

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0950892	(X3) Date Survey Completed 09/27/2023
Name of Provider or Supplier Buffalo Medical Group	Street Address, City, State 425 Essjay Road, Williamsville, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy, lack of QA documentation, and interview with the laboratory director (LD), the laboratory failed to perform annual 2022 QA review as required by the approved QA policy. FINDINGS: 1. No documentation of 2022 annual QA review was available. 2. The established QA policy included instructions for annual QA review. 3. The LD confirmed on September 27, 2023, at approximately 11:00 A.M. the 2022 QA review was not performed and documented.</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. (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:</p>

Based on direct observation, lack of room temperature records, Avantik cryostat QS12 temperature records, and interview with the Mohs technician, the laboratory failed to document Mohs processing laboratory room temperature as well as the second Avantik QS12 cryostat instrument temperature. FINDINGS: 1. Two cryostat QS12 instruments (S/N S22110180 and S/N 5029173) were utilized for processing specimens. It was noted the temperatures were in acceptable range of -18 to -21 C in accordance with the temperature log sheet. However, the laboratory failed to indicate which of the two cryostat instrument temperatures were documented from calendar year 2022 through the survey date. 2. The laboratory failed to document Mohs processing laboratory room temperatures where reagents, stains, and inking materials were stored. 3. The Mohs technician confirmed on September 27, 2023, at approximately 11:00 A.M. that the laboratory failed to document room temperatures where reagents, stains, and inking materials were stored as well as failed to define which of the two cryostat instrument temperatures were documented from 2022 through the survey date.

D5415

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

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

This STANDARD is not met as evidenced by:
Based on direct observation, review of the Mohs slide staining procedure, and interview with the Mohs technician, the laboratory failed to label staining jars utilized for Mohs slide processing. FINDINGS: 1. Surveyor observed staining jars utilized for Mohs slide processing were not labeled with the reagent name and alcohol concentration. 2. The Mohs technician confirmed on September 27, 2023, at approximately 10:00 A.M. the laboratory failed to label staining jars utilized for Mohs slide processing.