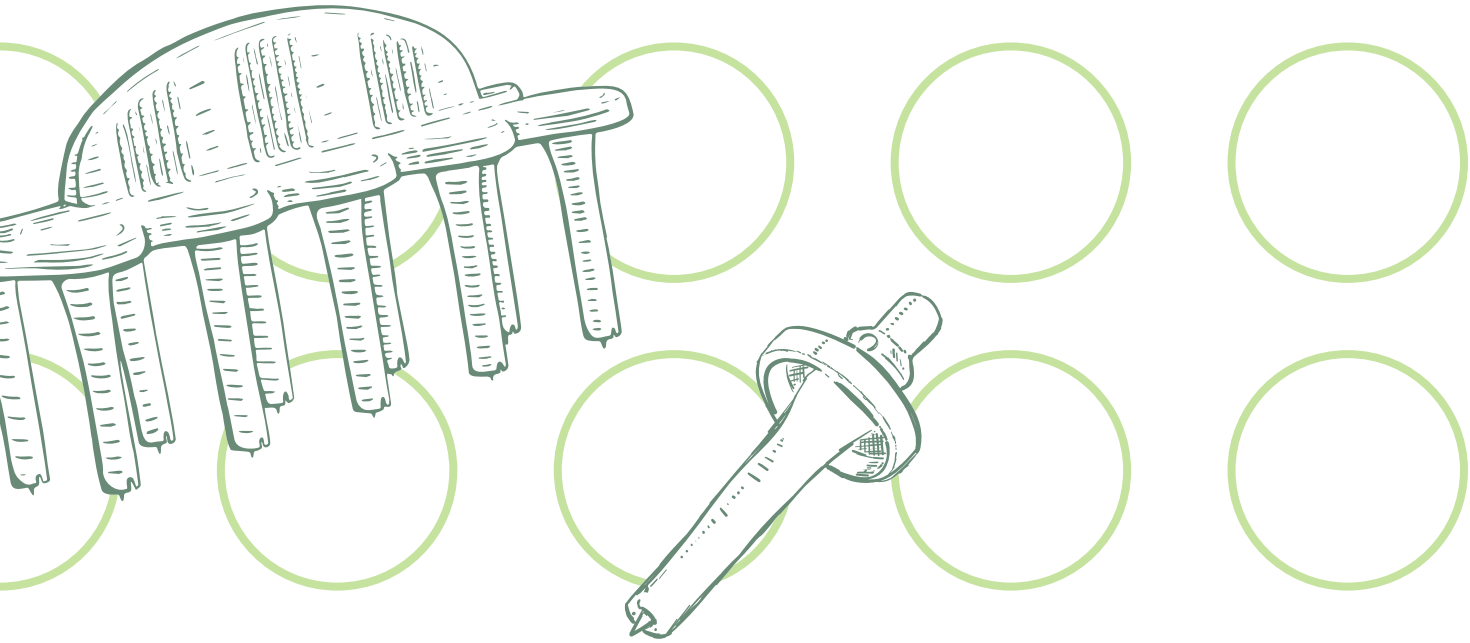
HollisterStier Allergy

ComforTen®

SKIN TEST SYSTEM

Elevating Allergy Testing

The **Comfor**Ten® Skin Test System was designed in collaboration with allergy nurses to provide reproducible, accurate testing results, without overcomplicating the process.[1]



Both the **Comfor**Ten® Multiple Skin Test and **Quin**Tip® Individual Skin Test devices integrate seamlessly within our testing system, offering precise results alongside our expert-recommended Histamine Positive Control.[2,3]

HollisterStier Allergy

ONLINE ORDERING

Our user-friendly website is desktop and mobile device compatible allowing you to access your account online anywhere!

FEATURES

- Place new orders
- Review open orders
- Track shipping details
- View statements and invoices
- Make secure payments
- Download physician resources

ORDER NOW

ComforTen®

SKIN TEST SYSTEM

- COMFORTEN® MULTIPLE SKIN TEST DEVICE
- QUINTIP® INDIVIDUAL SKIN TEST DEVICE
- 30-HOLE TRAY
- 60-HOLE TRAY
- REMOVABLE RESERVOIRS
- OPTIONAL SPACERS

ORDERS.HSALLERGY.COM
1.800.495.7437

Designed with You in Mind

The **Comfor**Ten® Skin Test System was designed in collaboration with allergy nurses in clinical settings. With their feedback, we created a versatile and easy-to-use testing system.

ComforTen® Multiple Skin Test Device

This device has ten tips which save you time by administering multiple tests at once. The precise layout of each tip prevents wheals from overlapping, resulting in easy-to-read results.

QuinTip® Individual Skin Test Device

A single-use skin test that allows a customized testing experience for every patient by testing one antigen at a time.

