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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 35D0408602 | (X3) Date Survey Completed 07/31/2019 |
| Name of Provider or Supplier Northwood Deaconess Health Center - Northwood | Street Address, City, State 4 N Park St, Northwood, ND | |
| 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 |
|---------------------------|---|
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy for 1 of 1 qualitative endocrinology test (serum pregnancy) implemented in 2019 before reporting patient results. The laboratory performed three serum pregnancy tests since implementation. Findings include: 1. Reviewed at 10:30 a. m. on 07/31/19, the laboratory's 2019 performance specification verification records for qualitative serum pregnancy lacked evidence the laboratory evaluated the accuracy data. 2. During interview at approximately 11:25 a.m. on 07/31/19, a technical consultant (#1) confirmed the laboratory began patient testing for serum pregnancy in June 2019, and the laboratory did not have evidence the laboratory director and/or technical consultant had evaluated and approved the accuracy verification data. 3. Reviewed at approximately 11:50 a.m. on 07/31/19, the policy "Validation Guidelines," effective 11/01/11, stated, "Purpose: To provide guidelines when validating a piece of equipment into operation; laboratory must verify the manufacturer's performance specification for each new test prior to reporting patient results. . . . Element [sic] involved in validations are: 1. Accuracy . . ."</p> |