

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D2170607	<b>(X3) Date Survey Completed</b>  03/30/2021
<b>Name of Provider or Supplier</b>  Dean Mcgee Pathology - Mcgee Eye Surgery Center	<b>Street Address, City, State</b>  1000 N Lincoln Blvd, Oklahoma City, OK	
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>D0000</b>	The initial survey was performed on 03/30/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory director and general supervisor, failed to ensure the cryostat was maintained at an acceptable temperature 1 of 5 days; and failed to ensure materials were stored as required. CRYOSTAT TEMPERATURE (1) On 03/30/2021 at 10:00 am, the general supervisor stated to the surveyor the laboratory performed frozen sections on ophthalmic specimens using the Tissue Tech II Cryostat; (2) The surveyor reviewed cryostat temperature records for testing performed from 04/03/2020 through 03/26/2021. The defined acceptable temperature range, as stated on the temperature log, was -15 to -25 degrees C (Centigrade). The review showed the cryostat temperature had not been documented 1 of 5 days of patient testing. The specific day was 03/26/2021; (3) The surveyor reviewed the records with the general supervisor, who stated to the surveyor on 03/30/2021 at 10:30 am, the cryostat temperature had not been documented on 03/26/2021. ROOM TEMPERATURE (1) On 03/30/2021 at 11:10 am, the surveyor observed the frozen section room and identified the following,</p>

including the manufacturer's storage requirement: (a) Rapid Chrome H&E Frozen Section Staining Kit, lot #496135, with a storage requirement of 15-30 degrees C; (b) Sakura Tissue-Tek Optimal Cutting Temperature Compound, lot 9975-00, with a storage requirement of 15-30 degrees C. (2) The surveyor asked the general supervisor if the laboratory had monitored the room temperature of the frozen section room during the review period of April 2020 through the current time. The general supervisor stated to the surveyor on 03/30/2021 at 11:15 am, the room temperature had not been monitored.

**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: