Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0940659	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Lackawanna Valley Dermatology Assoc	**Street Address, City, State** 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
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 Mohs proficiency testing procedure, review of Mohs proficiency records and interview with the Clinical coordinator and Testing personnel (TP) #10, the laboratory failed perform at least twice annually the accuracy for Mohs slide reading from 08/24/2017 to the date of survey. Findings Include: 1. The laboratory's Proficiency Testing Procedure states "every 6 months, there will be 5 random cases pulled and reviewed..). 2. On the day of survey, 03/19/2019, review of Mohs peer review records revealed, the laboratory did not perform Mohs proficiency at least twice annually in 2017, 2018 and 2019. 3. TP # 10 confirmed the findings above on 03/19/2019 around 11:15 am.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the Mohs laboratory's records and interview with Clinical

coordinator and Testing personnel (TP) # 10, the laboratory failed to document all general laboratory systems quality assessment activities from 2017 to the date of survey. Findings include: 1. On the day of survey, 03/19/2019, the Mohs laboratory could not provide documentation of quality assessment activities, that assess the quality of the Mohs laboratory systems from 08/24/2017 to 03/19/2019. 2. The Clinical coordinator and TP #10 confirmed the finding above on 03/19/2019 around 11:50 am.

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 clinical coordinator and testing personnel (TP) #10, the laboratory failed document Quality control (QC), each day of patient testing for KOH and Scabies examinations in 2018 and 2019. Findings include: 1. On the day of survey, 03/19/2019, review of KOH and scabies QC records revealed, that physicians performing KOH and scabies examination were not documenting QC at the beginning of each day of patient testing on the following days: - 2018: 08/27, 09/11, 10/04, 10/17, 10/25, 10/30, 10/31 and 11/13. - 2019: 01/22, 02/11, 02/22, 03/08, 03/11, 03/15 and 03/19. 2. The clinical coordinator confirmed the findings above on 03/19/2019 around 13:15 pm.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the Dermatophyte Test Medium (DTM) room temperature logs and interview with the Clinical Coordinator and Testing personnel (TP) #10, the laboratory failed to document corrective actions taken when DTM room temperature readings exceeded the acceptable ranges from 2017 (27 of 54 days) to 2018 (24 of 238 days). Findings include: 1. On the day of survey, 03/22/2019, review of the DTM 2nd floor room temperatures logs revealed, the acceptable temperature range (68 degrees Fahrenheit to 86 degrees Fahrenheit), were exceeded: a. 27 of 54 days from August 25th, 2017 to December 31st, 2017. b. 24 of 238 days from January 1st, 2018 to December 31st, 2018. 2. On 03/19/2019 around 12:50 pm, the clinical coordinator confirmed the laboratory did not document the corrective action taken for exceeded DTM room temperatures from August 25th, 2017 to December 31st, 2018.
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 competency assessment records, proficiency testing (PT) records and interview with the clinical consultant and testing personnel (TP) # 10, the Technical Consultant failed to assess the competency of 4 of 7 TP through internal blind testing samples or external PT samples for DTM, KOH and Scabies examination in 2017 and 2018. Findings Include: 1. On the day of survey, 03/19/2019, review of the laboratories PT records, revealed the laboratory did not assess the test performance of 4 of 7 TP through internal blind testing samples or external PT samples in 2017 and 2018. 2. TP#10 confirmed the finding above on 03/19/2019 around 12:00 pm. ***KOH = Potassium Hydroxide ***DTM = Dermatophyte Test Medium