

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0689141	(X3) Date Survey Completed 02/01/2024
Name of Provider or Supplier Bethany Children's Health Center	Street Address, City, State 6800 Nw 39th Expressway, Bethany, OK	
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
D0000	The recertification survey was performed on 02/01/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for storage of testing kits and quality control materials. Findings include: QUALITY CONTROL STORAGE: (1) On 02/01/2024 at 3:30 pm, the laboratory director stated waived testing was performed in room BT1026; (2) Observation of room BT1026 on 02/01/2024 at 3:30 pm, revealed five boxes of Biofire Spotfire RSP quality control, lot #A05JUL22D, with a storage temperature of 2-25 degrees Celsius, in a freezer; (3) The findings were discussed with the laboratory director who stated on 02/01/2024 at 3:30 pm, the materials were stored below the manufacturer's stated temperature requirements. REAGENT STORAGE: (1) Observation of room BT1006 and interview with the laboratory director on 02/01/2024 at 12:00 pm, identified the following: (a) Five boxes of Biofire Spotfire respiratory test panels, lot # 2753209, storage temperature of 15-30 degrees Celsius. (2) Interview with the laboratory director on 02/01/2024 at 12:00 pm confirmed the laboratory was not monitoring the temperature of room BT1006.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

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 and interview with the laboratory director, the laboratory failed to ensure testing supplies were stored as required by the manufacturer, in a room denoted as BT1026. Findings include: (1) Observation of room BT1026 and interview with the laboratory director on 02/01/2024 at 12:00 pm, identified the following: (a) Eight boxes of epoc BGEM test cards, lot # 04-23339-60, storage temperature of 15-30 degrees Celsius; (b) Eight boxes of epoc HCT quality control material, lot # 3244717, storage temperature of 2-30 degrees Celsius. (2) Interview with the laboratory director on 02/01/2023 at 12:00 pm confirmed the laboratory was not monitoring the temperature of room BT1026.