THERAPATH

Therapath
545 West 45th Street
New York, NY 10036
800-681-4338
www.therapath.com

PATIENT: **Sample, Report** **ACCESSION NUMBER:** **S08-00002**

PATHOLOGY REPORT

PATIENT: **SAMPLE, REPORT** **ACCESSION NUMBER:** **S08-00002**

D.O.B: 02/10/1961 *AGE:* 48 *SEX:* F
PHYSICIAN: Test Physician
COPY TO:

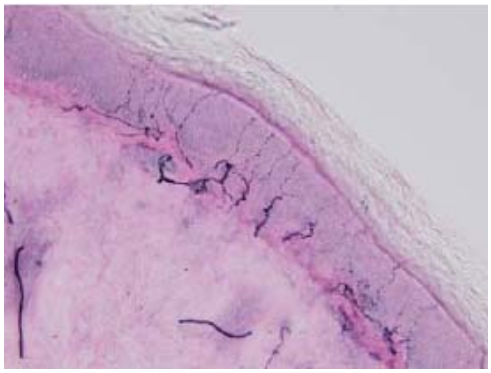
DATE COLLECTED: 04/14/2008
DATE RECEIVED: 04/15/2008
DATE REPORTED: 04/22/2008

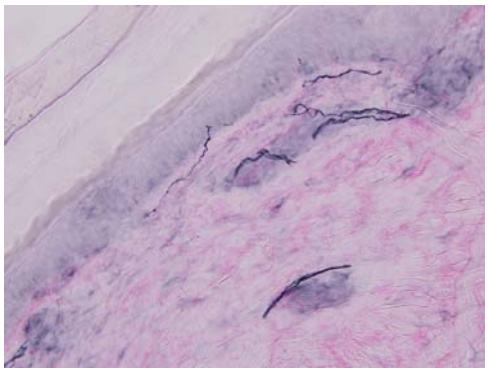
Clinical History: 356.0, 709.3 R/O Small Fiber Neuropathy

DIAGNOSIS:

A. Lt Thigh, Epidermal Nerve Fiber Density: **Skin with normal epidermal nerve fiber density.**

B. Lt Calf, Epidermal Nerve Fiber Density: **Skin with significantly reduced epidermal nerve fiber density, consistent with small fiber neuropathy**





Each image above is magnified 400X and represents 3-4% of the total epidermis examined by the pathologist.

MICROSCOPIC DESCRIPTION:

A. From the samples that have been tested, there is no evidence of vasculitis or other histological abnormalities based on the H & E stain. No amyloid is detected by the Congo Red stain. Both of these disorders are very focal and this analysis does not exclude the diagnosis.

B. From the samples that have been tested, there is no evidence of vasculitis or other histological abnormalities based on the H & E stain. No amyloid is detected by the Congo Red stain. Both of these disorders are very focal and this analysis does not exclude the diagnosis.

EPIDERMAL NERVE FIBER DENSITY TEST:

Specimen	Result Value	ABNORMAL	LOW NORMAL
A. Lt Thigh	8.7	< 6.8	6.8 -8.0
B. Lt Calf	0.66	< 5.4	5.4 -5.7

THERAPATH

Therapath
545 West 45th Street
New York, NY 10036
800-681-4338
www.therapath.com

PATIENT: Sample, Report **ACCESSION NUMBER: S08-00002**

GROSS DESCRIPTION:

A. Specimen received fixed in 2% PLP in one vial labeled "Lt Thigh". It consist of a soft tan punch biopsy of skin, measuring 0.3 cm in diameter by 0.3 cm.

B. Specimen received fixed in 2% PLP in one vial labeled "Lt Calf". It consist of a soft tan punch biopsy of skin, measuring 0.3 cm in diameter by 0.1 cm.

Electronic Signature

Therapath MD

INTERPRETATION OF RESULTS:

The epidermal nerve fiber density (ENFD) of each sample is determined by using the published counting rules (Lauria G et al. Eur J Neurol 2005; 12:1-12 and Kennedy WR et al. in Dyck PJ, Thomas PK (eds) Peripheral Neuropathy. 4th ed. Philadelphia: WB Sanders, 2004. pp 869-95. The analysis is performed by counting the number of epidermal fibers that cross the basement membrane, counting 5 separate tissue sections. The total number of fibers is divided by the length of the epidermis in the five sections, giving the ENFD (fibers per millimeter length of epidermis).

The ENFD is compared to the values in specimens from normal control subjects determined by Therapath. The lower limit of normal (95% confidence interval) for ENFD is 6.8 at the thigh, 5.4 at the calf, and 3.1 at the foot. Lower ENFD values are considered to be significantly decreased and consistent with the diagnosis of small fiber neuropathy.

Values that are in the low normal range (90% confidence interval), may be suspicious for early or mild neuropathy. These range between 6.8 to 8 at the thigh, 5.4 to 5.7 at the calf, and 3.1 to 4.5 at the foot.

On occasion, the ENFD can be normal, but morphological examination reveals structural abnormalities such as axonal swelling or excessive branching. These are considered to be pre-degenerative changes that are also associated with small fiber neuropathy (Lauria et al, J Neurol Sci 1999; 164: 172-8; Lauria et al, Neurology 2003; 61: 631-6).

In length dependent neuropathies, the ENFD is more severely reduced at the level of the calf or foot than at the thigh, consistent with the distal accentuation. A greater reduction of the ENFD at the thigh than the calf may indicate the presence of a multifocal sensory neuropathy or sensory neuronopathy (Chai et al, Neurology 2005; 65: 925-7).

The presence of normal ENFD does not by itself rule out a diagnosis of small fiber neuropathy. A reduced ENFD also does not indicate a particular cause for the neuropathy or predict a response to therapy. The diagnosis and treatment of any medical condition depends on the patient's clinical presentation and results of all laboratory investigations as interpreted by the physician.

This test was developed and its performance characteristics determined by Therapath LLC. Therapath is licensed under the Clinical Laboratory Improvement Amendments of 1998 (CLIA) to perform epidermal nerve fiber density testing. Therapath LLC. has performed assay validation studies and has developed its laboratory protocols and operating procedures in accordance with the standards of the National Committee on Clinical Laboratory Standards (NCCLS).

CPT CODES: 88305x2, 88356x2, 88342x2, 88314x2 **OTHER CODES:** 59x4