Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D1071178	(X3) Date Survey Completed 03/28/2023
Name of Provider or Supplier Fairlight Medical Center	Street Address, City, State 3 4th St E, Williston, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, manufacturer's instructions review, record review, and staff interview, the laboratory failed to store Cliniqa chemistry quality controls according to the manufacturer's instructions on 18 of 20 days of operation in February 2023 (2 /01-2/03, 2/06-2/10, 2/13-2/17, 2/20, 2/21, 2/23, 2/24, 2/27). Findings include: 1. Observation of the laboratory's freezer occurred at 2:10 p.m. on 03/28/23. The freezer contained the following Cliniqa Liquid QC (quality control): one box Level 1 and one box Level 2. 2. Reviewed at 2:10 p.m. on 03/28/23, the manufacturer's labels on the Cliniqa Liquid QC chemistry controls stated to store at -20 Celsius or less. 3. Review of the February 2023 freezer temperature record occurred at 2:15 p.m. on 03/28/23. This record showed the temperature of the freezer was warmer than -20 degrees Celsius on eighteen days of operation in February 2023: 2/01-2/03, 2/06-2/10, 2/13-2 /17, 2/20, 2/21, 2/23, 2/24, 2/27. 4. During interview at 2:20 p.m. 0n 03/28/23, the laboratory director (#1) stated the laboratory used the Cliniqa Liquid QC for thyroid stimulating hormone, prostatic specific antigen, and testosterone testing. The laboratory director (#1) confirmed the freezer had not been at the proper temperature for storage of the Cliniqa Liquid QC in February 2023 on the above listed days.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to monitor the postanalytic system for 1 of 1 year reviewed (2022). Findings include: 1. Reviewed at 12:50 p.m. on 03/28/23, the 2022 quality assessment records lacked evidence of postanalytic monitoring. 2. Upon request on 03/28/23, the laboratory failed to provide evidence of postanalytic monitoring in 2022. 3. Reviewed on 03/23 /28, the policy "General Laboratory," dated 05/19/21, stated, ". . . Intended Use To identify sources of pre-analytical, analytical, and post analytical variations that involves patient care. To integrate the quality control program with the overall care of the patients. . . ." 4. During interview at 1:05 p.m. on 03/28/23, the laboratory director (#1) confirmed the laboratory had not documented postanalytic monitoring in 2023.