Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0950211	05/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Burlington Clinic Amg	248 Mchenry St, Burlington, WI	

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
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 surveyor observation of supplies in the laboratory and interview with histology staff, the laboratory director used one of three tissue marking inks for more than 16 months past the December 31, 2020 expiration date printed on the vial label. Findings include: 1. Observation of tissue marking inks in the laboratory on May 16, 2022 at 9:45 AM revealed the opened bottle of Delasco yellow ink had expired on December 31, 2020. Two additional bottles of yellow ink with the same expiration date were in the cabinet available for use. 2. Interview with histology staff A on May 16, 2022 at 9:45 AM confirmed the laboratory director used the expired ink for tissue marking.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance records, manufacturer's instructions, laboratory procedures and interview with histology staff, the laboratory did not perform weekly maintenance as defined by the manufacturer and required by

	laboratory procedures for the two Leica CM1520 cryostats on three of four weeks in April 2022. Findings include: 1. Review of 'WI - MOHS Cryostat Maintenance and Disinfection/Decontamination Sheet' logs from 2022 showed "Lubricate cylinder" was required weekly maintenance. Further review showed performance of this task was documented monthly. The April log showed the staff had not completed the maintenance on three of four weeks. 2. Review of the manufacturer's manual for the Leica CM1520 cryostat showed the manufacturer required weekly lubrication of the cylinder. 3. Review of the 'WI - MOHS Dermatology Cryostat Decontamination and Maintenance' procedure (document number 60429, revised August 11, 2021) showed step four of the weekly maintenance is "Oil specimen holder cylinder with cryostat oil." 4. Interview with histology staff (staff A) on May 16, 2022 at 9:45 AM confirmed staff had lubricated the cylinder monthly and confirmed staff did not perform maintenance with the frequency required by the manufacturer.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with histology staff, the laboratory had not developed a record system that maintained the time of specimen receipt in the laboratory for seven of seven Mohs tissue specimens from three random reviewed patients. Findings include: 1. Review of laboratory records including patient logs, Mohs maps and patient test reports for three randomly chosen patients showed staff did not record the time of specimen receipt in the laboratory for seven tissue samples from the three patients. Patient 1: tissues from two stages received. Patient 2: tissues from three stages received. Patient 3: tissues from two separate sites received. 2. Interview with histology staff (staff A) on May 16, 2022 at 10:00 AM confirmed the time of specimen receipt in the laboratory was not documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and logs and interview with the Supervisor of Clinic Operations, the laboratory had not followed written policies and procedures to monitor analytic systems. Findings include: 1. Review of the "WI - MOHS Dermatology Cryostat Decontamination and Maintenance" procedure (Document number 60429, revised August 11, 2021) showed the procedure included instructions to give the 'WI - MOHS Cryostat Maintenance and Disinfection/

	Decontamination Sheet' to the supervisor for monthly review and sign-off. 2. Review of the 'WI - MOHS Cryostat Maintenance and Disinfection/ Decontamination Sheets' include an area to document the identity of the reviewer and the date. Review of the worksheets from 2022 showed the supervisor had not signed or dated the worksheets. Further review showed staff did not perform required weekly maintenance (See D5429) and the supervisor did not identify that staff had not completed maintenance as required. 3. Interview with the Supervisor of Clinic Operations (staff B) on May 16, 2022 at 9:30 AM confirmed the laboratory had not followed their procedures to monitor analytic systems and the supervisor had not identified that staff did not perform maintenance as required.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 surveyor review of laboratory quality assessment (QA) procedures and QA records and interview with histology staff, the laboratory director did not ensure staff followed QA procedures in three of the last four QA events and did not ensure staff completed QA evaluations with the required frequency in 2021. Findings include: 1. Review of the 'WI Mohs Dermatology Quality Assessment - Burlington' procedure showed the procedure required the review of a minimum of three Mohs cases, three times per year by a Dermatopathologist at Aurora West Allis Medical Center. 2. Review of QA records showed the laboratory sent cases for review twice in 2021. Staff sent two cases for review in April and two cases in September 2021. Staff sent two cases for review in March 2022 and three cases in May 2022. 3. Interview with histology staff (staff A) on May 16, 2022 at 10:00 AM confirmed staff did not send a third set of cases for evaluation in 2021 and confirmed three of the last four events did not include the required number of cases.