

Graduated System

| <u>Grade</u> | <u>Wheal (mm)</u> | <u>Erythema (mm)</u> |
|--------------|-------------------|----------------------|
| 0 | <3 | <15 |
| 2+ | <6 | <15 |
| 3+ | 7-9 | 16-30 |
| 4+ | >9 | >30 |

A positive skin reaction to any allergenic extract must be interpreted in light of the patient's history of symptoms, time of the year, known allergen exposures, and eating habits.

The skin tests are in no way a substitute for a careful allergic history. Rather, they serve as additional information to aid in identifying causative allergens in patients with allergic disorders.

HOW SUPPLIED

| Item # | Description |
|---------------|--|
| 8392ZA | QUINTEST® Multiple Skin Test Device (sterile), Shelf Pack of 16. Manufactured in England. |
| 8930ZA | QUINTEST® Covered Tray. Manufactured in the U.S.A. |
| 8924ZA | QUINTIP® Reservoirs (sterile), 30 per pouch. Manufactured in the U.S.A. |

Distributed in the U.S.A. by:
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QUINTEST®

Multiple Skin Test System

FOR PUNCTURE SKIN TESTING

QUINTEST® is a skin test device designed to apply test extract using the puncture technique.



Figure 1

QUINTEST® is designed for use by allergy practitioners who are trained in the application and interpretation of the puncture technique and who are trained in the recognition and treatment of adverse allergic reactions should they occur.

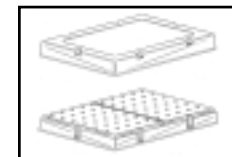


Figure 2

QUINTEST® Multiple Skin Test System consists of three components: The **QUINTEST®** skin test device (Figure 1) and the tray (Figure 2) that holds the allergenic extracts. The test devices are provided two per sterilized bubble pack containers, 16 units per shelf pack. The **QUINTEST®** covered tray (Figure 2) is provided as a single unit that holds 60 **QUINTIP®** reservoirs (Figure 3) and accommodates 12 **QUINTEST®** skin test devices (Figure 1).

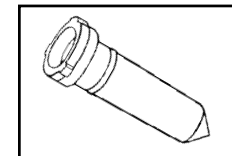


Figure 3

PRODUCT DESCRIPTION

The **QUINTEST**[®] device is a molded plastic handle with five testing probes (Figure 1). Inserted into each testing probe is a stainless steel lancet tip that protrudes from the probe enough to give the proper testing depth (Figure 4). The testing probes have a breakaway design for flexibility in use and easy disposal. The **QUINTEST**[®] device is to be used once and discarded.



Figure 4

SET-UP INSTRUCTIONS

Remove the **QUINTEST**[®] covered tray from the box. The **QUINTEST**[®] covered tray is supplied with pressure-sensitive labels. Each label strip has five designated areas corresponding to the reservoirs. Write the name of each antigen in the area provided, remove the label backing and place on the tray to correspond with the antigen. Peel back the paper label as indicated on the pouch of the reservoirs. Firmly place a reservoir into each hole in the **QUINTEST**[®] covered tray. Fill the appropriate reservoir with 3-4 drops using the dropper from the test extract vial.

Once the tray is prepared, remove a **QUINTEST**[®] device from the bubble pack by peeling off the label. Pick up the device by the handle and place the tips in the reservoirs. With the **QUINTEST**[®] device on the tray, the reservoirs are covered to prevent foreign matter from entering the extract. To assure that test extracts are applied to the proper test sites, it may be helpful to always place the test device handle with the **QUINTEST**[®] name facing outward from the center of the tray.

Each tray holds 12 **QUINTEST**[®] devices. Once loaded, it can be

used immediately or covered and stored in the refrigerator until needed. When the extract-filled tray is not in use, store in the refrigerator with the test devices submersed in the reservoirs. Because of the breakaway design, if less than five test sites are desired, the undesired probe(s) can be removed before use.

SKIN TEST PROCEDURE

Prior to testing, clean the test area with alcohol and allow to dry. (See “Allergenic Extracts for Scratch and Prick/Puncture Testing” package insert for more detailed instructions.) Remove a **QUINTEST**[®] skin test device from a prepared tray by lifting it vertically, being careful not to touch the tips on the reservoirs. With the **QUINTEST**[®] perpendicular to the skin, press down on the skin with medium pressure and rock the device end to end, without lifting the device from the skin, twice to ensure all tines have contacted the skin. Remove by lifting vertically and discard the **QUINTEST**[®]. Small circles about 4mm in diameter should remain at the test site indicating the correct amount of pressure was applied. The visibility of the circles will vary between patients according to the thickness, fragility, or pigmentation of their skin. The amount of pressure needed to produce a satisfactory test site requires that all of the five depth guards come in full contact with the skin.

Following the above instructions will produce five uniform skin tests all at the proper depth without inducing bleeding. All test sites are three centimeters apart to avoid the axon reflex.

STORAGE AND DISPOSAL

Once you have completed a patient’s test session, place new

QUINTEST[®] devices in the antigen tray, cover and store at 2°-8°C until the next test session.

QUINTEST[®] devices are designed to be used once and discarded (in accordance with all local, state and federal regulations). The breakaway tips may be removed before discarding, and the handle may be disposed of via non-biohazard routes. These devices cannot be cleaned sufficiently to prevent cross contamination from repeated use or to protect subsequent patients from possible transfer of serum hepatitis or other bloodborne pathogens.

The reservoirs in the **QUINTEST**[®] tray should be replaced periodically. If a used **QUINTEST**[®] device is inadvertently placed in a reservoir(s), the individual reservoir(s) should be discarded and a new reservoir(s) prepared prior to the next test session.

READING SKIN TEST REACTIONS

Measure wheal and erythema responses for histamine positive control at 10 minutes and allergens at 15 minutes. To improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response, we recommend recording wheal and erythema measurements. Reactions from the **QUINTEST**[®] device may be graded as follows:

European Prick Test Grading System

| Grade | Wheal (mm) | Erythema |
|----------|------------|--------------|
| Negative | <3 | Not Measured |
| Positive | >3 | Not Measured |