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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0190154 | (X3) Date Survey Completed 08/09/2018 |
| Name of Provider or Supplier Lehigh Valley Dermatology Assoc | Street Address, City, State 940 North New Street, Bethlehem, 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 |
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| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Cryostat temperature records and interview with Testing Personnel #6 (TP#6), the laboratory failed to record the internal temperature of the 2 of 2 cryostats used for Dermatopathology from 2017 to the date of survey. Findings Include: 1. On the day of survey, 08/09/2018, review of Cryostat temperature records revealed that temperature records for each day of patient testing were marked off for 2 of 2 cryostats, but no daily temperature record was documented. The reference range for the cryostats is -20 to -30 degrees Celsius. 2. In 2017, 475 Mohs cases were performed. 3. In 2018 (01/01/2018 to 08/09/2018), 280 Mohs cases were performed. 4. TP #6 confirmed the finding above on 08/09/2018 around 10:00 am.</p> |
| D6053 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> |

This STANDARD is not met as evidenced by:

Based on review of personnel competency assessment records and interview with the Testing Personnel (TP) #6, the Technical Consultant failed to evaluate and document the performance of 1 of 5 testing personnel (TP#5) for their semi-annually competency during the first year of potassium hydroxide (KOH) testing. Findings include: 1. On the day of survey, 08/09/2018, the laboratory was unable to produce TP#5's semi-annually competency assessment record for their first year of KOH testing. 2. During the interview on 08/09/2018, around 09:30 am, TP#6 confirmed that TP#5 was hired January of 2017 and their first competency assessment was performed November 2017, but no competency assessment was performed at the semi-annual requirement the first year of testing.