Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0896179	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Central Health Services Dba River Bend	2900 N River Rd, West Lafayette, IN	

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 document review and interview, the laboratory failed to restrict testing to waived testing for one (Accu-Clear 2 minute pregnancy test) of two tests performed. Findings include: 1. Review of the laboratory's CLIA (Clinical Laboratory Improvement Amendments) Certificate indicated the laboratory has a "Certificate of Waiver." 2. On 4-30-2018 at 2:08 PM, two "Accu-Clear 2 minute pregnancy test" kits were observed in the Omnicell in the medicine room of the inpatient unit, available for use. 3. Review of a package insert titled "Accu-Clear 2 minutes pregnancy test," copyright 2011, did not indicate the test was categorized as waived. 4. Review of Food and Drug Administration (FDA) test categorization database indicated the test was not categorized as waived, nor was is approved or cleared by FDA. 5. In interview on 5-2-2018 at 10:14 AM, L9, customer service representative for Accu-Clear, was unaware of CLIA and didn't know if the test was categorized as waived. 6.

	Review of patient test reports indicated urine pregnancy testing was performed on patients # 32 (4-5-2018), # 33 (3-17-2018) and #36 (11-17-2017).