

## Important Notes for Duotip-Test<sup>®</sup> Users

Lincoln Diagnostics, Inc.

1. Medications- the same guidelines for all skin testing methods apply to Duotip-Test in regard to such medications as anti-histamines, anti-depressants, and beta-blockers. The patient must be free of any medications that suppress skin test whealing.
2. Pressure and comfort- the rotation technique is used by many, but reliable results are realized with the modified-prick method as well. With the modified-prick method, it is important to "catch" the patient's skin with only one point. With the 'Rotation Technique,' only enough pressure is needed to create a small fold or wrinkle in the skin. Bleeding should not occur and discomfort is minimal with either technique.
3. Extract and Controls- you must use undiluted non-standardized or standardized glycerinated extracts, usually at 1:10 or 1:20 w/v, or equivalent potency with standardized extracts. Glycerinated controls for the Duotip-Test come in 5ml dropper bottles and the histamine must be 1mg/ml strength, that is, 2.75 mg histamine phosphate per ml. Intradermal strength positive and negative controls are not to be used.
4. Reading Reactions- reactions to glycerinated histamine peak at about 17 minutes, but remain well defined at 20 minutes. Antigen reactions can be read between 15 and 20 minutes as can the negative control. At 20 minutes, non-specific irritant responses have subsided at negative sites and *therefore we recommend reading all test sites at 20 minutes.*
5. Extract Usage and Sterility- Duotip-Test provides approximately 3,000 test doses from a 5ml bottle of diagnostic extract. It is recommended that you fill the dipwell tray with *no more than 5 drops of extract/testing controls which equal 150 tests per well.* Glycerinated extracts are *bacteriostatic and hygroscopic.* This means that your glycerinated extracts, in the dipwell tray, stay potent, stable, and free from evaporation. The most important thing to remember is to handle the trays with care. When picking up a tray and lid, or stacked trays, always place your hand under the bottom tray.
6. Refilling and cleaning trays- glycerinated extracts, while requiring refrigerated storage, are very stable and potent at room temperature during use. Expired extracts can be removed with a small dropper or syringe and the well replenished with fresh material. Any residual extract can be further removed with a small sterile cotton swab before refilling the well with the same, but fresher extract material. When cleaning a tray, a mild detergent should be used and the tray should be rinsed thoroughly with distilled water and allowed to dry completely. Each well should be refilled with its original extract. The dipwell trays are very inexpensive; i.e., \$8 each. You may want to consider having a small supply of trays on hand for periodic replacement. They can, however, be used for a long period of time when handled and stored carefully.

### Important Information Related to “Capped Wells” and Duotip-Test Dipwell Trays

1. Competitors, who sell wells that are “capped” by insertion of the testing device, represent that such an approach provides a “closed system.” In regard to microbes, there are no closed systems after each vial of extract is opened. As you know, when a vial dropper is passed through room environment many times, it is exposed to microbes. This does not pose a problem because glycerin is a good antimicrobial. Then too, the two largest manufacturers of concentrated diagnostic extracts also include in these products the antiseptic, phenol.
2. In regard to the Duotip-Test wells, there is less exposure to microbes than with the vial dropper. When the dropper is removed **once** from the vial and dispenses **5 drops** of extract into a well, the volume is adequate for about 150 patients. If the dropper is removed 150 times for dispensing each extract onto the skin, there is much more microbial exposure. Again, this is not a problem with the dropper because of the presence of 50% glycerin, and in most cases phenol.
3. When the Duotip-Test wells are overfilled, extracts can and do migrate out of wells, which could cause “cross contamination” of extracts. This can also occur with any overfilled well used with other products, “capped” or not. When Duotip-Test wells are each **filled to the 5 drop level**, the tray can be stood on end or laid on its side, without glycerinated extracts running out. At the 5 drop level, extracts stay in place because of capillary attraction.
4. When Duotip-Test is used with its wells, about 3,000 test doses of extract are gained from a single 5 ml vial. Also, when used as a system, the procedure is very fast. Both factors translate to significant cost reduction.
5. When the testing device is used as the well “cap,” extract soon adheres to the upper well circumference following repeated removal of the devices. When extract is picked up from the well circumference by part of the device gripping area, extract may transfer to the user’s fingers. This does not occur with Duotip-Test wells.

## Tray Replacement and 50% Glycerinated Extracts

Points that you need to remember about Lincoln Dipwell trays and 50% glycerinated extracts:

1. 50% glycerinated extracts ensure consistent and uniform loads of each test head. Aqueous extracts will not give consistent loads on Multi-Test II or Duotip-Test test points.
2. 50% glycerin is a protein stabilizer.
3. 50% glycerin is anti-microbial.
4. 50% glycerin is a protease (proteolytic enzyme) inhibitor.
5. 50% glycerin is naturally hygroscopic (Inhibits evaporation). Aqueous extracts do evaporate.

If you have an expired extract, just remove it from the well with a dropper or syringe and replace it with the same but fresher material. Cleaning a well does not ensure that you will remove all of the extract protein and therefore you risk contaminating a different extract. You are better off replacing the tray with a new tray and transferring the extract to the newer tray. Lincoln keeps the trays purposely inexpensive to accommodate this type of situation. The Multi-Test II and Duotip-Test Dipwell trays have been shown to have stability properties similar to the glass vial that the extract comes out of.

