Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0950892	04/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Buffalo Medical Group	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	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of laboratory systems Quality Assessment (QA) Standard Operating Procedures (SOPs), QA records, as well as interview with the Laboratory Director (LD), the laboratory failed to establish, perform, maintain, and document QA. FINDINGS: 1. There was no documentation of QA records. 2. There current, approved SOPs did not include instructions for monitoring, assessing, and correcting problems in the general laboratory system or any phases of the testing process. 3. The LD confirmed the findings on April 23, 2025, at approximately 4:15 P.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective

	action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of SOPs, lack of thermometer calibration records, as well as interview with the Testing Person (TP), the laboratory failed to draft and approve procedures for thermometer calibration and certificate retention. FINDINGS: 1. There was no calibration certificate documentation for the Traceable Digital Thermometer, SN: 221229682, utilized for monitoring the room temperature and humidity of the Mohs processing laboratory. It was noted that the respective digital thermometer included a calibration tag indicating recalibration due February 28, 2024. 2. The current, approved SOPs did not include instructions for performing such activity. 3. The TP confirmed the findings on April 23, 2025, at approximately 3:30 P.M.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observations, review of the Safety Data Sheets (SDS), reagent manufacturer's storage requirements, SOPs, as well as interview with the TP, the laboratory failed to properly store flammable reagents in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on April 23, 2025, at approximately 3:00 P.M. the following reagents and processing materials were not properly stored in a flammable materials storage cabinet as required by the SDS and the reagent manufacturer's storage requirements: a. Harris Hematoxylin lot: 21103 expiration: April 30, 2026, was retained in a lower cabinet in the Mohs processing laboratory. b. Epredia Bluing Reagent lot: 148226 expiration: October 28, 2027; lot: 152550 expiration: March 12, 2028, were stored in a lower cabinet in the Mohs processing laboratory. c. 100% Reagent Alcohol lot: 218655 expiration: January 3, 2027, was stored in a lower cabinet in the Mohs processing laboratory. d. Fisher Chemical Permount Mounting Medium lot: 234786 expiration: January 2026, was stored in a lower cabinet in the Mohs processing laboratory. e. Epredia Eosin-Y lot: 145660 expiration: February 20, 2026; lot: 150791 expiration: July 8, 2026; lot 151191 expiration: August 7, 2026, was stored in a lower cabinet in the Mohs processing laboratory. f. Vintage Eosin-Y lot: 075062 expiration: July 1, 2020, was stored in a lower cabinet in the Mohs processing laboratory. g. Avantik Acidified Alcohol 1% lot: 44060292 expiration: July 1, 2026; lot: 44100004 expiration: October 10, 2026, were stored in a lower cabinet in the Mohs processing laboratory. h. Medical Chemical Corporation Acetone lot: 5953-00 Expiration: July 31, 2027, was stored in a lower cabinet in the Mohs

	processing laboratory. i. Acetone lot: 211917 expiration: November 30, 2026, was stored in a lower cabinet in the Mohs processing laboratory. 2. The current, approved SOPs did not include instructions for properly storing flammable reagents. 3. The TP confirmed the findings on April 23, 2025, at approximately 3:30 P.M. 4. The LD confirmed the findings on April 23, 2025, at approximately 4:00 P.M.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 direct observations, review of SOPs, as well as interview with the TP, the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on April 23, 2025, at approximately 3:00 P.M. the following reagents were not removed from inventory. a. Vintage Eosin-Y, lot: 075062 expiration: July 1, 2020, was stored in a lower cabinet in the Mohs processing laboratory. b. Source Medical Products 10% Neutral Buffered Formalin lot: 30539 expiration: January 2018, was stored in a lower cabinet in the Mohs processing laboratory. 2. The current, approved SOPs did not include instructions for removal and disposal of expired reagents from inventory. 3. It was noted that "For Emergency Use Only" was written on the respective expired reagent containers. 4. The TP informed the surveyor that the respective expired reagents were not utilized for patient specimen processing. 5. The TP confirmed the findings on April 23, 2025, at approximately 3:30 P.M.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards; This STANDARD is not met as evidenced by: Based on direct observations, review of the SDS, reagent manufacturer's storage requirements, SOPs, as well as interview with the TP, the LD failed to provide a safe environment in which employees were protected from chemical hazards. Refer to D5411.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on lack of written laboratory systems QA procedures, QA records, as well as

	interview with the LD, the laboratory failed to establish, perform, maintain, and document QA. Refer to D5291.