Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1056730	12/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Unmh Dermatology	1021 Medical Arts Ave 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 a recertification survey on 12/09/2020 for 42 CFR part 493 Laboratory Requirements.
D2039	MYCOLOGY CFR(s): 493.827(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of 2019-2020 proficiency test records and interviews with laboratory staff, the laboratory failed to submit test results for KOH (Potassium Hydroxide) tests (used to identify fungal elements under a microscope) for 2 events in 2019. Findings are: A. Review of 2019 proficiency test records from American Proficiency Institute (API) revealed the laboratory failed to submit test results for the 1st and 3rd events. 1. 2019 - 1; results printed on 03/26/2019 Note on results: "Plan - enter results the same day the test is returned to me. Acknowledge reminder emails." 2. Notes for the 2019 - 3 event indicated the proficiency agency (API) had sent 2 photos with the same name for the event. "Received two specimens/slides both labeled API-2019 KOH-05" "KOH - 06 replacement rec'd later than 05" B. Review of the "[Facility Name] Dermatology Clinic Laboratory Procedure" and "Quality Improvement Plan" signed by the previous Laboratory Director (now Testing Person #1) on 12/04/20 revealed no process for Proficiency Testing including corrective

	actions. C. During interview on 12/08/2020 at 03:36 pm, Testing Person #1 stated that "perhaps" the Director of Dermatology didn't get the proficiency testing modules to her on time.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the review of 10 (PT#1-PT#10) of 10 (PT#1-PT#10) Patient Final Reports, the Mohs (surgical procedure that uses the microscope to examine removed tissue for cancer cells) patient log for 2019 and 2020, and interview with the Laboratory Director, the laboratory failed to ensure positive patient identification from the specimens unique (Slide ID number and Mohs case number) collection through reporting of results. Findings are: A. Review of 10 (PT#1-PT#10) Final Operative Reports revealed; 1. Patient Final reports did not contain the unique identifier (Mohs Case number) on the slide and on the Mohs patient log, linking the slide to the operative report. 2. Two patient reports (PT#1, PT#10) out of 10 reviewed were collected from multiple (2) sites and (2) separate operative reports, one for each site. The Final Reports for PT#1 and PT#10 did not include the Mohs case number found on the slide. The slides were also labeled with the level (the depth of the surgical incision) as indicated by a letter/number system such as A1, A2, B1 or B2, In order to locate the site-specific sample slide for each site, a map indicating the location of excision and the slide ID numbering pattern, a separate document, had to be retrieved from the patient electronic record. PT#1 - tested on 2/6/2019, MRN (Medical Record Number)#4358847 - Excision site #1 (forehead) - Mohs# D19-25 - Slide # A1-2, A2-3 (multiple slides prepared for this site) PT#1 - tested on 2/6/2019, MRN#4358847 - Excision site #2 (left eyelid) - Mohs#D19-26 - Slide # A3-2, A4-2 (multiple slides prepared for this site) PT#10 - tested on 11/18/2020, MRN#5280127 - Excision site #1 (Left Lower leg) - Mohs#D20-179 - Slide # A1-3, A2-3 (multiple slides prepared for this site) PT#10 - tested on 11/18/2020, MRN#5280127 - Excision site #2 (Right Lower leg) - Mohs#D20-180 - Slide # A3-4 (multiple slides prepared for this site) 4. Eight other patient electronic records also did not contain the unique identifier (Mohs Case number) on the slide and on the Mohs patient log, linking the slide to the operative report. PT#2 - tested on 4/3/2019, MRN#5501877 - Excision site #1 (Left Ala (nasal) - Mohs#D19-60 - Slide # A1-2, A2-2, B1-4, C1-2 (multiple slides prepared for this site). PT#3 - tested on 6/19/2019, MRN#5503632 - Excision site #1 (Right Lower eyelid) - Mohs#D19-98 - Slide # A1-6, B1-2, B2-2, B3-2, B4-2 (multiple slides prepared for this site). PT#4 - tested on 08/21/2019, MRN#4588530 - Excision site #1 (Left Dorsal Hand) - Mohs#D19-129 - Slide # A1-3, A2-5 (multiple slides prepared for this site). PT#5 - tested on 10/09/2019, MRN#561861 - Excision site #1 (Left Forehead) - Mohs#D19-150 - Slide # A1-3, A2-3 (multiple slides prepared for this site). PT#6 - tested on 12/04/2019, MRN#275757 - Excision site #1 (Left Nose) - Mohs#D19-174 - Slide # A1-4, A2-2, A3-3 (multiple slides prepared for this site). PT#7 - tested on 04/15/2020, MRN#4963966 - Excision site #1 (Right Nasal Rim (ala)) - Mohs#D20-62 - Slide # A1-2, A2-2, B1-3, B2-2 (multiple slides prepared for this site). PT#8 - tested on 07/08/2020, MRN#4617299 - Excision site #1 (left temple) - Mohs#D20-109 - Slide # A1-2, A2-3, B1-3, B2-4 (multiple slides prepared