Innovative Devices, Precise Results, **One System**

Both the Comfor Ten® **and Quin**Tip® **devices:**

- 1.2mm surgical-steel lancet tips
- Depth control guards
- Less traumatic to the reaction site
- More comforting to the patient
- Easily reproducible results

Our devices produce a 0mm reaction at the negative control site, allowing readings of 3mm + to read positive.[1,4,5,6]

Two Tray Options

The 60-hole and 30-hole tray options are stackable for easy storage and clear for quick antigen inspection. These trays are uniquely designed to prevent evaporation and foreign material entering the stored antigen.

Spacers that Save Time

Spend less time filling reservoirs, and more time with your patients. Our spacers sit on top of the reservoirs, creating additional space for antigen.

Removable Reservoirs

There's no need to dispose of an entire tray of antigen due to a small mistake. Save time, and money, with clear, removable reservoirs that can be replaced at any time.

Histamine

The highest histamine concentration on the market for precise, easy-to-read results and accurate diagnosis.

Our positive control is histamine dihydrochloride, which has a long history of scientific data documenting its efficacy; this is widely accepted as the European standard, dating back to the original Nordic guidelines.[7]

The Concentration Recommended by Experts[8]

- Middleton's Allergy: Principles and Practice recommends 10 mg/mL as the "preferred positive control for prick-puncture tests."[2] This is the exact concentration in our Histamine Positive Control.
- Skin Prick Testing and the Use of Histamine References recommends "histamine 10 mg/mL as an international positive reference."[9]
- "Histamine Dihydrochloride at 10mg/mL (equivalent to 6 mg/mL Histamine base) has been shown to elicit fewer false negative and false positive reactions"[3] using the same skin testing device than 1mg/mL histamine base.

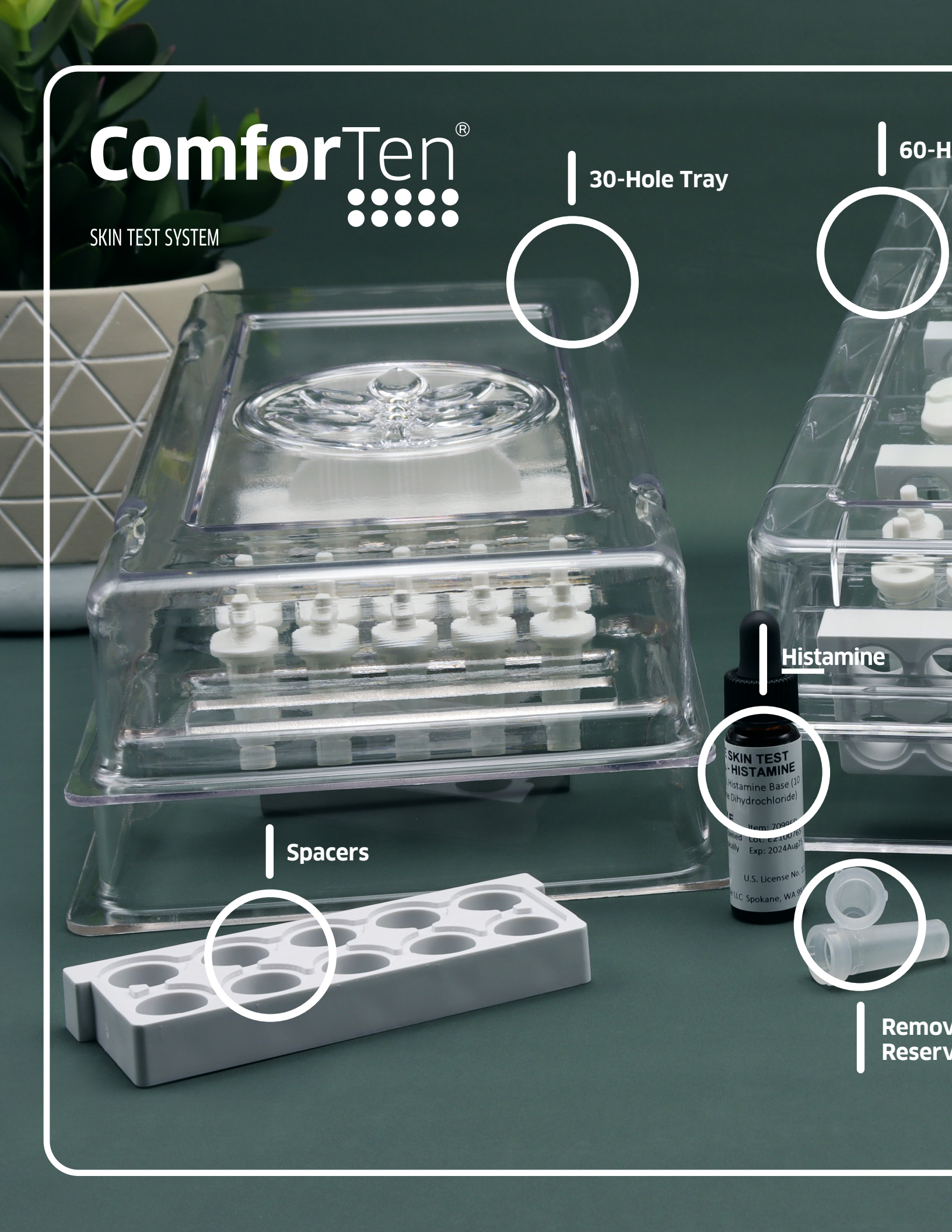
We're committed to making the switch to our ComforTen® Skin Test System easy.

