

DUOTIP-TEST® II

Duotip-Test II is a sterile, disposable, plastic bifurcated needle used to administer skin test substances. When employed with allergenic extracts it provides a quick, convenient and standardized procedure that is well accepted by patients. Before using Duotip-Test II, or any testing device, the administrator must study carefully the package inserts accompanying allergenic extracts and control solutions.

The Duotip-Test II system consists of these components:

1. The sterile disposable applicator (Fig. 1).
2. The Dipwell Tray and its protective lid (Fig. 2).

Each tray consists of forty wells into which extracts and controls are placed. Points of individual Duotip-Test II units are immersed into test solutions and pick up test doses via capillary attraction. **See Dipwell Tray package insert for complete instructions on its use with Duotip-Test II.**

Directions for Use: Duotip-Test II will administer test solutions via modified prick procedure (Fig. 3) or by rotation technique (Fig. 4).

When using either approach, these steps must be followed after cleansing skin and loading the points:

1. Modified Prick - Hold gripping area of device so its shaft forms an approximate 45° angle with the skin plane. Prick and lift skin simultaneously **with one point**.
2. Rotation Technique - Hold gripping area between index finger and thumb. Press points vertically against skin with enough pressure to **slightly** indent skin. Maintain pressure on skin while rotating shaft clockwise or counter-clockwise.

With either procedure allow test solutions to remain over test sites three to five minutes before wiping.

Reading Results: Because patients differ in response to mechanical and chemical stimulation of the skin, interpretations of test results are most reliable when positive (glycerinated histamine) and negative (glycerosaline) controls are used. Response to histamine (1mg/ml) is considered 3+, while response to glycerosaline is considered negative.



Figure 1

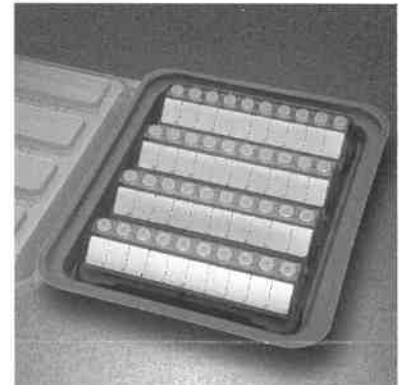


Figure 2



Figure 3

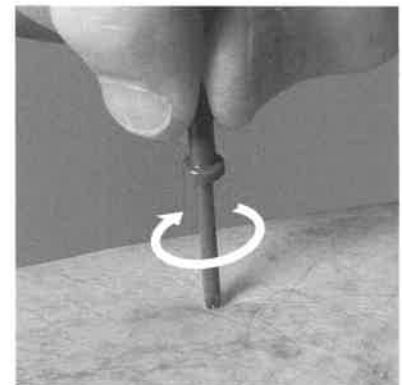


Figure 4

Diagnostic extract sites are graded against positive and negative controls. Histamine results and results from negative controls and diagnostic extracts are read fifteen to twenty minutes after administration. Positive reactions to diagnostic extracts can occur up to thirty minutes following administration. Use of histamine provides information on whether or not a patient's ability to react adequately to extracts is being impaired by drugs or other causes. Typical reactions from Duotip-Test II, **rotation technique**, are as follows:

- No wheal or a wheal no larger in size than that produced at the negative control site. Erythema absent or area of erythema no larger than area of erythema occurring at the negative control site.
- 1+ Wheal may or may not be present. If present, wheal must be as large or larger than negative control. Area of erythema significantly larger than area of erythema at negative control site.
- 2+ Wheal 5mm. to 6mm. and area of erythema usually larger than 10mm.
- 3+ Wheal 7mm. to 9mm. and area of erythema usually larger than 20mm. Slight pseudopodia and itching may occur.
- 4+ Any reaction with a wheal larger than 9mm. or pronounced pseudopodia. Area of erythema may or may not be larger than that of a 3+ reaction. Pseudopodia and itching are likely to occur.

The above information is a guide to reading, but skin test results are not a substitute for carefully compiled allergic history and physical examination. Adults usually exhibit 7mm. to 9mm. wheals (3+) from properly administered histamine, **via rotation technique**, unless ability to react is impaired. Unimpaired histamine reactions in young children may not exceed 5 mm.-6mm. wheals. Reactions comparable to those from negative controls are negative regardless of size. **Modified prick test reactions may be smaller than those from rotation technique and are graded against histamine (3+) and negative controls.** Convenient recording forms are available on request.

⚠ CAUTION: Sterility of Duotip-Test II is guaranteed only when the container seal is unbroken. Duotip-Test II will not withstand heat sterilization or exposure to alcohol, ether or acetone. Attempts to resterilize can result in transmission of blood-borne diseases. Repeated use of a single device may produce inaccurate test results.

⚠ CAUTION: All cautions and precautions contained in package inserts for allergenic extracts must be observed.

⚠ CAUTION: All cautions and precautions contained in package inserts for histamine must be observed.

⚠ CAUTION: Federal Law restricts this device to use by or on the order of a physician.

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LINCOLN DIAGNOSTICS, INC.