Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2135172	(X3) Date Survey Completed 11/02/2021
Name of Provider or Supplier Zitelli&Brodland,Pc,Dba Keystonedermptnrs	**Street Address, City, State** 216 Mall Blvd Suite 101, King Of Prussia, PA	

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
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histotechnician, the laboratory failed to establish a maintenance policy to assess the maintenance/function for 1 of 1 Emate thermometer from 2019 to the day of survey. Findings Include: 1. On the day of survey, 11/02/2021, the surveyor observed 1 of 1 Emate thermometer in use to monitor room temperatures in the laboratory. 2. The laboratory could not provide a thermometer maintenance policy or maintenance records for the thermometer. 3. The histotechnician confirmed the findings above on 11/02/2021 around 09:30 am.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of Hematoxylin and Eosin (H&E) quality control (QC) records and interview with the histotechnician, the laboratory failed to document H&E QC stain acceptability each day of patient testing for Mohs micrographic examinations from January 2021 to July 2021. Findings include: 1. The H&E Quality Control policy states, "an H&E control form is initialed by the Mohs surgeon confirming the control is adequately stained prior to diagnostic slides being run on the strainer." 2. On the day of survey, 11/02/2021, review of the H&E QC form revealed, daily H&E forms were not initialed by the Mohs surgeon (the testing personnel) on the following number of days from January 2021 to July 2021: - 3 of 5 days in January. - 4 of 4 days in February. - 6 of 6 days in March . - 4 of 4 days in April. - 4 of 4 days in May. - 6 of 6 days in June. - 3 of 3 days in July. 3. The histotechnician confirmed the findings above on 11/02/2021 around 9:30 am.