Request a Quote

Training Your Staff
We offer in-person and remote skin test training sessions, in addition to providing a detailed demonstration video, ensuring every staff member is confident.

Customizing Your Trays
Start with an optional, complimentary panel review before your personal sales representative customizes your tray with personalized antigen labels.

Prepare for Testing
Request our free, patient skin test record designed to work with the system and organize your testing results with ease.


ComforTen®
SKIN TEST SYSTEM
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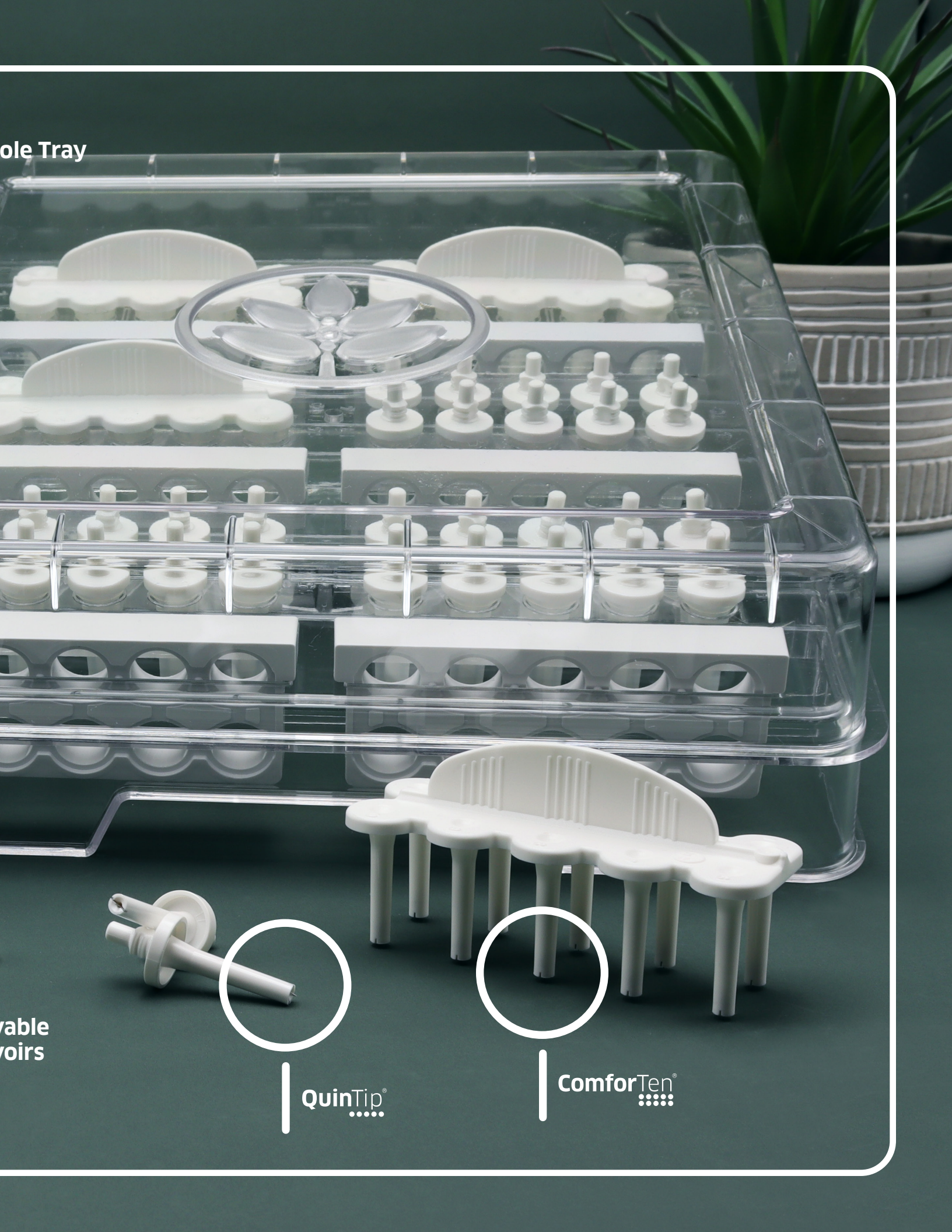

QUINTIP®

Individual Skin Test System

FOR PUNCTURE SKIN TESTING

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

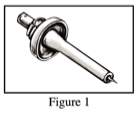

Figure 1

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.

Figure 2

QUINTIP® System consists of three components: The **QUINTIP®** skin test device (Figure 1), the **ComforTen®** 60-hole covered tray (Figure 2), and the reservoir (Figure 3). A 30-hole tray is also available.

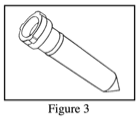

Figure 3

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 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.

