

Epidermal Nerve Fiber Density Testing Specimen Procedure and Submission




BakoDx ENFD Kit Contents

- AccuPunch complete disposable kit for skin biopsy procedures containing:
 - 1x Curved Scissors
 - 2x Gauze Pads
 - 1x Disposable Forceps
 - 1x Povidone Iodine Prep Pad
 - 1x Alcohol Prep Pad
 - 1x Adhesive Bandage
 - 1x CSR Wrap
- Zamboni's Fixative (orange cap: vial No. 1)
- Phosphate Rinse (clear cap: vial No. 2)
- Cryoprotectant (blue cap: vial No. 3)
- Rise Procedure Instruction Sheet
- Biohazard Specimen Bag
- BakoDx ENFD Requisition Form
- ENFD Medical Necessity Card
- Leakproof Nontoxic Ice Pack
- Styrofoam Cooler
- FedEx Clinical Pak (or UPS Laboratory Pak) with Prepaid Shipping Label

BakoDx ENFD Requisition Form

- A** Your office information will be pre-printed here, including provider names, office address, phone and fax numbers. If any information is missing/incorrect/requires updating, please call your Bako Account Manager.
- B** Fill out sections or write "see attached" if attaching patient insurance info. If attaching, provide a copy of both sides of insurance and attach patient demographic/face sheet containing patient billing information.
- C** Include Patient Symptomology. i.e. "Rule Out Neuropathy".
- D** **Important: These sections must be completed. For each specimen, include the patient initials, date of birth, and anatomical site location (Right or Left Calf) on Vial No. 3, the Requisition Form, and bio bag.**

EPIDERMAL NERVE FIBER DENSITY REQUISITION FORM																																							
 Bako Diagnostics 6240 SHILOH ROAD ALPHARETTA, GA 30005 PH: 877-376-7284 • FAX: 770-475-0533		PHYSICIAN/CLINIC INFORMATION <div style="border: 1px solid black; padding: 5px; text-align: center; font-size: 2em; color: white; background-color: #e0e0e0;"> LAB USE ONLY </div>																																					
PATIENT INFORMATION LAST NAME: D FIRST NAME: _____ M.I.: _____ STREET ADDRESS: _____ APT. # _____ CITY: _____ STATE: _____ ZIP CODE: _____ PHONE NUMBER: _____ DATE OF BIRTH: D / ____ / ____ AGE: ____ SEX: ____ PATIENT ID: _____ BILL: <input type="checkbox"/> INSURANCE <input type="checkbox"/> PATIENT																																							
BILLING/INSURANCE INFORMATION (Attach a copy of primary / secondary insurance cards – both sides) SUBSCRIBER NAME/RELATIONSHIP TO SUBSCRIBER: <input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Dependent INSURANCE NAME: _____ MEMBER ID: B ADDRESS: _____ GROUP/CONTRACT #: _____ CITY: _____ STATE: _____ ZIP: _____																																							
ICD-10 CODE <input type="checkbox"/> G60.8 (Other hereditary idiopathic neuropathies) D <input type="checkbox"/> G60.9 (Hereditary and idiopathic neuropathy, unspecified) <input type="checkbox"/> Other _____		CLINICAL INFORMATION C																																					
DATE COLLECTED: ____ / D / ____ TIME COLLECTED: D : ____ AM PM REPEAT BIOPSY <input type="checkbox"/> Shipped in: <input type="checkbox"/> Zamboni's/#1 (24-hr maximum exposure) <input type="checkbox"/> Cryoprotectant/#3 (after >8 hours Zamboni's fixation and rinse) **For specimen fixation and rinsing techniques video instruction is available at www.bakodx.com Indicate Test Selected: <input type="checkbox"/> Epidermal Nerve Fiber Density (ENFD) <input type="checkbox"/> ENFD and Amyloid Stain* In Cases of Lymphoma, Myeloma, Familial Amyloidosis, Etc.																																							
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PHYSICIAN SIGNATURE The requested test(s) is/are medically indicated for patient management. I authorize Bako Diagnostics to bill my insurance. <div style="display: flex; justify-content: space-between;"> D SIGNATURE REQUIRED DATE: ____ / ____ / ____ </div>																																							
<small>SPECIMEN CONTAINER MUST INCLUDE PATIENT NAME, SITE AND BARCODED LABEL. REQ. VERSION 040418 14942</small>																																							

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PERFORMING THE ENFD PUNCH BIOPSY PROCEDURE

The most studied ENFD biopsy location is the lower lateral leg at 10cm proximal to the lateral malleolus as normative values have been established at this location.

