Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1056730	02/23/2024
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	An onsite initial survey conducted at UNM Dermatology on February 22, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following conditions not met:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209 form, American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to ensure KOH (potassium hydroxide) PT samples were entered into routine testing workload and tested by different personnel for 2 of 3 PT events in 2023. Findings included: 1. Review of CMS 209 form showed 5 testing personnel listed as moderate complexity performing KOH testing. 2. Review of the API proficiency testing attestation forms from 2023 revealed the following: 1. Event 2 of 2023: Only signed by testing personnel #2. No other testing personnel indicated. 2. Event 3 of 2023: Only signed by testing personnel #2. No other testing personnel indicated. 3. Interview on 2/22/2024 at 10:00am with Unit Director confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to have the laboratory director or assigned designee sign the attestation forms for 2 of 3 PT events in 2023. Findings included: 1. Review of the API proficiency testing attestation forms from 2023 revealed the following: 1. Event 2 of 2023: Only signed by testing personnel #2, not laboratory director or designee 2. Event 3 of 2023: Only signed by testing personnel #2, not laboratory director or designee 2. Interview on 2/22/2024 at 10:53am with Unit Director confirmed the findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for potassium hydroxide (KOH) testing for 2 of 3 consecutive PT events in 2023. Refer to D2046.
D2046	MYCOLOGY CFR(s): 493.827(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for potassium hydroxide (KOH) testing for 2 of 3 consecutive PT events in 2023. Findings included: 1. Review of the API proficiency testing records from 2023 revealed the following unsatisfactory PT scores for KOH testing. 1. Event 1 of 2023: KOH PT not submitted; facility received score of 0% 2. Event 2 of 2023:

	KOH PT score of 0% 2. Interview on 2/22/2024 at 10:00am with Unit Director confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Mohs (micrographically oriented histographic surgery) Micrographic Surgery Procedure and interview, the laboratory failed to list intended reactivity for their hematoxylin and eosin (H&E) stain for 2340 of 2340 patient slides in 2023 Findings included: 1. Review of Mohs Micrographic Surgery Procedure showed general requirements for quality control of slides but no mention of intended reactivity for the H&E stain. 2. Laboratory was asked to provided documentation of intended reactivity. None was provided. 3. Interview on 2/22/2023 at 10:30 with the histotechnician confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Patient and Quality Control: KOH (potassium hydroxide) and Mineral Oil log, and interview, the laboratory failed to ensure the quality control (QC) for KOH was acceptable prior to reporting patient results for 12 (P1, P2, P3, P7, P8, P9, P10, P11, P13, P14, P15, P16) of 16 (P1-P16) patients from May through July of 2023. Findings included: 1. Review of Patient and Quality Control: KOH and Mineral Oil log, showed the following patients missing QC results for KOH testing: 1.P1: 802171 2.P2: 4258847 3.P3: 4462773 4. P7: 4805556 5. P8: 5758816 6. P9: 4158550 7. P10: 4260910 8. P11: 5522574 9. P13: 5226077 10. P14: 5078731 11. P15: 165397947 12. P16: 5423063 Log also revealed 5 undated entries and missing initials of providers performing testing. 2. Interview on 02/22/2024 at 11:00 am with Unit Director confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient reports and interview, the laboratory failed to include the facility name and address on 2 of 2 patient reports for December of 2023. Findings included: 1. Record review of 2 (P17, P18) dermatology patient reports pulled from December of 2023 showed the facility name and address were not included in the report. 2. Interview on 02/22/2024 at 2:00 pm with Unit Director confirmed the findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing (PT) records, CMS 209 form, and interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure successful participation for potassium hydroxide (KOH) testing for 2 of 3 consecutive PT events in 2023. Refer to D6089. 2. The Laboratory Director failed to ensure competency assessments were completed for 5 of 5 testing personnel performing KOH testing in 2023. Refer to D6103.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing (PT) records, and interview, the laboratory director failed to ensure successful participation for potassium hydroxide (KOH) testing for 2 of 3 consecutive PT events in 2023. Refer to D2046
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by:

	Based on review of CMS 209 form and interview, the laboratory director failed to ensure competency assessments were being done for 5 of 5 testing personnel performing KOH (potassium hydroxide) testing in 2023. Findings included: 1. Review of CMS 209 form showed 5 testing personnel listed as moderate complexity performing KOH testing. 2. The laboratory was asked to provide documentation of competency assessments being completed for testing personnel annually. None were provided. 3. During a phone interview on 02/22/2024 at 1:35 pm the laboratory director, confirmed findings and stated they were unaware of any competency assessments taking place and had not been signing off on any.