The stackable, covered trays hold 30 or 60 reservoirs. They are designed for testing and storage flexibility. Both trays are provided as single units and include optional-use spacers (Figure 5) for increasing the number of tests between filling the reservoirs.

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

Remove the **ComforTen®** covered tray from the box. Each **ComforTen®** covered tray is supplied with blank self-adhesive labels and spacers (Figure 4). Each label strip has five designated areas corresponding to the reservoirs. Note the name of each allergenic extract in the area provided. Remove the label backing and place on the tray inline with the corresponding reservoirs.

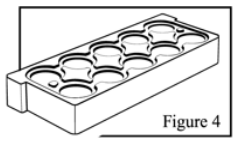

Figure 4

HollisterStier Skin Test Reservoirs are provided in a sterile pouch of 30. Peel back the paper label as indicated on the pouch of the reservoirs. Firmly place a reservoir into each hole in the **ComforTen®** tray. If using the optional spacers, fill the appropriate reservoir with approximately 20 drops (not more than 0.8 mL) using the dropper from the HollisterStier Allergy 5mL scratch test extract vial or from the bulk vial using a sterile syringe (Figure 5b). Place the spacers on top of the reservoirs as noted in Figure 5a. If the spacers are not used, fill the appropriate reservoir with approximately 12 drops (not more than 0.5 mL) using the dropper from the HollisterStier Allergy 5mL scratch test extract vial (Figure 5c). Store the unused spacers in the slots provided on the tray.

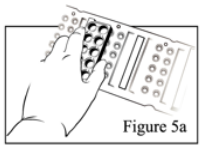

Figure 5a

Once the trays are prepared, remove a **QUINTIP®** device from the sterile pouch by peeling off the label as indicated on the package. Pick up the device by the plastic grip using caution not to touch any part of the leg or the lancet tip. Place the tips in the prefilled reservoirs. Continue until all of the reservoirs are filled.

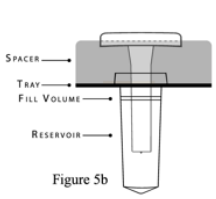

Figure 5b

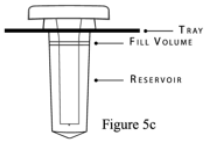

Figure 5c

The 30-hole and 60-hole trays hold 30 or 60 **QUINTIP®** devices respectively. With the **QUINTIP®** devices in the tray, the reservoirs are covered to prevent foreign matter from entering the extract. Once the tray is loaded, it can be used immediately or covered and stored at 2°- 8°C until needed.

SKIN TEST PROCEDURE

Prior to testing, clean the test area with alcohol and allow to dry. Refer to "Highlights of Prescribing Information" and "Positive Skin Test Control-Histamine" or other manufacturers' package inserts for more detailed testing 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 and 20 minutes.[2] For optimal response, use a positive control with a 6mg/mL histamine base. Immediate reactions to histamine typically peak at 8 minutes while allergens peak at 15 minutes.[1] HollisterStier Allergy recommends recording wheal and erythema measurements to improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response.

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.
8406ZA	**ComforTen®** Covered 30-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8407ZA	**ComforTen®** Covered 60-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8924ZA	**HollisterStier** Skin Test Reservoirs (sterile), 30 per pouch. Manufactured in England.

REFERENCES

1. Oppenheimer J, Nelson HS. Skin testing Ann Allergy Asthma Immunol. 2006; 96(Suppl 1):S6–S12.

2. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. Ann Allergy Asthma Immunol. 2008 Mar;100: S1-148.

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Spokane, WA 99220-3145
1.800.495.7437

www.hsallergy.com

HollisterStier Allergy

ComforTen®

Multiple Skin Test System
FOR PUNCTURE SKIN TESTING

ComforTen® is a ten-test skin test device designed to apply allergenic extract using the puncture test technique.

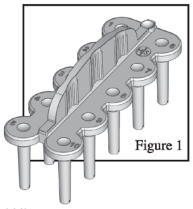


Figure 1

ComforTen® 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.

ComforTen® Multiple Skin Test System consists of three components:

The **ComforTen®** skin test device (Figure 1), the **HollisterStier Skin Test** reservoirs (Figure 2), and the **ComforTen®** 60-hole covered tray (Figure 3) that holds the reservoirs. A 30-hole tray is also available.

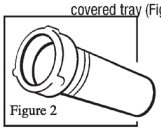


Figure 2

PRODUCT DESCRIPTION

The **ComforTen®** device has a molded plastic handle containing ten stainless steel lancet tips that slightly protrude from the legs of the device (Figure 4). The **ComforTen®** device is to be used once and discarded in an approved sharps container. The sterile test devices are packaged three per blister pack container, 27 blister packs (81 devices) per case. The stackable, covered trays hold up to 30 or 60 reservoirs and accommodates 3 or 6 **ComforTen®** skin test devices. They are designed for testing and storage flexibility. Both trays are provided as single units and include optional-use spacers (Figure 5) for

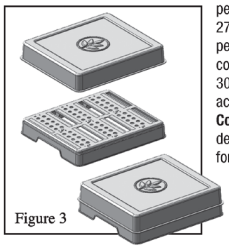


Figure 3

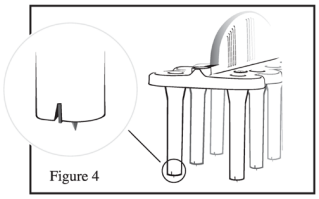


Figure 4

increasing the number of tests between filling the reservoirs. The reservoirs are supplied in sterile pouches of 30. The **ComforTen®** device covers the reservoir, helping protect the allergenic extract from foreign material and evaporation.

