Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1095122	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Big Sky Dermatology	4515 Valley Commons Drive, Ste 202, Bozeman, MT	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on reivew of patient slides, procedures and interview with Laboratory Manager (LM) #1 (not listed on the CMS 209 form), the laboratory failed to retain histology control slides for at least 10 years for years 2019 and 2020. Findings: 1. Review of patient slides #M19-119, tissue stained with Hematoxylin and Eosin (H&E) Stain revealed the quality control slide could not be located. 2. Review of patient slides #20-219, tissue stained with Hematoxylin and Eosin (H&E) Stain revealed the quality control slide could not be located. 3. Review of Procedure and Form 7: Histopathology-Mohs Surgery revealed "Slides and all copies of reported test results that are associated with the slides should be retained for five years". 4. Interview with LM #1 on 9/21/2021 at 10:07 AM, confirmed the quality control slide were not retained for at least 10 years for 2019 and 2020.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

	appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of records, procedures and interview with Laboratory Manager (LM) #1 (not listed on the CMS 209 form), the laboratory failed to establish and follow written procedures for histology specimen slide labeling, storage, and preservation. Findings: 1. Review of patient slides #M19-119, tissue stained with Hematoxylin and Eosin (H&E) Stain label lacked the date processed. 2. Review of patient slides #M20-219, tissue stained with Hematoxylin and Eosin (H&E) Stain label lacked the date processed. 3. Review of Procedure and Form 7: Histopathology-Mohs Surgery revealed "Slides are labeled with Mohs layer, specimen number, full patient name and date, and specimen source (if applicable)". 4. No procedures for histology slide storage and preservation were available for review. 5. Interview with LM #1 on 9/21 /2021 at 10:12 AM confirmed the laboratory failed to establish and follow written policies and procedures for specimen labeling, storage, and preservation for 2019 and 2020.
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 review of records, procedures, and interview with Laboratory Manager (LM) #1 (not listed on the CMS 209 form), the laboratory failed to record the lot number, expiration date, and maintain a room temperature log to ensure reagent storage requirements for years 2019 and 2020. Findings: 1. Review of Procedure and Form 2: Potassium Hydroxide (KOH) Examination of Skin, Hair or Nails revealed "Reagent preparation - KOH reagent and the Fungal Tzanck and Swarz-Lamkin stains are commercially available. Receipt of each new batch, lot, or shipment of reagent will be recorded on a Receipt Log." and "Reagent Storage, Use and Handling - Reagents are stored according to the manufacturer's instructions and temperature logs of storage sites are maintained as appropriate. 2. Review of Procedure and Form 7: Histopathology - Mohs Surgery revealed "Reagent Storage, Use and Handling - Reagents are stored according to the manufacture's instructions and temperate logs of storage sties are maintained as appropriate". 3. No Receipt log was available for review. 4. No room temperature log was available for review. 5. Interview with LM #1 on 9/21/2021 at 10:00 AM, confirmed that the laboratory failed to record the lot number, expiration date, and maintain a room temperature log to ensure reagent storage requirements.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as

	specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of records, procedures, and interview with Laboratory Manager (LM) #1 (not listed on the CMS 209 form), the laboratory failed to include in their QC records: date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, stains were opened or when the laboratory prepared these materials. Cross-refer (D3043 and D5311) Findings: 1. Review of Procedure and Form 7: Histopathology - Mohs Surgery revealed "Reagent Preparation: OCT Mounting compound, Cryospray, and staining reagents are commercially available. Receipt of each new batch, lot or shipment of reagent will be recorded on a Receipt Log." 2. No Receipt log was available for review. 3. Review of Mohs Slide QA QC procedure log lacks documentation of lot # of reagents used, expiration dates, date reagent opened and actual measurements. 4. Interview with LM #1 on 9/21/2021 at 9:30 AM, confirmed that the laboratory failed to record date prepared/opened, expiration dates, the actual measurements, reactions, and/or observations and demonstrate that controls were tested when shipments of reagents, stains were opened or when the laboratory prepared these materials.