Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0940659	11/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lackawanna Valley Dermatology Assoc	327 North Washington Avenue Suite 200, Scranton, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of documentation, and interview with the hisotechnologist (HT), the laboratory failed to establish a procedure for the use of Chlorazol Black E fungal stain for mycology microscopic examinations performed from 10/21/2021 to the date of the survey. Findings Include: 1. On the day of survey, 11/13/2023 at 11:37 am, the laboratory failed to provide a procedure for the use of

	Chlorazol Black E fungal stain used for mycology microscopic examinations performed from 10/21/2021 to the date of the survey. 2. The HT confirmed the finding above on 11/13/2023 at 01:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records, and interview with the histotechnologist (HT), the laboratory failed to monitor and document the refrigerator temperatures to ensure operating conditions were met for the proper storage of dermatophyte testing reagents from 10/21/2021 to the day of the survey. Findings Include: 1. On the day of the survey, 11/13/2023 at 12:35 pm, review of the laboratory's temperature records revealed the laboratory failed to monitor and document the temperature for 1 of 1 refrigerator used for the storage of dermatophyte testing media (ACU-DTM) on weekends and holidays when personnel were not on site in the laboratory from 10/21/2021 to 11/13/2023. 2. The manufacturer's instructions states, "refrigeration required, for maximum shelf life store at 2-8 degrees Celsius/36-46 degrees Farenheit." 3. The HT confirmed the findings above on 11/13 /2023 at 01:00 pm.
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 review of the laboratory's quality control (QC) records and interview with the histotechnologist (HT), the laboratory failed to document a negative and positive control material each day of patient testing for mycology and parasitology microscopic examinations performed from 06/16/2022 to 04/17/2023. Findings Include: 1. On the day of the survey, 11/13/2023 at 12:10 pm, a review of the laboratory's QC records revealed the laboratory did not document a negative and positive control material each day of patient testing for the following 5 of 5 mycology and parasitology microscopic slide examinations performed from 06/16/2022 to 04/17 /2023: - 06/16/2022: Mycology (KOH wet mount) - 08/23/2022: Mycology (KOH wet mount) - 11/2/2022: Mycology (KOH wet mount) - 12/22/2022: Parasitology (Scabies wet mount) - 04/17/2023: Mycology (KOH wet mount) 2. The HT confirmed the findings above on 11/13/2023 at 01:00 pm. *Potassium Hydroxide = KOH

D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with the histotechnologist (HT), the laboratory failed to document Hematoxylin and Eosin (H&E) QC monitoring activities for intended reactivity each day of patient testing for histopathology slide examinations performed from 07/01/2022 to 10/31/2022. Findings Include: 1. On the day of the survey, 10/13/2023 at 12:10 pm, review of the laboratory's QC records revealed the laboratory failed to document QC monitoring activities for intended reactivity each day of patient testing for histopathology slide examinations stained using H&E for the following 7 of 38 days from 07/01/2022 to 10 /31/2022: - 07/25/2022 - 07/26/2022 - 07/27/2022 - 08/29/2022 - 08/30/2022 - 08/31 /2022 - 10/05/2022 2. The HT confirmed the finding above on 11/13/2023 at 01:00 pm.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records, and interview with the histotechnologist (HT), the TS failed to assess the competency for 6 of 7 TP through external proficiency testing samples or internal blind testing samples for mycology and parasitology microscopic examinations performed in 2022. Findings include: 1. On the day of survey, 11/13/2023 at 11:31 am, review of TP competency assessment records revealed annual competencies performed in 2022 did not include the assessment of external proficiency testing samples or internal blind testing samples for 5 of 6 TP (CMS 209 personnel # 2, #4, #5, #6 , #7, and #8) who performed mycology and parasitology microscopic examinations in 2022. 2. The laboratory could not provide separate competency assessment records for mycology and parasitology testing performed by each TP. 3. The HT confirmed the finding above on 10/12/2022 at 01:00 pm.