

Cleveland Clinic Cutaneous Nerve Laboratory

Skin Biopsy Specimen Collection, Shipping, Processing, Reporting, and Billing Protocol (2/15/2021)

Cleveland Clinic Cutaneous Nerve Laboratory is a clinical diagnostic lab, which holds a valid CLIA license (ID:36D1018561). We offer a commercial test to referring physicians and hospitals to accept skin biopsy specimens for PGP 9.5 immunostaining and intra-epidermal nerve fiber density evaluation. To control the quality of this service, the guidelines listed below should be followed by all referring physicians and hospitals.

Note: Control values are generated for an adult population.
We do not have pediatric control values.

1) Skin biopsy kit:

The package contains a 3-mm biopsy punch, scalpel, forceps, ice packs, specimen tubes filled with Zamboni's fix solution and labeled *distal leg* and *distal thigh*. Zamboni's fix solution is stable at room temperature for up to a year. Expiration date is labeled on tubes.

Effective 2/15/2021, standard biopsy protocol has been reduced to 2 biopsy sites.
This change does not significantly alter sensitivity or specificity.

2) Authorization/Billing:

We request that the enclosed **Skin Biopsy Referral Form** be faxed one week prior to the biopsy date, so we can register the patient and verify their insurance.

Laboratory personnel will attempt to clarify any unclear or unreadable information on referral forms with the referring provider or their representative. If we are unable to confirm or verify necessary information, a kit will not be provided.

Laboratory personnel will verify that the requesting provider has a current license to practice as appropriate.

3) Skin biopsy specimen collection:

- Positively identify patient prior to specimen collection.
- Place the patient in a lateral position.

- Identify 2 standard biopsy sites on one leg: distal leg (10 cm above the lateral malleolus) and distal thigh (7 cm above the knee, lateral).
- Clean the biopsy sites with alcohol swabs and numb the areas with local anesthesia (**1% lidocaine or 1% lidocaine with Epinephrine to reduce bleeding**)
- Perform the skin biopsy using a 3-mm punch going down 2/3 of the punch in depth.
- Remove biopsy specimens using a surgical blades and forceps technique (**do not pinch epidermis**).
- Put each specimen into a tube containing Zamboni's fix solution immediately after removing it and tighten lids. The tube should be labeled with patient's name, DOB, and biopsy side and site (e.g. left distal leg) in the presence of the patient.
- Seal specimen tubes in plastic specimen bag with absorbent material.
- Refrigerate specimens until ready to ship. Use ice packs when shipping specimens.
- Licensed Independent Provider must sign and date the enclosed **Skin Biopsy Referral Form**. You can also download the Referral Form from the website.

4) Skin biopsy specimen shipping:

Please ship specimens using enclosed ice packs **via priority overnight delivery either by UPS or FedEx the same day as the biopsy is performed in the original kit box.**

Attn: Dr. David Polston
Cutaneous Nerve Laboratory
Neuromuscular Center, Cleveland Clinic
9500 Euclid Ave/TT3-05
Cleveland, OH 44195.

- Please include the signed and completed **Skin Biopsy Referral Form**.
- Please apply enclosed "Perishable" and "Human Specimen" stickers to shipping box.
- Please contact us via phone or email with the Tracking Number and shipping date and include patient's name and date of birth in the subject line.
- Please **do not** ship specimens on **Friday, weekends, or holidays**

5) Specimen processing:

- Upon receiving specimens, Dr. Polston or Dr. Li will do a gross examination. **Damaged, over-fixed, or poorly labeled specimens will be rejected.**
- Skin biopsy specimens will be processed and PGP 9.5 immunostaining will be performed per our protocol.

6) Reporting:

The original copy of the biopsy report will be faxed to the referring physician generally 2 weeks after the biopsy.