## Evaluation of Duotip-Test

Steven V. Stryk, MD, and Raymond G. Slavin, MD *St. Louis, Mo.*

Duotip-Test (Lincoln Diagnostics) is a recently developed skin testing device used in detecting immediate hypersensitivity. It is a plastic disposable cylinder that measures 3 mm in diameter and 41 mm in length. At one end of the device there is a notched finish for grasping, and at the other end are two fine tapered points (Fig. 1). Duotip-Test is used with either a modified prick method or a rotation technique. We studied this new device, by using the rotation technique, to determine its reproducibility, sensitivity, and specificity with histamine and glycerosaline.

### METHODS

This study was conducted in the outpatient Allergy and Immunology Clinic at St. Louis University Health Sciences Center. Subjects were recruited from patients seen in the clinic and from employees of St. Louis University Health Sciences Center. Institutional Review Board approval for the study was obtained, and each test subject gave written consent. Twenty subjects ranging in age from 26 to 65 years (mean age, 39.6 years) were tested. The subjects were nonatopic or atopic, were in good health, and had not used antihistamines or other

From the Division of Allergy and Immunology, Saint Louis University Health Sciences Center, St. Louis.

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Reprint requests: Steven V. Stryk, MD, Saint Louis University Health Sciences Center, 1402 S. Grand Blvd., R209, St. Louis, MO, 63105.

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#### *Abbreviation used*

CV: Coefficient of variation

inhibiting medications. Skin testing was performed on the volar surface of the arm, the right arm for 10 subjects and the left arm for 10 subjects.

The points of the device are loaded by capillary action after immersion in the test solution.

When the rotation technique is used, the shaft of the device is placed at a 90-degree angle to the skin, and just enough pressure is applied from the points to cause a small dimple in the test subject's skin. When rapidly rotated, the device makes a small circular abrasion in the epidermis and deposits the test solution.

In a blinded fashion, using the new device, one investigator administered a row of five epicutaneous tests spaced approximately 2.5 cm apart, four of which were 27 mg/ml histamine phosphate (10 mg/ml histamine base) in 50% glycerosaline and one of which was the negative control (50% glycerosaline). Another investigator, also in blinded fashion, read and recorded the wheal sizes at 15 minutes. A circular caliper disk, marked in 1 mm increments from 0 mm to 45 mm, was used to measure the wheals. Test solutions were obtained from Center Laboratories (Port Washington, N.Y.). Test devices were obtained from Lincoln Diagnostics (Decatur, Ill.).

### RESULTS

A total of 80 histamine and 20 glycerosaline test sites were graded in the 20 subjects. Mean histamine wheal size was 7.5 mm (range, 4.0 to 10.5 mm) with a standard deviation of 1.5 mm.



FIG. 1. Duotip-Test device.

The mean coefficient of variation (CV) was 8.8% (range, 0% to 21%). Ninety-five percent of wheals at the negative control site ranged in size from 1.5 to 3.5 mm, with a mean size of 2.6 mm. One of the 20 test subjects had a negative control site with a wheal size of 4.0 mm. When 4.0 mm was used as the minimum wheal size regarded as positive, Duotip-Test had a sensitivity of 100%, a specificity of 95%, and a low mean CV (8.8%).

#### DISCUSSION

In recent years there has been a proliferation of skin testing devices, each requiring evaluation

for sensitivity, specificity, and reproducibility of test results. Establishing wheal size confidence limits for each device, as suggested by Nelson et al.,<sup>1</sup> appears to be practical. At the 4 mm wheal size for Duotip-Test, the sensitivity was 100% and the specificity was 95%. The low CV (8.8%) from this device reflects high reproducibility of results.

When comparing our findings from Duotip-Test with those obtained by other techniques, we note that Nelson et al.<sup>1</sup> reported sensitivity and specificity at a 3 mm wheal positivity level from several one-at-a-time devices with histamine (10 mg/ml) and glycerosaline: HS lancet (Hollister Stier Miles Inc.), 98% and 100%; ALK lancet (ALK Laboratories), 100% and 95%; BN bifurcated needle (ALO Laboratories) prick, 100% and 87%; BN bifurcated needle puncture, 100% and 81%; DermaPIK (Greer Laboratories), 100% and 20%. The sensitivity and specificity results from Duotip-Test are comparable to those from HS lancet and ALK lancet but superior to results from the bifurcated needle and DermaPIK.

The 8.8% mean CV from Duotip-Test is substantially lower than the CV from any of the devices evaluated by Nelson et al.<sup>1</sup> In the study by Nelson et al.,<sup>1</sup> the CV ranged from 15% for the HS lancet to 19% for the bifurcated needle.

The Duotip-Test procedure was well accepted by all 20 adult subjects, and its administration was rapid and convenient.

#### REFERENCE

1. Nelson HS, Rosloneic DM, McCall LI, Ikle D. Comparative performance of five commercial prick skin test devices. *J Allergy Clin Immunol* 1993;92:750-6.