

QUINTIP®

Individual Skin Test System

FOR PUNCTURE SKIN TESTING

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

QUINTIP® 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.

QUINTIP® System consists of three components: The **QUINTIP®** skin test device (Figure 1), the interlocking, covered tray (Figure 2 – shown as 1 set of 2 trays), and the reservoir (Figure 3).

PRODUCT DESCRIPTION

Each **QUINTIP®** device has a molded plastic grip with one test probe (Figure 1). Inserted into each unit is a stainless steel lancet tip that protrudes from the probe

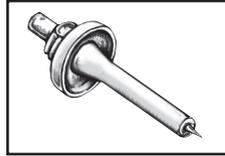


Figure 1

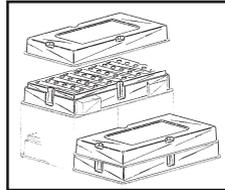


Figure 2

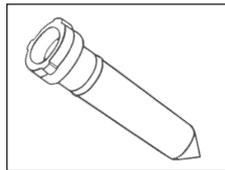


Figure 3

enough to give the proper testing depth. The **QUINTIP®** device is to be used once and discarded in an approved sharps container. The sterile test devices are provided as 20 units per pouch with 15 pouches in a shelf pack for a total of 300 units.

Each interlocking, covered tray holds up to 30 reservoirs and is designed so that it can be interlocked with one additional tray or stacked for testing and storage flexibility. Interlocking trays are provided in a set of 2.

The reservoirs are supplied in sterile pouches of 30. The **QUINTIP®** device covers the reservoir, helping protect the antigen from foreign material and evaporation.

SET-UP INSTRUCTIONS

The **QUINTIP®** system is supplied with self-adhesive labels used to identify the antigen contained in the reservoir. Carefully label the reservoir to correspond with the antigen.

Peel back the paper label as indicated on the pouch of the **QUINTIP®** reservoirs. Firmly place a reservoir into each hole in the **QUINTIP®** tray. Fill the appropriate reservoir with approximately 12 drops (about 0.5mL) of antigen, using the sterile dropper from the test extract vial or draw 0.25mL - 0.5mL from the bulk extract with a sterile syringe.

Once the trays are prepared, remove a **QUINTIP®** device from the sterile pouch by peeling off the label. Pick up the device by the plastic grip and place the tip in the reservoir. Continue until all of the reservoirs are filled.

Each **QUINTIP**[®] tray system holds 30 **QUINTIP**[®] devices. Once loaded, it can be used immediately or stored in the refrigerator until needed. When the extract-filled trays are not in use, store at 2° - 8°C with the test devices submersed in the reservoirs.

SKIN TEST PROCEDURE

Prior to testing, clean the test area with alcohol and allow to dry. (See “Allergenic Extracts for Scratch, Prick or Puncture Testing” package insert for more detailed instructions.) Remove a **QUINTIP**[®] skin test device from a prepared tray by lifting it vertically, being careful not to touch the tip against the reservoir. With the **QUINTIP**[®] perpendicular to the skin, press down on the skin with medium pressure without lifting the device from the skin. Remove by lifting vertically and discard the **QUINTIP**[®] in an approved sharps container. 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, and pigmentation of their skin. The amount of pressure needed to produce a satisfactory test site requires that the depth guard come in full contact with the skin.

Following the above instructions will produce uniform skin tests all at the proper depth without inducing bleeding.

STORAGE AND DISPOSAL

Once a patient’s test session has been completed, place new **QUINTIP**[®] devices in the antigen trays and store at 2° - 8°C until the next test session.

QUINTIP[®] devices are designed to be used once and discarded (in accordance with all local, state and federal regulations). 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.

QUINTIP[®] reservoirs should be replaced periodically. For best results, discard and replace the reservoirs as they are emptied and refill with fresh extract. If a used **QUINTIP**[®] device is inadvertently placed in a reservoir, the individual reservoir should be discarded and a new reservoir prepared before 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 **QUINTIP**[®] device may be graded as follows:

European Prick Test Grading System

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

Graduated System

Grade	Wheal (mm)	Erythema (mm)
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, known allergen exposures, and time of the year.

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
8400ZA	QUINTIP® Individual Skin Test Device (sterile), case of 1800 units. Manufactured in England.
8924ZA	QUINTIP® Reservoirs (sterile), 30 per pouch Manufactured in the U.S.A.
8399ZA	QUINTIP® Interlocking Covered Trays, set of 2. Manufactured in the U.S.A.

Distributed in the U.S.A. by:
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