

## UNITEST® PC

Unitest PC is a sterile, disposable, plastic skin test device used to administer skin test substances. When employed with allergenic extracts it provides a quick, convenient and standardized procedure that is virtually painless. Before using Unitest PC, or any testing device, the administrator must study carefully the package inserts accompanying allergenic extracts and control solutions.

The Unitest PC 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 Unitest PC 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 Unitest PC.**

**Directions for Use:** Unitest PC administers test solutions via prick puncture procedure (Fig. 3).

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

1. Contact skin with touch post (vertical to the skin) for one second, and then press Unitest PC **firmly** into the skin.
2. Enough pressure must be employed to produce a skin puncture pattern as seen in Fig. 4.

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

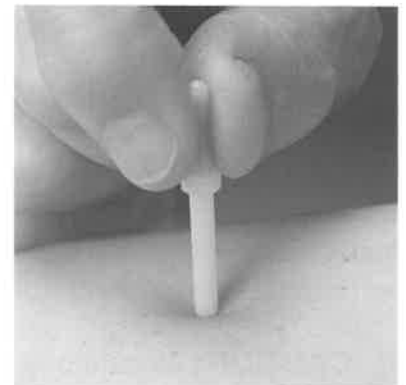


Figure 3

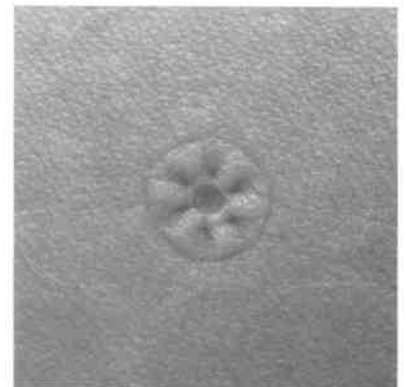


Figure 4

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 (1mg/ml) 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 Unitest PC 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 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 often 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, at a concentration of 1mg/ml, 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. Convenient recording forms are available on request.

**⚠ CAUTION:** Sterility of Unitest PC is guaranteed only when the container seal is unbroken. Unitest PC 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 will produce inaccurate test results. Discard after use - DO NOT RE-USE.

**⚠ 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.

Supplied: Box of 400 sterile devices containing ten individual packages of 40 each. Stock No. UT-400.

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**LINCOLN DIAGNOSTICS, INC.**

## **WARNING**

If the touch post on each test head of the UniTest PC is not brought into contact with the skin for one second before pressing the points into the skin, the alleviation of pain may not be realized. Be sure to read the package inserts that are found in each box.

Lincoln Diagnostics, Inc.