

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2015090	(X3) Date Survey Completed 06/01/2021
Name of Provider or Supplier Abbasi Dermatology	Street Address, City, State 21401 Allen Rd, Woodhaven, MI	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #2, the laboratory failed to ensure tissue marking inks used in tissue specimen grossing were not expired for the current lot in use. Findings include: 1. An observation on 6/1/21 at 9:02 am by the surveyor revealed 4 Platinum Line tissue marking inks with the following expiration dates: a. Green, expiration date 10/2020 b. Black, expiration date 10/2020 c. Yellow, expiration date 10/2020 d. Blue, expiration date 12/2020 2. A review of the laboratory's "Quality Assurance Policy" revealed a section stating, "In order to assure quality, the analytic system will be performed. All reagents, controls, kits, etc. that exceeded their expiration date will be discarded." 3. An interview on 6/1/21 at 9:02 with Testing Personnel #2 confirmed the tissue marking inks were beyond the expiration date.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to have preventative maintenance performed on the Microm HM525 Cryostat as required for 2 (2020 and 2021) of 2 years reviewed. Findings include: 1. An observation on 6/1/21 at 9:02 am by the surveyor revealed a Microm HM525 Cryostat with a sticker affixed on the side indicating the previous time preventative maintenance was performed was in April 2019 and the next service was due in April 2020. 2. A review of the laboratory's "Quality Assurance Policy" revealed a section stating, "Any required instrument maintenance will be performed and documented." 3. An interview on 6/1/21 at 10:36 am with the Laboratory Director confirmed the laboratory did not have preventative maintenance performed on the cryostat listed above since April 2019.