Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2222637	12/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kennebec Dermatology	13 Railroad Square, Suite 2, Waterville, ME	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow written procedure to assess the employee technician #1 (TP1). Findings include: 1. Review of the laboratory manual on 12/20/2021 revealed blank "Personnel Assessment" and technician competency review forms that are in use by the laboratory. 2. Review of the "Histology Technician" job description on 12/20/2021, revealed the technician must "... have documentation of training appropriate for the testing prior to analyzing patient specimens." 3. TP1 stated on 12/20/2021 at 10:00am that he/she did not recieve a documented training or competency assessment prior to working on patient samples.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review of the laboratory's procedure manual and interview with laboratory technician #1 (LT1), the laboratory director (LD) failed to ensure an approved procedure manual is available to laboratory personnel. Findings include: 1. Record review on 12/20/2021 of the laboratory procedure manual revealed that the

	manual was not signed by the LD. 2. Staff interview with the LT1 on 12/20/2021 at 9: 30am confirmed the laboratory procedure manual was not signed by the LD.
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 maintenance record review and interview with the Laboratory Technician #1 (LT1) the laboratory failed to document routine maintenance for a laboratory microscope. Findings include: 1. Record review on 12/20/2021 of the laboratory's microscope maintenance documentation revealed the laboratory did not have documented maintenance for 1 of 2 laboratory microscopes for 2021. 2. Record review of the laboratory manual on 12/20/2021 revealed that the laboratory microscopes should have documented "daily, monthly care". 3. During interview with LT1 on 12/20/2021 at 9:30am, confirmed 1 of 2 laboratory microscopes in use does not have documentated mainenance.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor record review, and interview with the laboratory technician #1 (LT1), the laboratory failed to include the name and address of the laboratory were testing was performed on the final test report. Findings include: 1. Record review on 12/20/2021 of final patient test reports revealed 6 of 6 final patient test reports from September 2021 did not have the name and address of the laboratory where testing was performed. 2. Record review on 12/20/2021 of the laboratory Mohs log revealed 88 tests to have been completed from 7/16/2021 to 10/17/2021. 3. LT1 confirmed on 12/20/2021 at 11:00am that the final test reports did not state the name and address of the laboratory where testing was performed.