SET-UP INSTRUCTIONS

Remove the **ComforTen®** covered tray from the box. Each **ComforTen®** covered tray is supplied with blank self-adhesive labels and spacers (Figure 5). Each label strip has five designated areas corresponding to the reservoirs. Note the name of each allergenic extract in the area provided. Remove the label backing and place on the tray inline with the corresponding reservoirs.

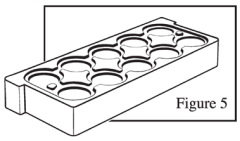


Figure 5

HollisterStier Skin Test Reservoirs are provided in a sterile pouch of 30. Peel back the paper label as indicated on the pouch of the reservoirs. Firmly place a reservoir into each hole in the **ComforTen® tray.** If using the optional spacers, fill the appropriate reservoir with approximately 20 drops (not more than 0.8 mL) using the dropper from the HollisterStier Allergy 5 mL scratch test extract vial (Figure 6b). Place the spacers on top of the reservoirs as noted in Figure 6a. If the spacers are not used, fill the appropriate reservoir with approximately

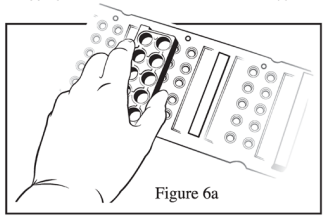


Figure 6a

12 drops (not more than 0.5 mL) using the dropper from the HollisterStier Allergy 5 mL scratch test extract vial (Figure 6c). Store the unused spacers in the slots provided on the tray. Once the tray is prepared, remove a **ComforTen®** device from the blister pack by peeling off the label as indicated on the package. Pick up the device by the handle using caution not to touch any part of the legs or the lancet tips. Place the tips in the prefilled reservoirs. Important: To assure that test extracts are applied to the proper test sites, several directional indicators are built into the device and tray (Figure 7). When placing the device into the

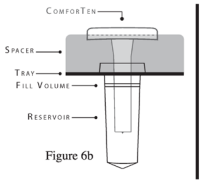


Figure 6b

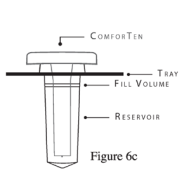


Figure 6c

tray always ensure that the indent on the device located between legs 1 and 6, are aligned with the spot on the tray and that the notch in the opposite end of the device is furthermost away. When removing the device to apply to the patient's skin, place the test device handle with the directional indicators plus the numbers 1 and 6 facing upward and toward the patient's head.

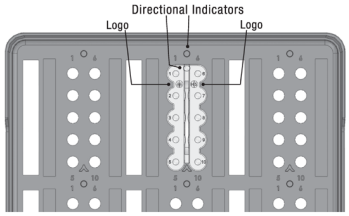


Figure 7

The 30-hole and 60-hole trays hold 3 or 6 **ComforTen®** devices respectively. With the **ComforTen®** device in the tray, the reservoirs are covered to prevent foreign matter from entering the extract. Once the tray is loaded, it can be used immediately or covered and stored at 2°–8°C until needed.

SKIN TEST PROCEDURE

Prior to skin testing, clean the test area with alcohol and allow to dry. (Refer to Highlights of Prescribing Information and "Positive Skin Test Control – Histamine" or other manufacturers'

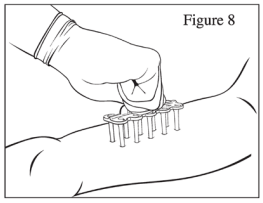


Figure 8

package inserts for more detailed testing instructions.) Remove a **ComforTen®** skin test device slowly from a prepared tray by lifting it vertically, being careful not to touch the tips on the reservoirs or spacer. With the **ComforTen®** perpendicular to the skin, press down on the skin with medium pressure (Figure 8).

While maintaining this pressure, slightly tilt the device once to the right, and then to the left while ensuring that all 10 lancets remain in contact with the skin. Remove by lifting vertically and discard the **ComforTen®**. Small circles about 4mm in diameter created by the device's depth-control guards should remain at the test site indicating the correct amount of pressure was applied (Figure 9). The actual duration and 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 ten depth-control guards (Figure 9) come in full contact with the skin. When used as described above, the **ComforTen®** device will produce ten uniform skin tests all at the proper depth without inducing bleeding.

