



CHEMOTECHNIQUE
DIAGNOSTICS



Patch Testing & Contact Allergy

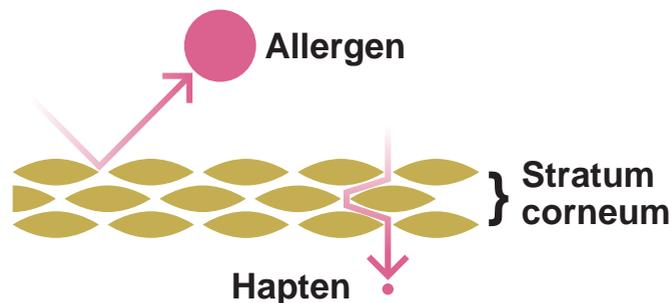


Contact Allergy

Contact Allergy & Allergic Contact Dermatitis (ACD)



Contact Allergy is the result of specific immune responses caused by **antigens**. Unlike **allergens** (such as pollens and animal proteins) causing other forms of allergy, the culprits of Contact Allergies, **haptens**, are not antigens by themselves. Haptens (typically small, chemically reactive molecules with low molecular weight) need to penetrate the horny layer of the skin in order to conjugate to epidermal and dermal proteins forming "hapten-carrier complexes" with antigenic properties capable of causing **contact allergy**. Examples of widely recognized haptens include nickel, formaldehyde and preservatives in cosmetics



Contact allergy is the state of being sensitized to a hapten.

Sensitization to a hapten occurs when the accumulated exposure to the hapten surpasses a certain threshold. This threshold is individual and varies greatly, some will develop an allergy the first time encountering the hapten while others withstand a life time of exposure without becoming sensitized. The median prevalence of contact allergy to at least one hapten is around 25% in the general population.

Allergic Contact Dermatitis (ACD) is a disease of the skin that can emerge in people that are exposed to specific haptens after having developed contact allergy to them. Once allergic, the subject might respond with skin inflammation (redness, flaking skin or blisters) whenever exposed. Individuals handling haptens as part of their profession run a higher risk of developing **ACD**. ACD accounts for 20% of all reported work related skin diseases. Occupational fields with high occurrences of ACD include (but are not limited to) hairdressing, construction work, cleaning and health care. Chronic once developed, and with no known cure, contact allergy is of major distress for those affected.

Diagnosis



While contact allergy cannot be treated it can be diagnosed; by **Patch Testing** and not by **Skin Allergy Testing** (such as skin prick testing - used for the diagnosis of, for instance, respiratory allergies). Knowing what hapten is causing the allergic reactions helps the patient stay clear of that specific hapten, avoiding **ACD** and thereby effectively improving the quality of life for the individual.

The indication for Patch Testing is to **test all patients in whom contact allergy is suspected or needs to be ruled out**, regardless of age or anatomical site of dermatitis. Patch testing may also be advised when suspecting conditions that mimic contact allergic reactions, indications include:

- Erythema multiforme-like
- Lichen planus-like
- Psoriasis of the hands
- Granulomatous or lymphomatoid reactions
- Worsening of pre-existing dermatitis (stasis, atopic or seborrhoeic dermatitis)
- Mucous membrane reactions (conjunctivitis, stomatitis, vulvitis)
- Discoid (nummular) eczema
- Implant reactions
- Certain drug eruptions

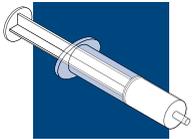
Patch Testing should however never be performed on patients with a known history of severe allergic reactions to suspected haptens or with generalized active dermatitis.



Patch Test Material

Chemotechnique MB Diagnostics AB (Chemotechnique) provides all tools required to perform patch tests the IQ way - the gold standard for diagnosing contact allergy. In order to perform a diagnostic Patch Test, two crucial components are required; **Patch Test Haptens** and **Patch Test Units**.

