

Recording of results should be done on forms provided by suppliers of allergenic extracts, on forms designed to meet the specific needs of individual practices, or on convenient MULTI-TEST II recording forms supplied by Lincoln Diagnostics.

**⚠ CAUTION:** The sterility of MULTI-TEST II is guaranteed only when the seal of the individual unit container is unbroken. The plastic MULTI-TEST II unit 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 result in inaccurate test results.

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

**⚠ CAUTION:** All cautions and precautions contained in the package insert for histamine phosphate must be observed.

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

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Printed in U.S.A.

June 2020

## MULTI-TEST® II

MULTI-TEST II is a sterile, disposable, multiple test head applicator used to administer skin test substances. When used to apply allergenic extracts it provides a quick, convenient, and standardized procedure. Before employing allergenic extracts with MULTI-TEST II or any testing device, the user should be completely familiar with the information contained in the package insert accompanying the extracts.

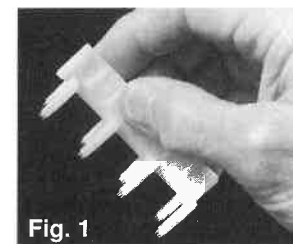


Fig. 1

The MULTI-TEST II system for applying diagnostic allergenic extracts consists of these components:

1. The sterile disposable applicator. See Figure 1.
2. The Dipwell Tray and its protective lid. See Figure 2.

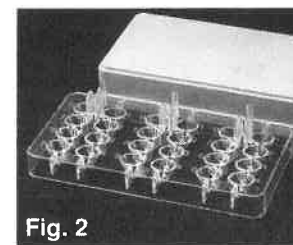


Fig. 2

### DIRECTIONS FOR USE

#### Loading MULTI-TEST II with Allergenic Extracts

1. Remove each sterile MULTI-TEST II device from its container by grasping the sealed label at the blue dot and pulling it off. See Figure 3.
2. Place MULTI-TEST II applicator into the Dipwell Tray containing extracts and control solutions. See Figure 4. The test heads of the device are numbered 1 through 8. The wells of the Dipwell Tray are also numbered 1 through 8. Each time a new MULTI-TEST II device is placed into its Dipwell Tray, test head No. 1 goes into well No. 1, test head No. 2 into well No. 2 and likewise for all test heads and well positions, numbers 1 through 8. This occurs each time because MULTI-TEST II will fit into the Dipwell Tray in only the correct position. **See Dipwell Tray package insert for complete instructions on its use with MULTI-TEST II.**



Fig. 3

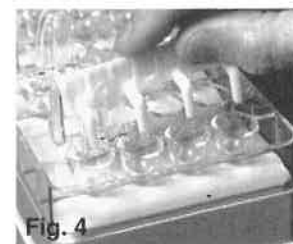


Fig. 4

#### Administration of Allergenic Extracts with MULTI-TEST II

With the points of all eight test heads properly loaded, MULTI-TEST II is used as follows:

1. Select only testing sites that will permit sufficient surface area and sufficient subcutaneous tissue to allow adequate penetration of all points on all eight test heads. The preferred sites are the volar

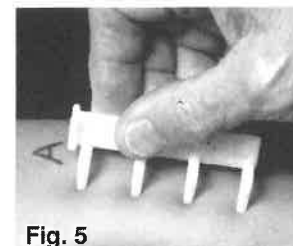


Fig. 5

surfaces of each arm and the back. Skin of the posterior thighs may be used if necessary. Avoid hairy areas whenever possible since the reactions are more difficult to interpret in these areas. Cleanse sites with alcohol, ether, or acetone and allow to dry.

