

HEALTH-CHEM DIAGNOSTICS LLC

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FOOT HEALTH *Diabetic Neuropathy Tester*



An aid in the early detection of Peripheral Diabetic Neuropathy

Diabetic Neuropathy – Overview

People with diabetes need to take special care of their feet. Neuropathy and blood vessel diseases, both increase the risk of foot ulcers. The nerves to the feet are the longest in the body and are most often affected by neuropathy. Because of the loss of sensation caused by neuropathy, sores or injuries to the feet may not be noticed and may become ulcerated.

Diabetic Neuropathy can cause insensitivity or a loss of ability to feel pain, heat and cold. Diabetics suffering from neuropathy can develop minor cuts, scrapes, blisters, or pressure sores that they may not be aware of due to the insensitivity.

Up to 60% of diabetics may experience neuropathy. It is estimated that 1 out of every 6 patients with neuropathy will develop foot ulcers and of those, 1 in 6 will eventually require amputation.

The **Health-Chem Foot Health Test** is an easy to use, rapid test, which determines the ability of the skin to “breathe normally”. The upper layer of normal human skin tissue (*stratum corneum*), is porous allowing internal moisture to permeate.

The loss of micro-capillary circulation associated with Diabetic Neuropathy may cause the upper level of the skin to thicken and become impermeable, preventing normal transmission of moisture through the stratum corneum.

The **Health-Chem Foot Health Test** is an accurate and sensitive moisture detector, which may provide an early sign of developing Neuropathy. While restrictive moisture transmission may be an early sign of Diabetic Neuropathy, this test is not intended to be used in the diagnosis of any disease. Only a physician, equipped to perform more specific diagnostic procedures, can make a proper diagnosis.

New and better understandings of the mechanisms leading to nerve fiber degeneration, has recently resulted in development of successful prevention and treatments of Diabetic Neuropathy.

Early detection is a key to the prevention and treatment of this debilitating disorder.

Description of the Test (How the Health-Chem Diabetic Neuropathy Tester Works)

The **Health-Chem Foot Health Test** is composed of a medical grade adhesive foam. Three (3) circular detection areas encapsulates 3 different, highly specific Cobalt Chloride based moisture detectors. Simply remove the adhesive backing and affix the detector to the sole of the feet for 10 minutes. The device forms a pocket which traps humidity, allowing the chemistry to detect normal skin permeation. The 3 circular indicators will change color based on different humidity conditions, indicating moisture transmission as normal or possibly impaired. *Indicative* or *Predictive* results, should be brought to your Doctor’s attention for more sensitive and accurate electronic detection.

- **Easy to Use & Convenient:** You can test any time of the day.
- **Fast Results:** Provides results in as little as 10 minutes.
- **Unmistakable Results:** Provides an easy-to-read color comparison.
- * **Safe:** No chemistry is in direct contact with the skin
- **For *in vitro* diagnostic use only.**
- **Do not take any part of this test internally.**
- **Keep out of the reach of children.**
- **Read all instructions before performing the test.**

Before You Begin

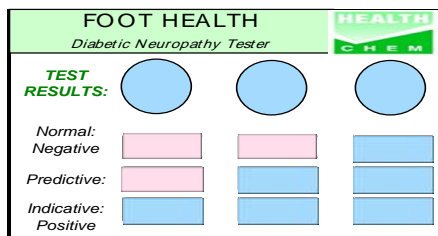
1. Read the entire instructions carefully. Do not open the foil packets until you are ready to perform the test.
2. Select a well-lighted room. Make sure you have a timer or clock within view and a comfortable bed or couch to put the feet up and keep them comfortable for the duration of the test.
3. Do not use this test if the soles of the feet have cuts, blisters, visible irritation, or if any abnormal skin condition exists.

Instructions for Testing

1. Remove socks and shoes, drying any perspiration from the soles of the feet. Allow 5 minutes for the soles of the feet to become air dry before applying the **Foot Health Test**
2. Remove each Tester from its foil pouch applying separately to the soles of both feet. Try to avoid any built-up calloused area. One tester should be applied to each foot. **Note: All three (3) circles should be Blue at the time of application.**
3. Note the time of each application and wait exactly 10 minutes.
4. After 10 minutes, reading from left to right through the label side, observe the colors of each of the reagent circles and compare with the rectangular label colors. For ease of reading, testers may be removed from the feet at the end of 10 minutes and read immediately. **Important Note:** Once testers are removed from the feet, they will continue to change due to humidity in the air and therefore, must be read immediately.

Interpreting Your Results

(See illustration below, reading from left to right)



Read test results in circles and compare to rectangular color blocks

Normal (Negative): Test position #1 & #2 change to Pink in color as per the rectangular illustration. Note: Test position #3 may also be pink or changing, particularly if your foot is prone to sweating or the test is performed in a highly humid (not air-conditioned) area.

Predictive: Test position #1 has changed to Pink, but test position #2 & #3 are still Blue at the end of 10 minutes, as per the above rectangular illustration. Skin permeation is slightly below normal limits, and should be retested after several days and if duplicated, reported to your Physician.

Indicative (Positive): All test positions remain Blue, indicating abnormal skin permeation. This condition should be immediately reported to your Physician and is an early indication of conditions which may lead to Neuropathy. Your Physician has several more accurate electronic devices for quantitative assessment of small nerve fiber dysfunction.

If You Have A Question

If you have a question about the instructions or your test results, please view the Health-Chem® website for assistance at <http://www.healthchemdiagnostics.com>, or call our Help Line at 1.800.482-2907. Our technical staff will gladly answer your questions.

Storage conditions and Shelf life

The contents of the test kit should be stored at room temperature 5°C–30°C (68-85°F).

The shelf life of the test is 24 months from production date. Unopened product stored at room temperature (5-30°C) is stable for at least 18 months (and as much as 24 months). Do Not Use after the expiration date shown on the package.

Limits of the Test

The **Health-Chem Foot Health Test** is not reusable. The test works only if the instructions are followed precisely. It should be noted that the **Health-Chem Foot Health Test** determines relative humidity, based on skin permeation. This is one of the conditions that may be caused by Peripheral Neuropathy. While indicative, it may be possible that neuropathy may exist with normal skin moisture permeation. If you are experiencing loss of sensation, pain or any other symptoms, consult your Physician.

While restrictive moisture transmission may be an early sign of Diabetic Neuropathy, this test is not intended to be used in the diagnosis of any disease. Only a physician, equipped to perform more specific diagnostic procedures, can make a proper diagnosis.

It is recommended that the **Health-Chem Foot Health Test** be used on both feet at least, every 6 months, to gain the benefit of early detection.

While the test may be performed on children, Diabetic Neuropathy is usually a late finding in Type I (juvenile) diabetes, but it can be an early finding in Type II diabetes. Strict glycemic control and good daily foot care are key to preventing complications of diabetic neuropathy.

The Tester must be freshly removed from its pouch before performing the test. Do Not Use unless all three (3) results circles are Blue when removed from the foil pouches. The components of this test may be discarded as normal household waste.

A review article: DIABETIC NEUROPATHIES, a statement by the American Diabetes Association is available. See Diabetic Care, 2005 Apr, 28(4); 956-62

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