

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D2055020	<b>(X3) Date Survey Completed</b>  09/21/2021
<b>Name of Provider or Supplier</b>  Teresa Mann, Md, Pc DbA Pure Dermatology	<b>Street Address, City, State</b>  2233 West Kagy, Suite 2, Bozeman, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, 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. Observation of KOH reagent bottle revealed temperature requirements of 2-25C and had expired in 2017. 2. No room temperature log was available for review. 3. No documents were available with the lot number and expirations date. 4. No procedure was available for documentation of reagent lot number, expiration date and storage requirements to ensure proper use of KOH reagent. 4. Interview with LM #1 on 9/21/2021 at 2:00 PM, confirmed that the laboratory failed to record the lot number, expiration date, and maintain a room temperature log to ensure reagent storage requirements.</p>