

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2182284	(X3) Date Survey Completed 08/19/2024
Name of Provider or Supplier Gb Diagnostics	Street Address, City, State 3915 Carlisle Blvd Ne, Albuquerque, NM	
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	An onsite recertification survey conducted on August 19, 2024, at GB Diagnostics found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvements Amendments (CLIA) Application for Certification CMS - 116, lack of documentation, and interview with testing personnel (TP1), the laboratory failed to verify the accuracy at least twice annually for 6 of 6 of their non-regulated analytes since last inspection. Findings included: 1. A Review of CMS - 116, the laboratory reported testing the following analytes: - Zonulin - Diamine Oxidase - Histamine - 8 - OhdG - Total Bile Acids - Indican 2. Laboratory was asked to provide documentation they were verifying the accuracy of their analytes at least twice annually. No documentation was provided. 3. An Interview on 08/19/2024 at 11:30 am with TP1, confirmed the above findings. 4. The laboratory reported performing 11,300 chemistry tests annually</p>
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.</p>

(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 direct observation, review of manufacturer's instructions, refrigerator and freezer temperature logs, and interview with testing personnel (TP1), the laboratory failed to ensure the freezer temperature was within manufacturer's specifications for 4 of 4 of the Elabscience ELISA (enzyme - linked immunosorbent assay) testing plates since last inspected. Findings included: 1. During a tour of the laboratory on 08/19 /2024 at 10:00 am the following ELISA testing plates were observed being stored in the freezer: - 1 package of Elabscience HIS ELISA Plate: Lot WE03ZR44856, Expiration 05/14/2025 - 1 package of Elabscience 8 - OHdG ELISA Plate: Lot WS09D2DB7332 Expiration 06/21/2025 - 1 package of Elabscience Human DOA ELISA Plate: Lot WA0382T27896 Expiration 07/24/2025 - 1 package of Elabscience Human Zonulin ELISA Plate: Lot WA04TJ049152 Expiration 07/24/2025 2. A review of the manufacturer's instruction listed the following temperature requirements for storage: - Elabscience HIS ELISA Plate: Storage at 4 - (-20) C (Celsius) - Elabscience 8 - OHdG ELISA Plate: Storage at 4 - (-20) C - Elabscience Human DOA ELISA Plate: Storage at 4 - (-20) C - Elabscience Human Zonulin ELISA Plate: Storage at 4 - (-20) C 3. A random sampling review of the laboratory's refrigerator and freezer logs in 2024 revealed the following dates room temperature fell out of the manufacturer's specified temperature ranges: - 06/27/2024: Freezer Temperature = - 24 C - 06/28/2024: Freezer Temperature = - 24 C - 06/29/2024: Freezer Temperature = - 22 C - 06/30/2024: Freezer Temperature = - 23 C - 07/19/2024: Freezer Temperature = - 26 C - 07/20/2024: Freezer Temperature = - 27 C - 07/21/2024: Freezer Temperature = - 24 C - 07/22/2024: Freezer Temperature = - 25 C - 07/23 /2024: Freezer Temperature = - 26 C - 08/04/2024: Freezer Temperature = - 22 C - 08 /05/2024: Freezer Temperature = - 22 C 4. An interview on 08/19/2024 at 11:30 am TP1 stated, freezer range is kept below - 20 C, confirming the above finding. 5. The laboratory reported performing 11,300 chemistry tests annually