

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2069206	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Lackawanna Valley Dermatology Assoc Ltd	Street Address, City, State 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of the American Proficiency Institute (API) proficiency testing (PT) records for Mycology and interview with the Clinical Coordinator, the Laboratory failed to provide 4 of 6 API PT attestation statement documents from 2020 and 2021. Findings include: 1. On the day of survey, 1/6/2022 at 11:50 a.m., the Clinical Coordinator could not provide the the following: - 2020: Attestation statement: Event #1 and Event #3. - 2021: Attestation statement: Event #2 and Event #3. 2. The Clinical Coordinator confirmed the finding above on 1/6/2022 at 12:00 p.m.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with Clinical Coordinator, the laboratory failed to have a policy to assess the competency of 3 of 4 laboratory personnel who performed the Clinical Consultant (CC) roles and 5 of 6 Testing Personnel (TP) who performed potassium hydroxide (KOH), Dermatophyte Screen, and Scabies from 01/06/2020 to the date of survey. Findings include: 1. On the day of survey, 01/06/2022 at 10:20 a.m., the Clinical Coordinator could not provide a competency assessment policy to assess the competency of the following</p>

personnel from 01/06/2020 to the date of survey: - 3 of 4 CC (on CMS 209, listed as personnel #2 , #3 and #4) - 5 of 6 TP (on CMS 209, listed as personnel #2, #3, #4, #5, and #6) 2. The laboratory could not provide competency assessments for 3 of 4 CC. 3. The laboratory could not provide separate competency assessments for each analyte for 5 of 6 TP who performed KOH, Dermatophyte Screen, and Scabies for 2020 and 2021 . 4. The Clinical Coordinator confirmed the findings above on 01/06/2022 around 12: 00 p.m.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory and interview with Clinical Coordinator, the laboratory failed to calibrate 1 of 1 room temperature thermometer where Dermatophyte Test Medium (DTM) is incubated and 1 of 1 digital Thermofisher refrigerator thermometer where DTM is store from 01/06/2020 to the day of survey. Findings include: 1. On the day of survey, 01/06/2022 at 12:00 p.m., while touring the laboratory the surveyor observed the following thermometers were due for calibration: - 1 of 1 Fisher Scientific Traceable refrigerator thermometer was due for calibration on December 04, 2017. - 1 of 1 Big digit Hyro-thermometer Extech instrument for room temperature thermometer was not calibrated from 01/06/2020 to the day of survey. 2. The Clinical Coordinator confirmed the findings above on 01/06/2022 at 12: 30 pm

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 clinical coordinator, 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 01/06/2020 to the date of survey. Findings Include: 1. On the day of survey, 01/06/2022, 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 1/06/2020 to 01/06/2022. 2. In 2020: 35 DTM tests were examined. 3. In 2021: 79 DTM tests were examined. 4. The clinical coordinator confirmed the finding above on 01/06/2022 around 12:30 pm.