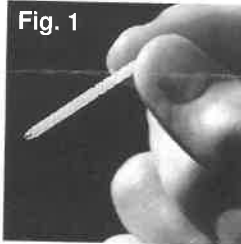


# DUOTIP-TEST®

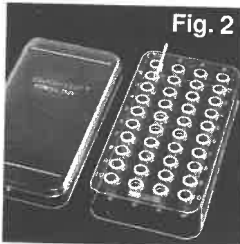
Duotip-Test is a sterile, disposable, plastic bifurcated needle used to administer skin test substances. When employed with allergenic extracts it provides a quick, convenient and standardized procedure that is well accepted by patients. Before using Duotip-Test, or any testing device, the administrator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

The Duotip-Test system consists of these components:

1. The sterile, disposable applicator (Fig. 1).



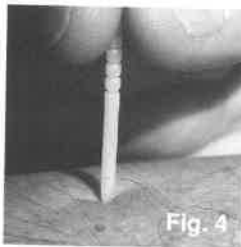
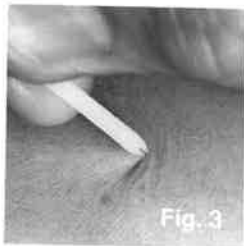
2. The Dipwell Tray and its protective cover (Fig. 2).



Each tray consists of forty wells into which extracts and controls are placed. Points of individual Duotip-Test 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.

**Directions for Use:** Duotip-Test 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 device so its shaft forms an approximate 45° angle with the skin plane. Prick and lift skin simultaneously.
2. **Rotation Technique** – Hold shaft 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 360°.

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 their skin, interpretations of test results are most reliable when positive (histamine) and negative (glycerosaline) controls are used. Response to histamine (1 mg/ml) is considered 3+, while response

to glycerosaline is considered negative. Diagnostic extract sites are graded against positive and negative controls. Histamine results are read fifteen to twenty minutes after administration. 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. 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, 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 10mm. 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. Record actual size.

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 unless ability to react is impaired. Unimpaired histamine reactions in young children may not exceed 5mm.-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 is guaranteed only when the unit container seal is unbroken. Duotip-Test will not withstand heat sterilization or exposure to alcohol, ether, or acetone. Attempts to resterilize can result in transmissions 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

STERILE R



CE 2797

**LINCOLN DIAGNOSTICS, INC.**

**240 E. Hickory Pt. Rd. Decatur, Illinois 62526 USA**

Printed in U.S.A.

March 2020