

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2193461	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Vb Medical Services, Pc	Street Address, City, State 46-01 Greenpoint Avenue, #2d, Sunnyside, NY	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the packet insert for the Bio Screen Quality Control (QC) beads and Mercedes Quick Dip stain set ambient temperature requirements, lack of laboratory temperature log sheets from 3/19/2021 through 12/30/2022, direct observation of the laboratory area and an interview with the laboratory testing person, the laboratory failed to monitor the room temperatures for the laboratory area from 3/19/2021 through 12/30/2022 FINDINGS: 1. The Bio Screen Quality Control (QC) beads and Mercedes Quick Dip stain set manufacturer's temperature requires are: ambient 18-30 C and or 68-86 F 2. No Temperature log sheets for ambient/room temperatures were available for review at survey. 3. The laboratory testing person confirmed on January 12, 2023, at approximately 2:30 PM, that the testing person was aware that the room temperature was to be monitored.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation and confirmation by the laboratory testing person, the laboratory failed to ensure that expiration dates were included on the three bottles of Quick Dip stain labeled as container 1, 2, 3 used for staining the sperm slides for morphology.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on review of the Mercedes Mercedes Quick Dip stain set packet insert, direct observation of the stain set and confirmed in a interview with the laboratory testing person, the laboratory used the expired stain set from 12/9/22 through 12/30/22
FINDINGS: 1. Methanol Lot #2032852 Expiration date 12/8/2022 2. Xanthese Dye Lot#2033853 Expiration date 12/8/2022 3. Thianhye Lot#2033854 Expiration date 12/8/2022 4. Nine patient samples were tested and reported for sperm morphology using the Quick Dip stain set.