Patch Test Haptens



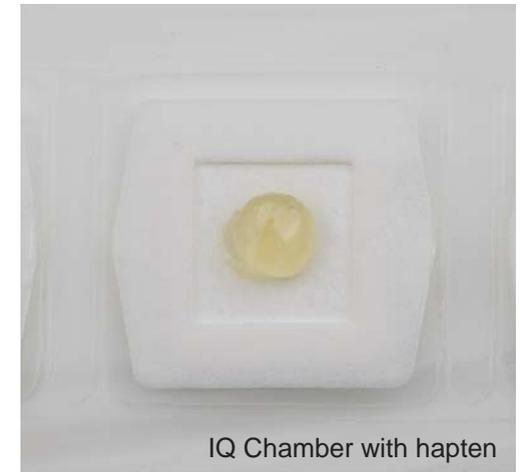
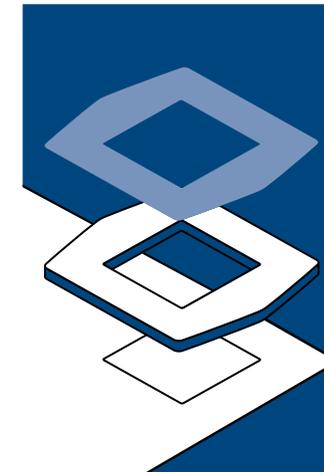
The hapten preparations used in patch testing should ideally be specifically developed for patch testing purposes. The Patch Test Haptens manufactured by Chemotechnique are standardized and prepared by mixing high purity fine particle ground raw material, with high purity grade white petrolatum using state of the art technology.

Patch Test Units



To ensure that the hapten remains in direct contact with the skin for the time required (48h) to create a standardized controlled reaction, a Patch Test Unit is needed. A Patch Test Unit is composed of sets of chambers mounted on an adhesive tape.

The purpose of the Patch Test Chambers is to provide a defined area in which the skin will be exposed to the haptens during the testing. Due to the nature of patch testing it is important that the Patch Test Units used have good occlusion to the skin and that they are made of inert materials that do not interfere with the haptens tested or elicit an allergic reaction in sensitized patients.



IQ - Inert Quadrate

The Inert Quadrate (IQ) chambers are the most technologically advanced Patch Test Chambers ever developed. The laminated tape/foam/filter paper construction results in a comfortable chamber providing a unique closed-cell and leak-free system which defines a test area.

The quadrate shape allows for easy differentiation between allergic and irritant reactions. This patented Patch Test Chamber design is found in both **IQ Ultra™** and **IQ Ultimate™** Patch Test Units. The integrated filter papers makes handling of loose filter papers unnecessary.

Adhesive chamber rim



The adhesive eliminates hapten leakage and enhances the adhesion of the test unit to the skin.

Integrated filter paper



The integrated filter paper facilitates easy handling of liquid haptens.

Foam frame for high comfort

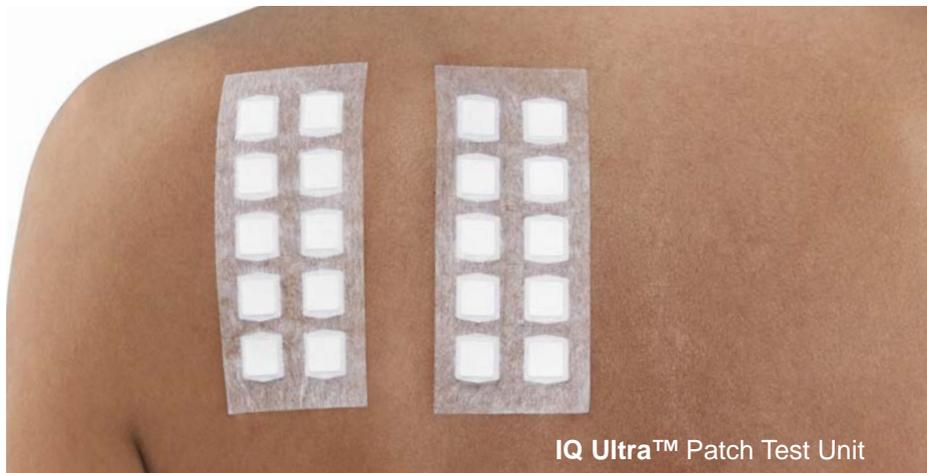


The chambers are made of inert additive free soft polyethylene foam.

