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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>24D0974198                   | <b>(X3) Date Survey Completed</b><br><br>03/04/2020 |
| <b>Name of Provider or Supplier</b><br><br>William R Kennedy Laboratory  | <b>Street Address, City, State</b><br><br>516 Delaware St Se, Rm 12-231 Pwb, Minneapolis, MN |   |
| 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>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>                     . Based on document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of a Histopathology test procedure at least twice annually in 2018 and 2019. Findings are as follows: 1. The laboratory performed peripheral nerve imaging and count under the specialty of Histopathology as confirmed by the Histology Technician (HT) during a tour of the laboratory at 1:05 p.m. on 03/04/20. 2. A process to verify the accuracy of the testing was not established in the Skin Biopsy Processing Manual. 3. Documentation of twice annual verification of testing accuracy was not found for 2018 and 2019 during review of laboratory records. The laboratory was unable to provide verification documentation upon request. 4. In an interview at 2:50 p.m. on 03/04/20, the HT confirmed the above finding.</p> |
| <b>D5481</b>              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/>                     . Based on document review and interview with laboratory personnel, the laboratory</p>  |

failed to document Histopathology quality control (QC) performance in 2018 and 2019. Findings are as follows: 1. The laboratory performed peripheral nerve imaging and count under the specialty of Histopathology as confirmed by the Histology Technician (HT) during a tour of the laboratory at 1:05 p.m. on 03/04/20. 2. The Clinical Biopsy Immunostaining Standard Operating Procedure, located in the Skin Biopsy Processing Manual, indicated quality control assessment was performed using sections 1 and 2 of the first slide for every patient. 3. Documentation of the quality control assessment was not included in laboratory records or the patient test reports from 2018 and 2019 reviewed on date of survey. 4. In an interview at 3:00 p.m. on 03/04/20, the HT confirmed the above finding.