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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>31D0861298 | <b>(X3) Date Survey Completed</b><br>09/13/2018 |
| <b>Name of Provider or Supplier</b><br>Gary Karakashian Md Pa  | <b>Street Address, City, State</b><br>2640 Route 70, Manasquan, NJ     |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D3041</b>              | <p><b>RETENTION REQUIREMENTS</b><br/>CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have accurate retention policy from 9/27/16 to the date of survey. The finding includes: 1. The Biopsy PM stated to retain pathology reports for seven years but the regulation requires for 10 years. 2. The LD stated on 9/13/18 at 10:00 am that he was not aware of retention requirements.</p> |
| <b>D5805</b>              | <p><b>TEST REPORT</b><br/>CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Final Report (FR) and interview with the Laboratory</p>  |

Director (LD), the laboratory failed to ensure that the FR included all the required information from 9/27/16 to the date of survey. The findings include: 1. The Mohs maps and Biopsy reports in the patients' charts did not have the address of the facility where testing was performed. 2. The Biopsy reports did not have the "Report Date". 3. The LD confirmed on 9/13/18 at 10:30 am that FR did not have all the required information.