Cleveland Clinic Cutaneous Nerve Laboratory

Skin Biopsy Specimen Collection, Shipping, Processing, Reporting, and Billing Protocol (1/12/2012)

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 intraepidermal nerve fiber density evaluation. To control the quality of this service, the guidelines listed below should be followed by all referring physicians and hospitals.

1) Skin biopsy preparation:

Please contact our lab, Dr. David Polston or Sherry Zhao (216-444-4131) to inform us about the biopsy, and we will send you the biopsy kit overnight via express mail. The kit contains a 3-mm biopsy punch, scalpel, forceps, specimen tubes filled with 2% PLP fix solution and labeled distal leg, distal thigh, and proximal thigh, 0.08M Sorenson’s phosphate buffer, and cryoprotectant solution. The 2% PLP fix solution should be used fresh, within 2 days after making.

2) Skin biopsy specimen collection:

a) Place the patient in a lateral position.
b) Identify 3 standard biopsy sites in one leg: distal leg (10 cm above the lateral malleolus), distal thigh (7 cm above the knee, lateral), and proximal thigh (7 cm below the hip, lateral).
c) Clean the biopsy sites with alcohol swabs and numb the areas with local anesthesia.
d) Perform the biopsy using a 3-mm punch.
e) Remove biopsy specimens using a surgical blades and forceps technique (do not pinch epidermis).
f) Put each specimen into a tube containing 2% PLP fix solution immediately after removing it. The tube should be labeled with patient’s name, DOB, and biopsy side and site (e.g. left distal leg). Fix specimen overnight at 4°C but no more than 24 hours.

g) Fill out the Skin Biopsy for Neuropathy Specimen Referral Form included in the biopsy kit or download from: http://my.clevelandclinic.org/neuromuscular_center/services/cutaneous_nerve_laboratory.aspx
h) Wash specimens with 0.08M Sorenson’s phosphate buffer 3 times and 10 minutes each at room temperature.

i) Remove Sorenson’s phosphate buffer from each tube and fill the tube with cryoprotectant solution and ship.

3) Skin biopsy specimen shipping:

   The specimens should be **shipped at room temperature with icepacks overnight via express mail** to the Cleveland Clinic Cutaneous Nerve Laboratory (Attn: Dr. David Polston, Cleveland Clinic Cutaneous Nerve Laboratory, Cleveland Clinic, 9500 Euclid Ave/TT3-05, Cleveland, OH 44195). The completed Request Form should be included. Please do not ship specimens on Friday, weekends, or holidays. You may call (216-444-5353 or 216-444-4131) to check our schedule. The specimens can be kept in the cryoprotectant solution for as long as 7 days.

4) Specimen processing:

   a. Upon receiving the specimens, Dr. David Polston will do a gross examination. **Damaged, over-fixed, or poorly labeled specimens will be rejected.**

   b. Skin biopsy specimens will be processed and PGP 9.5 immunostaining will be performed per our protocol.

5) Reporting:

   a. The biopsy will be interpreted and the biopsy report will be generated within 2 working days after finishing PGP 9.5 immunostaining. The original copy of the biopsy report will be mailed and/or faxed to the referring physician within 2-3 weeks after the biopsy.

6) Billing:

   a. Cleveland Clinic will contact the patient’s insurance carrier to obtain insurance approval prior to a skin biopsy kit being mailed. This process may take up to 2 business days. For any billing questions, please call 216-444-2407.