Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2069206	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lackawanna Valley Dermatology Assoc Ltd	440 Pierce Street, Kingston, 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
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 Clinical Coordinator, the laboratory failed to establish a written policy to assess the competency of 3 of 4 clinical consultants (CC) and 7 of 9 Testing Personnel (TP) for their responsibilities in 2022 and 2023. Findings Include: 1.On the day of the survey, 02/15/2024 at 10:17 am, the laboratory could not provide a competency assessment policy to assess the competency of the following personnel for 2022 and 2023: - 3 of 4 CC (CMS 209 personnel #2, #3, #4) for their supervisory responsibilities. - 7 of 9 TP (CMS 209 personnel #2, #3, #4, #5, #6, #7, #8) who performed potassium hydroxide (KOH), Dermatophyte screen and Scabies microscopic examinations. 2. The Clinical Coordinator confirmed the findings above on 02/15/2024 at 11:18 am. *Repeat deficiency
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 the laboratory's Microbiology procedure manual and interview with Clinical Coordinator, the laboratory failed to provide a complete test procedure for potassium hydroxide (KOH) and scabies microscopic examinations performed from 01/06/2022 to the day of survey. Findings include: 1. On the day of the survey, 02/15/2024 at 9:47 am, review of the laboratory's Microbiology procedure manual revealed the laboratory's test procedures for KOH and Ectoparasites (Scabies) did not include the following: - Quality control processes - Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. The Clinical Coordinator confirmed the above findings on 2/15/2024 at 11:18 am.
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 the laboratory's quality control (QC) log, Mohs procedure manual and interview with Clinical Coordinator, the laboratory failed to establish criteria for intended reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains used in Histopathology from 01/06/2022 to the date of survey. Findings include: 1. On the day of survey, 02/15/2024 at 11:00 am, a review of H&E QC logs and the laboratory's "Quality Control for the day" procedure revealed the laboratory did not establish or document criteria for intended reactivity to ensure acceptable H&E staining characteristics when Histopathology slides were examined from 01/06/22 to 02/15/24. 2. The laboratory reported an annual test volume of 1774 for histopathology. (CMS 116) 3. The Clinical Consultant confirmed the findings above on 02/15/24 at 11:18 am.