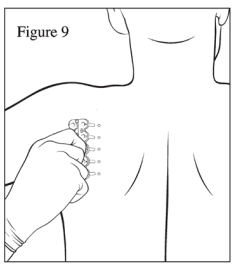


Figure 9

The spacers are used to increase the number of tests between refilling the reservoirs. Once the allergenic extract volume in the reservoirs has dropped to approximately half with a device in place, remove the spacer and continue using the extracts until reservoirs are nearly empty and need to be refilled. To maintain tray cleanliness, the spacers can be washed with soap and rinsed with warm water, then dried thoroughly.

STORAGE

Once a patient's test session has been completed, place new **ComforTen® devices in the extract filled tray, cover and store at** 2°-8° C until the next test session.

READING SKIN TEST REACTIONS

Measure wheal and erythema responses for histamine positive control at 10 minutes and allergens at 15 and 20 minutes.[2] For optimal response, use a positive control with a 6 mg/mL histamine base. Immediate reactions to histamine typically peak at 8 minutes while allergens peak at 15 minutes.[1] HollisterStier Allergy recommends recording wheal and erythema measurements to improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response. Reactions from the **ComforTen®** device may be graded as follows:

European Prick Test Grading System		
Grade	**Wheal (mm)**	**Erythema**
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, time of the year, and known allergen exposures.

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.

DISPOSAL

ComforTen® 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.

HollisterStier Skin Test Reservoirs in the **ComforTen®** tray should be replaced periodically. For best results, discard and replace the reservoirs as they are emptied and fill with fresh allergenic extract. If a used **ComforTen®** device is inadvertently placed in the reservoirs, the affected reservoirs should be discarded and new reservoirs prepared prior to the next test session.

REFERENCES

1.Oppenheimer J, Nelson HS. Skin testing *Ann Allergy Asthma Immunol.* 2006; 96(Suppl 1):S6–S12.

2. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol.* 2008 Mar;100: S1-148.

HOW SUPPLIED

Item#	**Description**
80000000021	**ComforTen®** Multiple Skin Test Device (sterile), Case of 27 blister packs (81 devices). Manufactured in England.
8406ZA	**ComforTen®** Covered 30-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8407ZA	**ComforTen®** Covered 60-Hole Tray (Includes Spacers and Labels). Manufactured in the U.S.A.
8924ZA	**HollisterStier Skin Test Reservoirs** (sterile), 30 per pouch. Manufactured in England.

HollisterStier Allergy

Distributed in the U.S.A. by:
Jubilant HollisterStier LLC
Spokane, WA 99220-3145
1.800.495.7437
hsallergy.com

385416-H05
Rev. 04/2022

POSITIVE SKIN TEST CONTROL – HISTAMINE

For Percutaneous (Scratch, Prick or Puncture) Administration

Histamine Base: 6mg/mL

(Histamine Dihydrochloride: 10mg/mL)

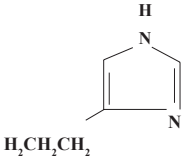
This product is to be used by a physician or under the supervision of a physician.

366140-H08 Printed in U.S.A.

HollisterStier Allergy

DESCRIPTION:

Histamine Dihydrochloride contains histamine, a potent vasodilator having the chemical name 2-(4-Imidazolyl) ethylamine. Histamine has an empirical formula of $C_5H_9N_3$, a molecular weight of 111.15, and the following chemical structure:



Histamine Dihydrochloride is available in the following strengths:

1. SCRATCH, PRICK or PUNCTURE TEST CONTROL:

Positive Skin Test Control – Histamine contains 6.0 mg/mL Histamine Base and is a clear, colorless, sterile solution. It consists of Histamine Dihydrochloride 10 mg/mL, Sodium Chloride 0.5%, Sodium Bicarbonate 0.275%, and Glycerin 50.0% (v/v) as a preservative.

CLINICAL PHARMACOLOGY

Pharmacological actions of histamine include the increase of capillary and post capillary venular permeability. This vascular change leads to the wheal-flare response. Large reactions can cause an amplification of a reaction to a nearby skin test.

Histamine is degraded either by oxidative deamination or by methylation and oxidative deamination so that the principal *excretion products* are imidazoleacetic acid-riboside and 1-methyl imidazoleacetic acid respectively.[2]

10 atopic subjects and 10 non-atopics were tested with Positive Skin Test Control – Histamine Solutions, and two negative control solutions. Thirteen females (35-49 years old; mean age 36.5) and 7 males (23-45 years old; mean age 36.4) were tested. This study included 19 Caucasian subjects and 1 African American subject.

Different skin test devices produce different skin test responses.[14,15] Study results are summarized in Table 1 and Table 2. Atopic and non-atopic subject information was combined, as there were no significant differences in their skin responses.

Summation of wheal (ΣW) or summation of erythema (ΣE) was determined by measuring the longest diameter and the mid-point orthoganol diameter of the wheal or erythema response and summing the two measurements.

