

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2155256	(X3) Date Survey Completed 07/21/2020
Name of Provider or Supplier Unm Comprehensive Cancer Center	Street Address, City, State 1201 Camino De Salud Ne, Albuquerque, NM	
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
D0000	The following deficiencies were cited as the result of an initial certification survey on 07/21/2020 for 42 CFR part 493 Laboratory Requirements.
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the review of quality assessment records and interviews with laboratory staff, the laboratory failed to establish and follow a written policy for twice per year assessment of the Mohs (Mohs surgery is a precise surgical technique used to treat skin cancer) test system using H & E (Hematoxylin & Eosin) stains. The laboratory reported performing 611 Mohs cases in a 12 month period. Findings are: A. Review of 2019 Peer Reviews (the method used for the twice per year test assessment) for H & E Stains/Mohs surgery revealed: 1. Two cases were reviewed on the same day, 05/01 /2019, by the peer reviewer but there was no documentation of the date each case was reviewed by the laboratory director or the date the case was sent to the reviewer. 2. No written criteria defining how the assessments were performed and how discrepancies were resolved. B. During interview on 07/21/2020 at 11:15 am, the Quality Program Manager stated the laboratory did not have a written policy for Peer Review.</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</p>

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 the review of microscope maintenance records and interviews with laboratory staff, the laboratory failed to establish a written maintenance protocol for either of the two microscopes used for the analysis of patient Mohs cases. The laboratory reported performing 611 Mohs cases in a 12 month period. Findings are: A. Review of 2018-2020 microscope maintenance records revealed: Each microscope had a form which listed a description of the service performed by an outside company performing the preventative maintenance, a copy of the Preventative Maintenance log, and copies of four invoices provided by company inspecting the microscopes. The Preventative Maintenance log indicated the recommended frequency for preventative maintenance to be performed "every 6 months." 1. Microscope BX40: The lab failed to perform preventative maintenance twice a year for 2019. a. The maintenance log had a total of four entries, 12/21/2018, 09/03/2019, 01/10/20, 06/26/20. b. Examination of the service invoices revealed that Microscope BX40 was serviced on 09/03/19, 01/10/20, and 06/26/20. No invoice or other record was provided for 2018 that correlated with the 12/21/2018 date listed on Preventative Maintenance log. 2. Microscope BH-2: The laboratory failed to perform Preventative Maintenance every 6 months for 2019. a. Inspection of the Preventative Maintenance log revealed only one entry for 2019 (09/03/19) and no entries for 2020. b. Examination of the invoices provided revealed that Microscope BH-2 was inspected on 12/21/18 and 09/03/19 (invoice #4173 and #4734). c. During interview on 7/21/2020 at 10:14 am, the Charge Nurse, when asked about the single entry for 2019, stated that they (the laboratory) did not acquire the scope until 2019 and placed it into use the same year. B. During interview on 07/21/2020 at 10:14 am with the Charge Nurse and the Quality Program Manager, the Charge Nurse stated that the lab had no written policy and no written manufacturer instructions, or recommendations, regarding maintenance. The Charge Nurse further stated that she had called the manufacturer who recommended that preventative maintenance should be performed twice a year. She also stated that the manufacturer did not provide these recommendations in writing in response to the phone call.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on the review of quality assessment records and interviews with laboratory staff, the laboratory director failed to ensure that the laboratory had an approved written procedure manual for all aspects of testing. The laboratory reported performing 611 Mohs cases in a 12 month period. Findings are: A. The laboratory failed to establish and follow a written policy for twice per year assessment of the

Mohs test system using H & E (Hematoxylin & Eosin) stains. See D5291 B. The laboratory failed to establish and follow a written policy for microscope maintenance. See D5433