	for this site). PT#9 - tested on 08/12/2020, MRN#5269471 - Excision site #1 (left nasal labial fold) - Mohs#126 - Slide # A1-3 (multiple slides prepared for this site). 2. During interview on 12/09/20 at 4:00 pm, the Laboratory Director acknowledged that the patient final reports did not contain the unique slide# identifier.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of 2019-2020 proficiency test records and interviews with laboratory staff, the laboratory failed to have a proficiency testing corrective action policy which resulted in the laboratory's failure to submit test results for KOH (Potassium Hydroxide) tests (used to identify fungal elements under a microscope) for 2 events in 2019. Findings are: A. Review of 2019 proficiency test records from American Proficiency Institute (API) revealed the laboratory failed to submit test results for the 1st and 3rd events. There was no documentation that indicated the laboratory identified the cause of the failure and performed corrective actions. 1. 2019 - 1; results printed on 03/26/2019 Note on results: "Plan - enter results the same day the test is returned to me. Acknowledge reminder emails." 2. Notes for the 2019 - 3 event indicated the proficiency agency (API) had sent 2 photos with the same name for the event. "Received two specimens/slides both labeled API-2019 KOH-05" "KOH - 06 replacement rec'd later than 05" B. Review of the "[Facility Name] Dermatology Clinic Laboratory Procedure" and "Quality Improvement Plan" signed by the previous Laboratory Director (now Testing Person #1) on 12/04/20 did not include Proficiency Testing including corrective actions. C. During interview on 12/08 /2020 at 03:36 pm, Testing Person #1 stated that "perhaps" the Director of Dermatology didn't get the proficiency testing modules to her on time. D. During interview on 12/08/2020 at 03:45 pm, the Director of Dermatology confirmed that the laboratory did not have a proficiency testing corrective action policy.
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: Based on the review of the Cryostat (instrument used in histology for the cutting of frozen tissue sections) maintenance record/log, the Cryostat Operator manual, the Mohs Micrographic Surgery (surgical procedure that uses the microscope to examine removed tissue for cancer cells) protocol, and interview with Histology Staff #1, the laboratory failed to establish and follow a written maintenance protocol, as defined by the manufacturer of the Leica 1850 Cryostat. The laboratory reported performing 492 Mohs cases in a 12 month period. Findings are: A. Review of the Leica 1850 Cryostat maintenance record/log and the existing Mohs Micrographic Surgery protocol revealed that the written protocol was not followed. 1. The daily maintenance log did not match the written protocol for performing Daily maintenance. a. The daily log

	contained the daily temperature, humidity, and daily disinfection of cryostat. b. The written protocol indicated the laboratory should disinfect the Cryostat box with 95% ethanol and log daily. This was not recorded on the maintenance log. c. The written protocol indicated the laboratory should clean the Ventilation Panels and the Condenser Coils semiannually or as needed. The maintenance log did not have a designated area for recording this information. B. Review of the Leica 1850 Cryostat Instrument Operator Manual revealed that the manufacturer's recommended maintenance was not performed and/or documented. a. Listed under Section 9.3.1, General maintenance, the manufacturer recommended that the cryostat be inspected by a qualified service engineer once a year. b. Oil lubrication to the plastic coupling to be done weekly. c. Oil lubrication of the specimen cylinder to be done weekly. d. Oil lubrication of the clamping piece (T-piece) on the microtome (an instrument for cutting extremely thin sections of material for examination under the microscope) base plate and the clamping lever to be done occasionally, or when required. e. Oil lubrication of the slot cover to be done occasionally, or when required. C. During interview on 12/09/20 at 2:57 pm, Histology Staff #1, when asked for maintenance records/logs for the Cryostat, stated that all the maintenance done for the Cryostat is documented on the daily log.
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 the review of the 2019-2020 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 (surgical procedure that uses the microscope to examine removed tissue for cancer cells) cases. The laboratory reported performing 492 Mohs cases in a 12 month period. Findings are: A. Review of microscope maintenance records/logs revealed: 1. Microscope BX51: a. The lab failed to perform and document microscope maintenance for 2019. b. The maintenance log for 2020 had preventative maintenance performed in Sept, 2020. No other entry was found on the log. 2. Microscope BX40: a. No maintenance record/log was available for 2019 and 2020. B. During interview on 12/09/20 at 2:57 pm, Histology Staff #1, when asked for maintenance records/logs for 2019, stated that they did not maintain the microscopes for 2019 and that they do not have an established maintenance protocol/policy for the microscopes.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on the review of 2019-2020 proficiency test records, laboratory policies and interviews with laboratory staff, the Laboratory Director failed to ensure test results were submitted on time for KOH (Potassium Hydroxide) tests (used to identify fungal elements under a microscope) for 2 events in 2019. Findings are: A. The laboratory failed to submit test results for KOH (Potassium Hydroxide) tests (used to identify fungal elements under a microscope) for 2 events in 2019. See D2039 B. The laboratory did not have a written policy for proficiency testing that included corrective action plans. See D5407