Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0925107	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mt Lebanon Dermatology Assoc, Pc	607 Washington Road, Lower Level, Pittsburgh, PA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Mycology test records and interview with the office manager, the laboratory failed to enroll in an approved proficiency testing (PT) program for Mycology from 09/12/2019 to 04/13/2022. Refer to Dtag: D6088
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Office Manager (OM), the laboratory failed to establish a procedure to assess the competency of 4 of 4 testing personnel who performed mycology and parasitology testing in 2020 and 2021. Findings include: 1. On the day of survey, 04/13/2022 at 09:15 am, review of

	laboratory's procedures revealed, the laboratory did not establish a competency assessment procedure to assess testing personnel. 2. The OM could not provide competency assessment records for 4 of 4 TP who performed Potassium Hydroxide (KOH), Scabies and Dermatophyte identification testing in 2020 and 2021 . 3. The OM confirmed the findings above on 04/13/2022 at 11:15 am.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records and interview with the Office Manager, the Laboratory failed to ensure QA programs were maintained and documented to ensure the quality of laboratory services provided in 2020 and 2021. Findings Include: 1. . The Quality Assurance Policy states, "A quality assessment will be done Bi-yearly by the laboratory director". 2. On the day of survey, 04/13/2022 at 10:45 am, the office manager could not provide 4 of 4 QA documentation for the periodic evaluation of the laboratory's pre-analytical, analytical, and post-analytical processes from 01/01/2020 to 12/31/2021. 3. The Office Manager confirmed the findings above on 04/13/2022 at 11:15 am.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation of the Laboratory and interview with the Office Manager (OM), the laboratory failed to ensure that 1 of 1 potassium hydroxide (KOH) reagent was not used beyond its expiration date. Findings Include: 1. At the Time of the survey 04/13 /2022 at 10:00 am, during the tour of the laboratory, 1 of 1 Delasco KOH (KOH 20% with DMJO, Lot # K183J2) was found that expired on 03/31/2021. 2. The laboratory performed 9 KOH microscopic examinations from 04/01/2021 to 04/13/2022. 3. The OM confirmed the findings above on 04/13/2022 at 11:15 a.m.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Office Manager (OM), the laboratory failed to include a positive and a negative control materials each day of performing Chlorazol, Potassium Hydroxide (KOH), and scabies microscopic examinations on patient specimens from 09/12/2019 to 04/13/2022. Findings include: 1. On the date of survey, 04/13/2022 at 10:10 a.m, the laboratory could not provide the documentation of quality control for Chlorazol, KOH, and Scabies microscopic examinations from 09/12/2019 to 04/13/2022. 2. The following number of specimens were examined: - Chlorazol: 09/12/2019 to 12/31/2019:6 01/01/2020 to 12/31/2020: 0 01/01/2021 to 12/31/2021: 0 - KOH: 09/12/2019 to 12/31/2019: 37. 01/01/2020 to 12 /31/2020: 4 01/01/2021 to 12/31/2021: 2 - Scabies: 09/12/2019 to 12/31/2019: 7 01/01 /2020 to 12/31/2020: 5 01/01/2021 to 12/31/2021: 8 3. The OM confirmed the findings above on 04/13/2022 at 11:15 a.m.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Office Manager (OM), the laboratory failed to check and document each batch or shipment of Hardy Mycobiotic Agar for its ability to support growth and select/inhibit specific organisms for fungal identification from 04/13/2020 to 04/13/2022. Findings include: 1. On the day of survey, 04/13/2022 at 10:15 a.m, the laboratory could not provide the documentation of quality control on new lots/shipments of Hardy Mycobiotic agar media for its ability to support growth and select/inhibit specific organisms for fungal identification from 04/13/2020 to 04/13/2022. 2. The laboratory analyzed the following fungal identification: - 04/13/2020 to 12/31/2020: 40. - 01/01/2021 to 12/31/2021: 63. - 01/01 /2022 to 04/13/2022: 9. 3. The OM confirmed the findings above on 04/13/2022 at 11: 15 a.m.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the Office Manager (OM), the laboratory director failed to ensure that the laboratory was enrolled in a proficiency testing (PT) program that is approved by HHS for Mycology testing performed from September 12, 2019 to April 13, 2022. Findings include: 1. On the day of survey 04/13/2022 at 09:30 a.m. review of the laboratory records revealed that the laboratory was not enrolled in an approved PT program for fungal (dermatophyte)

	identification from 09/12/2019 to 04/13/2022. 2. No documented proof of PT enrollment was available at the time of inspection. Interview with the Office Manager (OM) at the time of inspection confirmed that the laboratory did not enroll in an approved PT program for fungal identification. 3. According to the laboratory's testing records the laboratory performed the following number of fungal identifications: -2020: 56 patient testing. -2021: 64 patient testing. - 01/31/2022 to 03/31/2022: 9 patient testing. 4. An interview with the OM on 04/13/2022 at 09:30 a.m confirmed that the laboratory was not enrolled on a PT program. She stated they were unaware that fungal identification required an enrollment to a PT agency.