Peripheral Neuropathy Detection

DPNCheck®
Peripheral Neuropathy Detection
Overview

DPNCheck is a fast, accurate, and quantitative test to evaluate peripheral neuropathies. DPNCheck is designed for use at the point of care to detect and stage peripheral neuropathies. The device measures nerve conduction velocity and response amplitude of the sural nerve in the lower leg. These parameters are sensitive and specific biomarkers for peripheral neuropathy.

Point-of-care test of sural nerve conduction
- Standard biomarker for peripheral neuropathy
- Sensitive and specific
- Quantitative assessment of nerve function
- Identifies pre-clinical peripheral neuropathy

Easy operation
- 30-60 seconds per test
- Easily implemented in the clinic or home setting by medical assistants or other staff
- Reports standard, readily understood nerve conduction parameters
- Embedded quality control to ensure integrity of results

Testing in 4 Easy Steps

1. Position patient, prepare skin
2. Place biosensor, and apply conductive gel
3. Position device, start test
4. 10-15 seconds later get results

TEST RESULTS AND DOCUMENTATION
The DPNCheck generates two values, sural nerve conduction velocity and response amplitude. Interpretation is straightforward with established normal limits. Optional reporting software is included and provides either a PDF report, or HL7 and XML files for EMR integration.
Clinical Challenges of Peripheral Neuropathy

**PREVALENCE**
- The prevalence of peripheral neuropathy in the general population is 10% and in patients over 65 it increases up to 30\% \(^1\)
- Over 50% of patients with diabetes will develop neuropathy\(^2\)
- The rate of diagnosed neuropathy is often much lower than the prevalence rate resulting in unidentified risk

**DETECTION & DIAGNOSIS**
- Traditional screening tools often miss peripheral neuropathy\(^1\) and do not provide quantitative results or severity staging
- Peripheral neuropathy often has no clear signs or symptoms\(^2\)
- Up to 50% of diabetic peripheral neuropathies may be asymptomatic\(^2\)

**COMPLICATIONS**
- Sensory loss leads to unrecognized skin trauma
- Peripheral sensory neuropathy is a compounding factor in fall risk in the elderly\(^4\)
- Decreased quality of life
- Increased hospitalization rates\(^5\)

**Benefits of Nerve Conduction**
- The gold standard diagnostic test for neuropathy
- Early neuropathy detection, definitive diagnosis
- Quantitative and objective
- Assess severity of neuropathy

**Care Management**

**MEDICAL MANAGEMENT**
- Metabolic modifications (blood glucose, nutritional deficiencies)
- Identification and elimination of toxins
- Pain management

**PREVENTATIVE MANAGEMENT**
- Routine foot care
- Podiatry referrals
- Fall prevention programs
Validation

The accuracy, reliability and utility of DPNCheck has been established with over 30 studies published in peer-reviewed journals. The following table addresses sensitivity and specificity.

**DPNCHECK DETECTS PERIPHERAL NEUROPATHY WITH HIGH SENSITIVITY AND SPECIFICITY**

<table>
<thead>
<tr>
<th>Study Publication</th>
<th>Type 2</th>
<th>Type 1</th>
<th>No Diabetes</th>
<th>Total</th>
<th>Reference Diagnosis</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
<tr>
<td>Binns-Hall et al. 2018</td>
<td>231</td>
<td>5</td>
<td>0</td>
<td>236</td>
<td>Clinical</td>
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<td>0.68</td>
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<tr>
<td>Papanas et al. 2019</td>
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<td>0</td>
<td>53</td>
<td>Clinical</td>
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<td>0.93</td>
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<tr>
<td>Chatzikosma et al. 2016</td>
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<td>0</td>
<td>46</td>
<td>160</td>
<td>Clinical</td>
<td>0.91</td>
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<tr>
<td>Hirayasu et al. 2018</td>
<td>92</td>
<td>0</td>
<td>0</td>
<td>92</td>
<td>Clinical</td>
<td>0.85</td>
<td>0.86</td>
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<tr>
<td>Lee et al. 2014</td>
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<td>16</td>
<td>0</td>
<td>44</td>
<td>NCS</td>
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<tr>
<td>Kural et al. 2018</td>
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<td>0</td>
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<td>0.85</td>
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<tr>
<td>Scarr et al. 2018</td>
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<td>68</td>
<td>71</td>
<td>139</td>
<td>NCS</td>
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<td>0.79</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>633</strong></td>
<td><strong>142</strong></td>
<td><strong>117</strong></td>
<td><strong>892</strong></td>
<td></td>
<td><strong>0.88</strong>*</td>
<td><strong>0.82</strong>*</td>
</tr>
</tbody>
</table>

*Summary sensitivity and specificity determined by bivariate meta-analysis.

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