Table 1: Positive Skin Test Control Solutions (n = 20)

	Skin Test Technique (Skin Test Device)					
	Scratch† (Scarifier)		Puncture† (Prick Lancetter)		Puncture† (Bifurcated Vaccinating Needle)	
Histamine Base Concentration	6mg/mL		6mg/mL		6mg/mL	
Summation of Wheal/ Summation of Erythema	ΣW	ΣE	ΣW	ΣE	ΣW	ΣE
Skin Response (mm)§	20	76	12	49	13	56
Range	11-36	55-103	8-16	37-66	9-18	43-78
Standard Deviation	5.6	11.9	2.1	6.8	2.2	8.7

† Dose – 1 drop topically

§ Negative control values were not subtracted from response measurements

Table 2: Negative Skin Test Control Solutions (n = 20)

	Skin Test Technique (Skin Test Device)					
	Scratch† (Scarifier)		Puncture† (Prick Lancetter)		Puncture† (Bifurcated Vaccinating Needle)	
Control Solution	Sterile 50% (v/v) Glycerin		Sterile 50% (v/v) Glycerin		Sterile 50% (v/v) Glycerin	
Summation of Wheal/ Summation of Erythema	ΣW	ΣE	ΣW	ΣE	ΣW	ΣE
Skin Response (mm)	8	7	3	4	5	5
Range	0-11	0-11	0-10	0-10	3-8	2-8
Standard Deviation	2.4	3.0	2.8	2.2	1.3	1.5

† Dose – 1 drop topically

Malling tested 25 subjects using a straight needle prick technique with Histamine Dihydrochloride 10mg/mL and found wheal single diameters of 5.4-8.5mm (mean 7 mm).[13]

Histamine Dihydrochloride at 10mg/mL has been shown to elicit fewer false negative and false positive reactions than Histamine Dihydrochloride at 1mg/mL.[12] 10mg/mL Histamine Dihydrochloride has been shown to be the appropriate strength to perform biological standardization using skin reactivity to histamine as a standard of comparison.[11,13]

INDICATIONS AND USAGE

Positive Skin Test Control – Histamine is indicated as an adjunct in allergy skin test for diagnosis, as a positive control to test wheal-flare response of skin for evaluation of skin test response to allergenic extracts.

CONTRAINDICATIONS

Positive Skin Test Control – Histamine is contraindicated in patients with a history of hypersensitivity to histamine products, and in patients with hypotension, severe hypertension, vasomotor instability, severe cardiac, pulmonary or renal disease.

WARNINGS:

Attacks of severe asthma or other serious allergic conditions may be precipitated by the administration of Histamine Dihydrochloride in patients with bronchial disease. Caution is advised in using histamine in such patients and in those with a history of bronchial asthma. Histamine Dihydrochloride has not been approved for unlabeled use as gastric acid stimulus or for detecting bronchial hyperactivity.

PRECAUTIONS:

(1) General: It is necessary that scarifiers, syringes, and needles be properly sterilized before use on each patient to prevent the possibility of accidental transfer of serum hepatitis and other infectious agents from one person to another. Disposable products may also be used.

Always have injectable epinephrine and a tourniquet available when any skin tests are being made. (See ADVERSE REACTIONS Section)

Patients should be observed in the office for 30 minutes after administration of the test and instructed to return to the office promptly if symptoms of an allergic reaction or shock occur.

(2) Drug Interactions: Certain medications may lessen the skin test wheal and erythema responses elicited by histamine for varying time periods. Conventional antihistamines should be discontinued at least 5 days before skin testing. Long acting antihistamines should be discontinued for at least 3 weeks prior to skin testing.[7] Topical steroids should be discontinued at the skin test site for at least 2-3 weeks before skin testing.[7,8]

Tricyclic antidepressants such as Doxepin should be withheld for at least 7 days before skin testing.[9] The physician must determine whether the risk of severe depression occurring in patients who discontinue their medication outweighs the benefits that could be obtained from skin testing. Topical local anesthetics may suppress the flare responses and should be avoided in skin test sites.[10]

(3) Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies have not been performed on Positive Skin Test Control-Histamine.

(4) Pregnancy: Positive Skin Test Control-Histamine. Animal reproduction studies have not been conducted on Histamine Dihydrochloride. It is also not known whether Histamine Dihydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Histamine Dihydrochloride should be given to a pregnant woman only if clearly needed.

(5) Nursing Mothers: It is unknown whether Histamine Dihydrochloride affects lactation or is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Positive Skin Test Control-Histamine is administered to a nursing woman.

(6) Pediatric Use: Indications and dosage for the pediatric population are the same as for adults; however, the reactions to histamine are smaller. Studies have shown that the use of histamine solutions for skin test is safe in infants and young children.[4,5,6]

ADVERSE REACTIONS

Large doses of histamine may precipitate systemic reactions. These reactions may include flushing, dizziness, headache, bronchial constriction, urticaria, asthma, marked hypotension or hypertension, abdominal cramps, vomiting, metallic taste, local or generalized allergic manifestations.

An antihistamine preparation may be given orally, I.M. or I.V. to prevent or ameliorate systemic reactions to the drug.

