Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0042541	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Northern Ill Univ Health Services Lab	**Street Address, City, State** 385 Wirtz Drive, Dekalb, 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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory is conducting testing outside of its certificate type. Findings: 1. Review of laboratory records revealed that the laboratory has a CLIA Certificate of Waiver. 2. Review of the manufacturer's procedures for the Henry Schein One Step Pro + Mono test reveals that the laboratory may use serum, plasma, or whole-blood as its specimen type. However, on the front of page of the procedures, under "CLIA Complexity," it indicates that Serum/Plasma is non - Waived and Whole - Blood is waived. When the surveyor asked testing personnel what type of specimens are used when performing the Henry Schein One Step Pro + Mono test, she was told that they used blood from the tubes collected in EDTA and finger stick specimens. They were not aware that the difference in specimen type changed the complexity of the test. 3. During survey date 05/01/18, testing personnel confirmed the surveyor's findings.

D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review and interview, the laboratory failed to follow the manufacturer's instructions for performing waived tests. Findings: 1. Review of laboratory tests revealed that the laboratory performed the following waived tests: a Stanbio Laboratory Uri-Chek 10 SG Urinalysis Reagent Strips b. Henry Schein One Step Pro + Mono For Whole Blood, Serum, or Plasma c. Henry Schein One Step + hCG Combo Test d. Henry Schein One Step + Strep A Dipstick Test e. Henry Schein One Step + Influenza A & B Test 2. Review of manufacturer's instructions revealed that there were procedures for performing external quality quality control (QC) on all waived test kits before they are used to test patient's specimens. However, there was no documentation to show that TESTING PERSONNEL performed QC on each kit prior to testing patients specimens for the following waived test kits: a. Stanbio Laboratory Uri-Chek 10 SG Urinalysis Reagent Strips b. Henry Schein One Step Pro + Mono For Whole Blood, Serum, or Plasma c. Henry Schein One Step + hCG Combo Test d. Henry Schein One Step + Strep A Dipstick Test e. Henry Schein One Step + Influenza A & B Test 3. Review of manufacturer's instructions for storage of the kit revealed the following information: a. Stanbio Laboratory Uri-Chek 10 SG Urinalysis Reagent Strips stored between 15- 30 C. Once the bottle is opened, the remaining strips are stable for 3 months. b. Henry Schein One Step Pro + Mono For Whole Blood, Serum, or Plasma stored between 2- 30 C, until the expiration date. c. Henry Schein One Step + hCG Combo Test stored between 2- 30 C, until the expiration date. d. Henry Schein One Step + Strep A Dipstick Test stored between 2- 30 C. Record the initial opening date on the canister. One opened, the remaining test dipsticks are stable for 12 months. e. Henry Schein One Step + Influenza A & B Test stored between 15- 30 C, until the expiration date. There was no documentation to show that the laboratory recorded the temperature of the room where waived test kits are stored. 4. During survey date 05/01/18, testing personnel confirmed the surveyor's findings.