Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0869325	(X3) Date Survey Completed 12/30/2024
Name of Provider or Supplier Jacobson Memorial Hospital Care Center	**Street Address, City, State** 601 East St N, Elgin, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory failed to perform a positive and negative control each day of patient testing for Influenza A and B (Flu A & B), respiratory syncytial virus (RSV), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) molecular tests using the Cepheid GeneXpert Dx System for 8 of 8 patient testing days (11/02, 11/04, 11/05, 11/21, 11/22, 11/23, 11/25, and 11/30) in November 2024. The laboratory performed 44 patient tests on days with no quality control (QC) performance in November 2024. Findings include: 1. Reviewed on 12/30/24, the patient testing records for the Cepheid Quad Test (Flu A & B, RSV, and SARS-CoV-2) using the Cepheid GeneXpert Dx System indicated performance of the following patient tests in November 2024: 11/02 - one patient, 11/04 - one patient, 11/05 - one patient, 11/21 - two patients, 11/22 - one patient, 11/23 - two patients, 11/25 - two patients, and 11/30 - one patient. 2. Reviewed on 12/30/24, the November 2024 QC records for Flu A & B, RSV, and SARS-CoV-2 failed to include evidence of the performance of positive and negative controls on the following patient testing days: 11/02, 11/04, 11/05, 11/21, 11/22, 11/23, 11/25, and 11/30. 3. During interview at 2:15 p.m. on 12/30/24, a technical consultant (#1) confirmed the laboratory failed to perform QC each day of patient testing for Flu A & B, RSV, and SARS-CoV-2 using the Cepheid GeneXpert Dx System. 4. Reviewed on 12/30/24, the policy/procedure "Laboratory: Xpert Xpress CoV-2/Flu/RSV plus," dated 11/29/21, stated, ". . . Quality Control . . . External controls should be used in accordance with local, state, and federal accrediting organizations as applicable. Cepheid recommends that all laboratories perform

	external QC with each new lot and shipment of reagents, at a minimum . . ." The policy/procedure failed to require the performance of a positive and negative external control each day of patient testing.