If a systemic or anaphylactic reaction does occur, apply a tourniquet above the site of injection and inject 1:1000 epinephrine-hydrochloride intramuscularly or subcutaneously into the opposite arm. Loosen the tourniquet at least every 10 minutes. Do not obstruct arterial blood flow with the tourniquet.

Epinephrine Dosage:

ADULT: 0.3 to 0.5 mL should be injected. Repeat in 5 to 10 minutes if necessary.

PEDIATRIC: The usual initial dose is 0.01 mg (mL) per kg body weight or 0.3 mg (mL) per square meter of body surface area. Suggested dosage for infants to 2 years of age is 0.05 mL to 0.1 mL; for children 2 to 6 years, 0.15 mL; and children 6 to 12 years, 0.2 mL. Single pediatric doses should not exceed 0.3 mg (mL). Doses may be repeated as frequently as every 20 minutes, depending on the severity of the condition and the response of the patient.

After administration of epinephrine, profound shock or vasomotor collapse should be treated with intravenous fluids, and possibly vasoactive drugs. Oxygen should be given by mask. Aminophylline or adrenal corticosteroids may be used if necessary after adequate epinephrine and circulatory support has been given.

Emergency resuscitation measures and personnel trained in their use should be available immediately in the event of a serious systemic or anaphylactic reaction not responsive to the above measures (Ref. J. ALLERGY AND CLINICAL IMMUNOLOGY 77 (2): p. 271-273, 1986).[16]

Rarely are all of the above measures necessary, the tourniquet and epinephrine usually producing prompt responses. However, the physician should be prepared in advance for all contingencies.

Promptness in beginning emergency treatment measures is of utmost importance.

ADVERSE EVENT REPORTING

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant HollisterStier LLC at 1-800-495-7437 or Adverse.Reactions@jubl.com; or the FDA at 1-800-FDA-1088 or fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

OVERDOSAGE

Overdosage may cause severe symptoms, including circulatory collapse, shock, and even death. Intravenous administration of histamine in normal volunteers at doses of up to 1.0 µg/kg/min produced flushing, headaches, tachycardia and decreased diastolic blood pressure.[1,2,3]

See ADVERSE REACTIONS Section for emergency treatment steps.

DOSAGE AND ADMINISTRATION

(1) General: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Prior to testing, clean the skin area with ether or alcohol and allow to dry. The back or the volar surface of the arms are the most satisfactory sites for testing.

Skin of the posterior thighs or abdomen may be used if necessary. Avoid very hairy areas where possible, since the reactions will be smaller and more difficult to interpret there. The most satisfactory areas of the back are from the posterior axillary fold to 2.5 cm from the spinal column, and from the top of the scapula to the lower rib margins. The best areas of the arms are the volar surfaces from the axilla to 2.5 or 5 cm above the wrist, skipping the anti-cubital space.

The histamine test should be applied in the same test area as other allergenic extracts tests, but spaced no closer than 4 to 5 cm from adjacent test sites. Use the same technique or procedure that you use for allergen testing.

The negative control is the diluent used in the extract to be tested (e.g., 50% glycerin, Sterile Albumin Saline with Phenol, Sterile Buffered Saline with Phenol).

With each skin testing method, in order for the reaction to Positive Skin Test Control-Histamine (6 mg/mL Histamine Base) to be considered valid, erythema must be present which exceeds the respective negative control by 4 mm (ΣE). A wheal reaction does not have to be elicited *unless* there is a wheal reaction to the respective negative control. In this case, the wheal of the positive control must exceed the negative control by 4 mm (ΣW) in order to be considered appropriate. Record measurement of erythema and wheal diameters.

Tables 1 and 2 summarize skin testing results with histamine base and controls in atopic and non-atopic subjects using four different devices and methods.

(2) Scratch, Prick or Puncture Test: Positive Skin Test Control-Histamine, 6.0 mg/mL Histamine Base.

The Scratch, Prick or Puncture test should be read in 15 minutes. If a large wheal reaction occurs before that time, wipe excess histamine solution from test site.

a) Use a sterile scarifier for each patient.

Hold the scarifier between the thumb and index finger, press the sharp edge of the instrument against the skin and twirl instrument rapidly. The scratch should disrupt the outer layers of epidermis down to the germinal layer, but should not produce immediate oozing of blood. The amount of pressure needed to produce a satisfactory scratch will vary between patients according to the thickness or fragility of their skin.

Apply one drop of Positive Skin Test Control-Histamine to the scratch test site.

b) Prick or Puncture Test: Prick tests are performed by placing a drop of extract on the skin and piercing through the drop into the skin with a slight lifting motion. Puncture tests are performed by placing a drop of extract on the skin and piercing through the drop perpendicular to the skin with a device such as a Prick Lancetter. After about 1 minute the extract may be wiped away with a dry sponge.

HOW SUPPLIED:

SCRATCH, PRICK or PUNCTURE TEST: Positive Skin Test Control-Histamine (6.0) mg/mL Histamine Base), 5 mL sterile amber vial with dropper assembly.

STORAGE:

Store at 2°- 8°C. Protect from light when not in use.

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