Finding a path in neuropathy treatment.

NOVADX Reditus LABORATORIES

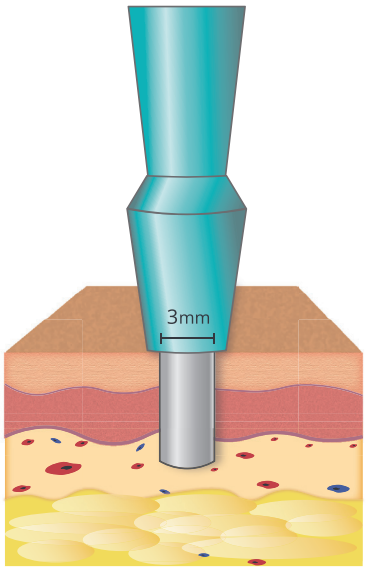
Skin Test for Small Fiber Neuropathy

WHAT IS ENFD TESTING?

Epidermal Nerve Fiber Density (ENFD) testing is a highly sensitive, skin biopsy, used to identify Small Fiber Neuropathy (SFN). SFN is a disorder of the peripheral nerves that affect small somatic fibers, autonomic fibers, or both, resulting in sensory changes and or autonomic dysfunction when both types of fibers are involved. ENFD testing is the most reliable tool and considered the "Gold Standard for Testing" when diagnosing SFN.[1] ENFD testing provides a definitive diagnosis, which assists the provider in treating and monitoring the prescribed regimen.

HOW IS THE SKIN PUNCH BIOPSY PERFORMED?

The biopsy is minimally invasive and performed using a 3 mm punch tool. The patient's skin is anaesthetized with 2% lidocaine with epinephrine, which alleviates the pain during the biopsy. The procedure takes the provider approximately 90 seconds to perform, with the entire procedure taking about 10 -15 minutes. Samples are placed in Zamboni tubes and shipped in pre-paid packaging. The biopsy sites are covered with a bandage and do not require any special treatment. A training video is available for review at novadx.com.



Essential steps while obtaining a punch biopsy:

1. Standard biopsy locations include:
   - Proximal Arm - Lateral surface midway between acromion and the elbow
   - Distal Arm - Upper surface of the forearm, 5 cm above the wrist
   - Proximal Thigh - 10 cm below greater trochanter
   - Distal Thigh - 10 cm above the lateral joint line of the knee
   - Calf - 10 cm below the lateral joint line of the knee
   - Ankle - 5 cm to 10 cm above the lateral malleolus
   - Foot - Dorsum of the foot, in the extensor digitorum brevis muscle belly
2. The biopsy is performed using a 3 mm circular punch.
3. The punch tool should be used by a rotational motion with even pressure into the epidermis to avoid distortion of the epithelium.
4. The biopsy samples are placed in Zamboni tubes to preserve the tissue.

[1]Peripheral Neuropathy Fact Sheet", National Institute of Health Neurological Disorders and Stroke, Publication date: August 2018. NIH Publication No. 18-NS-4853.

Services Offered

- √ **Biopsy kits and pre-labeled shipping packages at no cost.**
- √ **Detailed reports are available within 10-14 days of testing.**
- √ **Board Certified pathologists are available for consultation.**
- √ **The laboratory offers direct billing to patient insurance plans.**

CITED BENEFITS

- The diagnostic efficiency of skin biopsy is approximately 88%.
- For diagnosing SFN, it is more sensitive than quantitative sensory testing and more sensitive and less invasive than sural nerve biopsy.
- ENFD provides a definitive diagnosis for SFN.
- Aggressive cause-specific treatment, lifestyle modifications, and pain control are key elements of managing SFN.

Medical Conditions Associated with Small Nerve Neuropathy:

- Diabetes Mellitus
- Prediabetes Mellitus
- Metabolic Syndrome
- Connective Tissue Disease
- Vitamin B12 Deficiency
- Human Immunodeficiency Virus (HIV)
- Neurotoxin Drug Exposure
- Celiac Disease
- Hereditary Diseases
- Alcohol Abuse

APPROPRIATE PATIENTS FOR ENFD TESTING ARE:

Patients presenting with pain, numbness, and paresthesia, are appropriate for ENFD testing. Additionally, patients with diabetes mellitus, prediabetes, metabolic syndrome, fibromyalgia, autoimmune diseases, alcohol abuse, and idiopathic neuropathy are candidates, based on their presenting symptomatology. NovaDX offers an assessment survey to assist in the screening process to identify appropriate patients for the skin punch biopsy.

TREATMENT PLAN BASED ON ENFD TESTING?

Confirming the diagnosis of SFN will allow the provider to evaluate possible underlying etiologies efficiently, and aggressively manage the symptoms. Etiology-specific treatment is crucial in preventing SFN and or slowing its progression. Glucose control, weight control, well-balanced diets, regular exercise, physical therapy, vitamin supplements, prescription drugs, avoiding exposure to toxins and limiting or avoiding alcohol are components of the treatment regimen for SFN.

WHO WE ARE & WHAT WE DO

NovaDX is an in-network histopathology laboratory, located in Templeton, California partnering with Reditus Labs to offer ENFD testing. At NovaDX, Zeiss Axio Microscopes are used to provide state-of-the-art magnification and display for our pathologists. Our reflected light microscopes feature AxioVision technology to provide the highest standard of magnification available. We strive to provide timely results with exceptional customer service. Our goal is to assist in early detection of SFN allowing healthcare professionals to provide early intervention, maintain the health of the patient, and reduce overall healthcare costs.

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