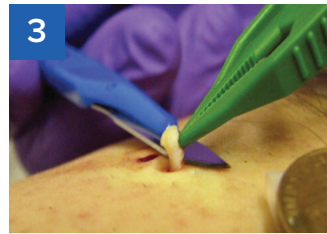
IMPORTANT: Avoid traumatizing the epidermal surface, even minor trauma may make the biopsy difficult or impossible to interpret.



1
Mark biopsy site then prep with alcohol wipe. Infiltrate lidocaine with epinephrine proximal to, but not directly at the biopsy site, using an inverted "V" pattern. Finish prepping surface with iodine wipe.



2
Perform 3mm punch biopsy. Softly push the punch instrument down while rotating back and forth, allowing blade to "do the work." Enter the skin to the level of the subcutis, cutting through the epidermis and dermis.



3
Gently remove biopsy specimen. When removing the biopsy specimen, use atraumatic forceps. Carefully grasp the biopsy deep to the surface epithelium. **Be gentle and avoid crushing the surface epithelium.**

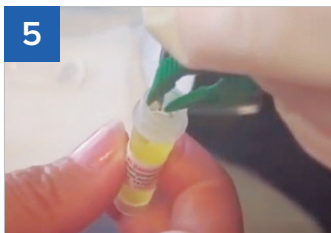


4
Biopsy Completed. Apply hemostatic agent, topical antibiotic, gauze, and bandage to the biopsy site. Primary closure with nonabsorbable monofilament suture can also be utilized in place of secondary intention.

PROCESSING THE ENFD PUNCH BIOPSY SPECIMEN FOR SUBMISSION

Processing the specimen for ENFD submission is different from a routine punch biopsy. Punches taken for ENFD cannot be placed in formalin. The specimen requires fixation in Zamboni's fixative for 8 hours, but not more than 24 hours. If left in contact with the specimen for more than 24 hours, the ENFD test may be compromised.

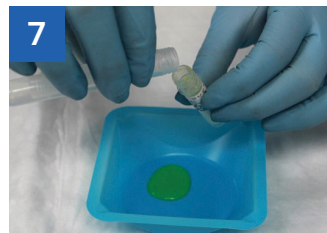
NOTE: Rinse is not required if shipped same day in Zamboni's fixative. See processing steps below.



5
Immediately place specimen in yellow Zamboni's fixative. Verify sample is floating in prior to sealing securely. Note: After this step, if specimen is sent same-day, proceed to step 9.



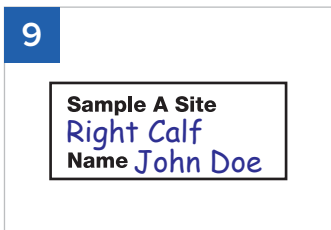
6
If same-day shipping is unavailable, in-office rinse is necessary. After a minimum of 8 hours in refrigerator (but no more than 24 hours), pour out Zamboni's into secondary tray, keep specimen in vial. Refill with buffer rinse.



7
Pour out, repeat buffer, rinse, and pour out.



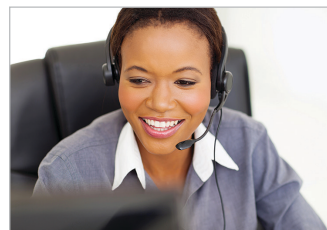
8
Refill with cryoprotectant, screw on blue cap tightly.



9
Label vials with appropriate patient and body site stickers from provided BakoDx Requisition form.



10
Shipping option via FedEx or UPS prepaid overnight shipping (use cool-pack and Styrofoam cooler).



For help, call BakoDx at 855-422-5628.

WATCH PROCEDURAL VIDEO ONLINE:



Scan code above to watch ENFD procedural video. More at: bakodx.com/learn