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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D1104449 | (X3) Date Survey Completed 06/25/2019 |
| Name of Provider or Supplier Kinnelon Dermatology Associates | Street Address, City, State 135 Kinnelon Road Suite 103, Kinnelon, NJ | |
| 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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| 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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP) via telephone, the laboratory failed to evaluate competency accurately on one of one TP from 6/29/17 to the date of the survey. The findings include: 1. The laboratory failed to use the CA evaluation tools accurately as follows: a. Document review was used to assess: 1. Does not discuss patients results outside the laboratory 2. Performance of Mohs frozen sections 3. Insures adequate grossing of specimen 4. Cuts satisfactory cryostat specimens 5. Stains slides and coverslips adequately 6. Files Mohs frozen sections 7. Direct observation 8, Maintains reagents 9. Keeps reagents fresh and filtered. 10. Disposes of reagents properly 11. Maintains equipment 12. Assures appropriate maintenance of same 13. Contacts repair person when needed 14. Safety issues 15. Maintains universal precautions 16. Troubleshooting problem solving ability 17. Work completed in a timely manner 18. Slide quality b. Direct observation was used to assess: 1. Patient confidentiality. 2. Does not discuss patient results outside the laboratory 3. Assures appropriate maintenance of same 4. Keeps current safety regulations 5. QC records reviewed 2. One section of the CA indicated the TP was reviewed and achieved competency by direct observation and document review but did not state what was observed or reviewed. 3. Direct observation of instrument maintenance was not assessed. 4. The TP stated via telephone on 6/26/19 at 9:30 am the laboratory did not uses the CA evaluation tools accurately.</p> |
| D5401 | PROCEDURE MANUAL |

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel via telephone (TP), the laboratory failed to follow the Quality Assurance (QA) procedure for Histopathology tests from 6/29/17 to 12/8/18. The finding includes: 1. The PM stated "All QC logs will be checked, signed and dated as each page is completed to make sure all the recorded data are within limits" but there was no documented evidence QC pages were signed when completed. 2. The TP confirmed via telephone on 6/26/19 at 9:30 am that the laboratory did not follow the PM.