DPNCheck®

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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.

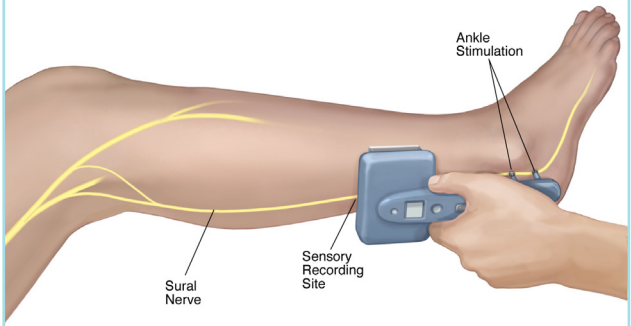
Point-of-care test of sural nerve conduction

- 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

SURAL NERVE CONDUCTION



DPNCheck stimulates the sural nerve at the ankle and records the resulting response on the calf.

Testing in 4 Easy Steps

Position patient, prepare skin

Place biosensor, and apply conductive gel

Position device, start test

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 25%[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[3] 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 25 studies published in peer-reviewed journals. The following table addresses sensitivity and specificity.

DPNCHECK DETECTS DIABETIC PERIPHERAL NEUROPATHY WITH HIGH SENSITIVITY AND SPECIFICITY

Study Publication	Type 2	Type 1	No Diabetes	Total	Reference Diagnosis	Sensitivity	Specificity
Binns-Hall et al. 2018	231	5	0	236	Clinical	0.84	0.68
Papanas et al. 2019	0	53	0	53	Clinical	0.96	0.93
Chatzikosma et al. 2016	114	0	46	160	Clinical	0.91	0.86
Hirayasu et al. 2018	92	0	0	92	Clinical	0.85	0.86
Lee et al. 2014	28	16	0	44	NCS	0.95	0.71
Kural et al. 2018	168	0	0	168	NCS	0.82	0.85
Scarr et al. 2018	0	68	71	139	NCS	0.86	0.79
Total	**633**	**142**	**117**	**892**		**0.88***	**0.82***

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

1. Mold JW, Vesely SK, Keyl BA, Schenk JB, Roberts M. The prevalence, predictors, and consequences of peripheral sensory neuropathy in older patients. *J Am Board Fam Pract.* 2004;17(5):309-318.
2. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic neuropathy: a position statement by the American Diabetes Association. Diabetes Care. 2017;40(1):136–154
3. Perkins et al. Simple Screening Tests for Peripheral Neuropathy in the Diabetes Clinic. Diabetes Care. 24:250-256, 2001
4. Richardson JK, Hurvitz EA. Peripheral neuropathy: a true risk factor for falls. *J Gerontol A Biol Sci Med Sci.* 1995 Jul;50(4):M211-5.
5. Romanelli RJ, Shah SN, Ikeda L, Lynch B, Craig TL, Cappelleri JC, Jukes T, Ishisaka D. Patient characteristics and healthcare utilization of a chronic pain population within an integrated healthcare system. *Am J Manag Care.* 2017 Feb 1;23(2):e50-e56.

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