Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0940659	10/20/2021
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
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 review of competency assessment records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory failed to establish a complete competency assessment procedure to assess the competency of TP at 6 months and 12 months during the first year of employment and perform competency assessment on TP analyzing Mohs microscopic examinations from 2019 to the day of survey. Findings Include: 1. On the day of survey, 10/20/2021, the laboratory could not provide a written procedure that states to assess TP for competency at 6 months and 12 months during the first year of employment. 2. The laboratory could not provide the following records. - TP #5 - Potassium hydroxide (KOH) and Scabies 6 month and 12 month competency. - TP #8 - KOH and Scabies 6 month and 12 month competency. - TP #4 - Mohs competency annual competency for 2019, 2020 and 2021. - TP #9 - Mohs competency annual competency for 2019, 2020 and 2021. 3. The medical assistant/ clinical coordinator and TP #9 confirmed the findings above on 10/20/2021 around 10:00 am.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of peer review records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory failed to ensure 1 of 2 high complexity TP performed verification of accuracy for Mohs microscopic examinations in 2020. Findings Include: 1. On the day of survey, 10/20/2021, the laboratory could not provide verification of accuracy or peer review records for 1 of 2 high complexity TP (TP #2) for Mohs microscopic examinations performed in 2020. 2. The medical assistant/ clinical coordinator and TP #9 confirmed the finding above on 10/20/2021 around 12:00 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 quality control records and interview with Medical Assistant/ Clinical Coordinator and testing personnel (TP) #9, the laboratory failed to perform document quality control (QC) each day of patient testing for potassium hydroxide (KOH) and Scabies microscopic examinations analyzed in 2019, 2020 and 2021. Findings include: 1. On the day of survey, 10/20/2021, review of KOH and scabies QC records revealed, each physician analyzing KOH and scabies microscopic examination were not documenting QC each day of patient testing on the following days: - 2019: 10/31. - 2020: 1/23, 6/12, 7/21, 10/27 and 10/28. - 2021: 1/21, 1/28, 3 /16, 3/22, 5/10, 5/13, 5/26, 6/14, 6/24, and 6/30. 2. The Medical Assistant/ Clinical Coordinator and TP #9 confirmed the findings above on 10/20/2021 around 09:40 am. *** Repeat deficiency from 3/19/2019 inspection.
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 Hematoxylin and Eosin (H&E) quality control (QC) records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory failed to document H&E QC stain acceptability each day of patient testing for Mohs micrographic examinations from 10/20/2019 to the day of survey. Findings include: 1. On the day of survey, 10/20/2021, review of the H&E stain QC log revealed, daily H&E QC records did not state if QC intended reactivity was acceptable and QC was not performed and documented by the physician analyzing the Mohs microscopic examination from 10/20/2019 to 10/20/2021. 2. The medical

	assistant/ clinical coordinator and TP #9 confirmed the finding above on 10/20/2021 around 11:35 am.
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 quality control records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory failed to check and document each batch or shipment of Acuderm Inc. Acu (DTM) media for sterility, its ability to support growth, select or inhibit specific organisms or produce a biochemical response, from 2019 to the date of survey. Findings Include: 1. On the day of survey, 10/20/2021, the laboratory could not provide end user QC performed on the Acuderm Inc. Acu (DTM) media for sterility, its ability to support growth, select or inhibit specific organisms or produce a biochemical response from 10/20/2019 to 10/20/2021. 2. In 2019 (10/20/2021 to 12/31/2021): 45 DTM tests were examined. 3. In 2020: 192 DTM tests were examined. 4. In 2021 (01/01/2021 to 10/20/2021): 146 DTM tests were examined. 5. The medical assistant/ clinical coordinator and TP #9 confirmed the finding above on 10/20/2021 around 10:45 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory director failed to ensure 1 of 3 PT events received, identified problems that require corrective actions in 2020. Findings include: 1. On the day of survey, 10/20/2021, review of the API PT records revealed, the laboratory did not perform or document corrective actions for 1 of 3 API events (Mycology, event #2 score 80%) in 2020. 2. The medical assistant/ clinical coordinator and TP #9 confirmed the finding above on 10/20/2021 around 10:15 am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the laboratory director (LD) failed to ensure QA programs were maintained to assure the quality of laboratory services provided from 10/20/2019 to 10/20/2021. Findings Include: 1. On the date of survey, 10/20/2021, review of monthly QA documents revealed the following QA activities were signed by the LD, but were not filled out and performed in 2019, 2020 and 2021: - October, November and December of 2019. - 12 of 12 months of 2020. - February, March and April of 2021. 2. The medical assistant/ clinical coordinator and TP #9 confirmed the findings above on 10/20/2021 around 9: 30 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 the review of testing personnel (TP) competency assessment records, review of peer review records and interview with the medical assistant/ clinical coordinator and testing personnel (TP) #9, the technical consultant failed to assess the competency of all (2 of 5) TP through internal blind testing samples or external PT samples for Dermatophyte Test Medium (DTM) testing in 2020. Findings Include: 1. On the day of survey, 10/20/2021, review of TP competency assessment records and peer review records revealed the laboratory did not assess test performance through internal blind testing samples or external PT samples for 2 of 5 TP performing DTM testing in 2020. 2. The medical assistant/ clinical coordinator and TP #9 confirmed the finding above on 10/20/2021 around 10:10 am.