPV AF5-11 2024 Event 3 - Hematology MPV AF5-12 2024 Event 3 - Hematology MPV AF5-13 2024 Event 3 - Hematology MPV AF5-14 2024 Event 3 - Hematology MPV AF5-15 2024 Event 3 - Microbiology Sensitivity Nitrofurantoin 2025 Event 1 - Hematology RDW-CV % AF5-1 2025 Event 1 - Hematology RDW-CV % AF5-2 2025 Event 1 - Hematology RDW-CV % AF5-3 2025 Event 1 - Hematology RDW-CV % AF5-4 2025 Event 1 - Hematology RDW-CV % AF5-5 2025 Event 1 - Hematology Platelets AF5-1 2025 Event 1 - Hematology Platelets AF5-2 2025 Event 1 - Hematology Platelets AF5-3 2025 Event 1 - Hematology Platelets AF5-4 2025 Event 1 - Hematology Platelets AF5-5 2025 Event 1 - Hematology Fecal smear PM-2 2025 Event 1 - Microbiology KOH***** PM-3 2025 Event 1 - Microbiology Sensitivity Ciprofloxacin 2025 Event 1 - Microbiology Sensitivity Trimethoprim/Sulfamethoxazole 2025 Event 1 - Microbiology Strep Culture TU-4 *RDW-CV = Red Cell Distribution Width - Coefficient variable **MCV = Mean Corpuscular Volume ***MCH = Mean Corpuscular Hemoglobin ****RDW-SD = Red Cell Distribution Width - Standard Deviation *****MPV = Mean Platelet Volume *****MCHC = Mean Corpuscular Hemoglobin Concentration *****KOH = Potassium Hydroxide 3. Review of laboratory records found no documented review of the ungraded PT analytes in the specialties of hematology and microbiology 2023 through 2025. 4. Interview with the GS on 05/01/2025, at 11:55 am, confirmed the laboratory failed to ensure accuracy of 89 of 89 analytes not evaluated by the PT provider for six of six PT events in the specialties of hematology and microbiology in 2023 through the date of survey, 05/01/2025.

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.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the general supervisor (GS); 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 Cepheid GeneXpert DX instruments used for Chlamydia trachomatis (CT) and Neisseria gonorrhoea (NG) testing in the specialty of microbiology from 2023 through the date of testing, 05/01/2025. Findings include: 1. Upon a tour of the laboratory on 05/01/2025, at 9:53 am, three Cepheid GeneXpert DX Systems used for CT/NG microbiology testing were observed. Instrument: Serial Number: Cepheid GeneXpert A 820963 Cepheid GeneXpert B 844021 Cepheid GeneXpert C 844026 2. Review of the laboratory's procedure for Cepheid GeneXpert CT/NG testing identified that the procedure failed to address how the relationship between the three analyzers will be evaluated twice yearly. 3. Review of laboratory records found the laboratory lacked documentation for instrument-to-instrument test result comparisons between the three Cepheid GeneXpert instruments used for CT/NG testing. 4. Interview with the GS on 05/01/2025, 10:03 am, confirmed 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 Cepheid GeneXpert DX instruments used for CT/NG testing from 2023 through the date of testing, 05/01/2025.