2. Point the "T-bar" end of the MULTI-TEST II toward a constant reference point such as the head of the subject being tested and press the loaded unit into the skin with sufficient pressure to allow adequate penetration of the points. Pointing the "T-bar" toward a constant reference point greatly reduces any possibility of incorrectly identifying the extract (or control) applied at each test site. See Figure 5. **With proper pressure, a distinct puncture pattern from the points will be observed at each test site.** If the skin is taut, less pressure is required to gain proper penetration of points. With proper pressure, bleeding rarely occurs. In some cases the contour of the testing area may be such that **slight** "rocking" of the MULTI-TEST II unit will be required to gain adequate and uniform penetration of points from all test heads. For example, particular attention must be given to proper penetration of points on test heads No. 4 and No. 5 when the volar surface of the forearm is used, because these two test heads will be closest to the wrist over an area where the contour of the forearm narrows. A "feel" for using MULTI-TEST II properly is gained quickly after just a few applications. It is desirable to visually check each test site to be sure that adequate point penetration has been achieved.
3. Make an identification mark such as A, B, C on the skin at the "T-bar" end of the testing device. Results are then read in a clockwise manner, starting at test site No. 1 that will always be in the one o'clock position. If, for example, three test batteries are used, battery A is read from test site 1 through 8, battery B from test site 1 through 8, and battery C likewise. As pointed out earlier, this procedure provides a high degree of accuracy in relating test extracts (or controls) to test site results.
4. Discard MULTI-TEST II after one use. **DO NOT REUSE.** Discard in accordance with all local, state and federal regulations.

## READING AND RECORDING MULTI-TEST II RESULTS

Because patients differ in their response to mechanical and chemical stimulation of the skin, interpretations of skin test results are most reliable when positive (histamine) and negative (glycerosaline) controls are used. It is preferred that testing be conducted so that positive and negative controls are applied at the same time and in the same general location as the diagnostic extracts. The response to histamine (1mg./ml.) is considered a 3+ reaction, while the response to glycerosaline is considered negative. The diagnostic extract test sites are graded against the positive and negative control sites. Reading of positive control results **is conducted 15 minutes following administration**, while reading of results from the negative controls and diagnostic extracts **is done 15 to 20**

**minutes after their administration.** However, positive reactions to diagnostic extracts can occur up to 30 minutes following administration. It should be noted that the use of histamine as a positive control also provides information as to whether or not the patient's ability to react adequately to diagnostic extracts is being impaired by use of drug products or other causes.

Typical reactions from the MULTI-TEST II technique are as follows:

- Negative 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. It should be noted that all scratch and prick type instruments do, on some patients, cause a wheal or erythema, or both, at the negative control site. Wheals may range in size from a barely detectable 1-2mm. to a well defined 5mm. Area of erythema may range from a faint 1-2mm. to a clearly defined 10mm. or larger. **THEREFORE, READING ALL TEST RESULTS AGAINST THE NEGATIVE CONTROL IS IMPERATIVE.**
- 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 7mm. and area of erythema usually larger than 10mm.
  - 3+ Wheal 7mm. to 10mm. 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.

**NOTE:** The above information is not absolute, but serves as a guide to reading MULTI-TEST II reactions. Readings should always be made against positive and negative controls. Almost all adults exhibit 7 to 10mm. wheals (3+) from properly administered histamine (1mg./ml.) unless their ability to react is impaired by use of drug products or other causes. Unimpaired histamine reactions in young children will often not exceed 6mm. wheals. Histamine wheal reactions less than 7mm. should not be considered 3+. Reactions comparable to those from negative controls are negative regardless of size.

A POSITIVE SKIN TEST REACTION TO ANY ALLERGENIC EXTRACT MUST BE INTERPRETED IN LIGHT OF THE PATIENT'S HISTORY OF SYMPTOMS, TIME OF THE YEAR, KNOWN EXPOSURES, AND EATING HABITS. SKIN TEST RESULTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFULLY COMPILED ALLERGIC HISTORY. THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

## NOTICE

1. Standard diagnostic allergens commonly used at concentrations of 1:10 and 1:20 (or standardized equivalents) in 50% glycerin are employed with Multi-Test, Multi-Test II and Multi-Test PC. When used with these concentrations, Multi-Test products are superior in diagnostic reliability to the intradermal technique, utilizing skin testing concentrations of 1:1000 or greater. See package inserts for grading reactions from Multi-Test products.
2. To gain optimal results from Multi-Test, Multi-Test II and Multi-Test PC, it is essential that the points of each test head be properly loaded and that the device be applied with sufficient pressure. Carefully read package insert instructions on loading and administration.
3. Test head spacing allows adjacent wheals of 20 mm. in diameter before coalescence occurs. Wheals from Multi-Test products are rarely 20 mm., but in subjects highly sensitive to antigenically related extracts, such as some grasses, wheals larger than 20 mm. can occur. Such extracts should be adequately separated during administration.