Specifications

IQ Chamber:
Inside area: 64 mm²
Chamber volume: 32 µl

IQ Patch Test Units



IQ Ultra™

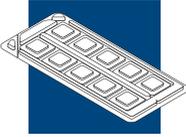
Comfortable and chemically inert - **IQ Ultra™** is the reliable patch test choice. The **IQ Ultra™** is designed to take full advantage of the acclaimed IQ Chambers. The strong adhesive properties of the premium quality, hypoallergenic and latex free carrier tape eliminates the need for extra reinforcement for patients with normal skin. The **IQ Ultra™** Patch Test Units are most cost effective as filter papers and protective covers are not add-ons, but integrated into the design.

IQ Chambers



The **IQ Ultra™** Patch Test Unit is designed to take full advantage of the IQ Chambers. With strong adhesion and compact size it is a versatile and reliable Patch Test Unit.

Preloadable



Preloading helps maximize staff efficiency as multiple tests can be prepared in advance. By using the **Application Device**, loading of the test units is made efficient and time saving.

Closed-cell & Leak-free



The closed-cell chamber provides a defined test area for standardized testing as the concept of dose/area can be used.

Aluminum free



No uncomfortable metal chambers that might react chemically to haptens ensures test reliability. Aluminum free means environmentally safe.

IQ Patch Test Units



IQ Ultimate™

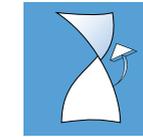
Elastic, transparent and water resistant. In addition to the features shared with the **IQ Ultra™**, **IQ Ultimate™** has the above named added benefits as a result of the 25 micron thin carrier film. Allowing for both showers and moderate exercise - **IQ Ultimate™** is the ideal Patch Test Unit for the diagnosis of contact allergy in active patients.

Water resistant



The **IQ Ultimate™** carrier tape is water resistant allowing for moderate exercise and showers during the patch test procedure.

Highly elastic



The elasticity of the **IQ Ultimate™** carrier tape permits the patient to continue an active lifestyle during the test.

Superior adhesion



IQ Ultimate™ is the perfect patch test choice in warm climate due to its superior adhesion to the skin.

IQ Ultra™/IQ Ultimate™:
The box includes 100 Patch Test Units as well as a Reading Plate.
Patch Test Unit:
Size: 52 x 118 mm
Chambers/Unit: 10 pcs



Preloading an IQ Ultimate™ using the Application Device

Hapten

Chemotechnique offers the widest range of commercially available high quality haptens. The 555+ different preparations are available for purchase in sets of series or as individual preparations. The petrolatum based preparations are supplied in a 5 ml polypropylene syringe and the liquid solutions are supplied in 8 ml polyethylene dropper bottles.

The composition of each of the 47 series has been carefully selected in close co-operation with leading dermatology organizations and contact dermatitis research groups.

Highest quality



The haptens are prepared by grinding high purity raw materials down to extremely fine particle size. The ground particles are mixed either with high purity white petrolatum or with the appropriate highest purity liquid vehicles.

National Baseline Series



In co-operation with contact dermatitis research groups and local clinics we develop and supply country-specific National Baseline Series. These are updated frequently, visit chemotechnique.se for the most recent composition developed for your region.

Series

- European Baseline
- International Comprehensive Baseline
- Bakery
- Corticosteroid
- Cosmetic
- Cutaneous Adverse Drug Reaction
- Dental Screening
- Dental Materials - Patients
- Dental Materials - Staff
- Epoxy
- European Photopatch Baseline
- European Photopatch Extended
- Fragrance
- Hairdressing
- International Standard
- Isocyanate
- Leg Ulcer
- Medicament
- Metal
- (Meth) Acrylate - Adhesives, Dental & Other
- (Meth) Acrylate - Nails Artificial
- (Meth) Acrylate - Printing
- Oil & Cooling Fluid
- Photographic Chemicals
- Plant
- Plastics & Glues
- Rubber Additives
- Shoe
- Sunscreen
- Textile Colours & Finish
- Various Haptens
- National Baseline

Haptens: ~150 patients per series with normal use. Store dark at 2-8°C.





Application Device

The **Application Device** significantly facilitates preloading multiple **IQ Ultra™** or **IQ Ultimate™** Patch Test Units. This is convenient when preparing test series in advance, such as the **Baseline Series**, for a suitable number of patients.

Syringe Cap Organizer

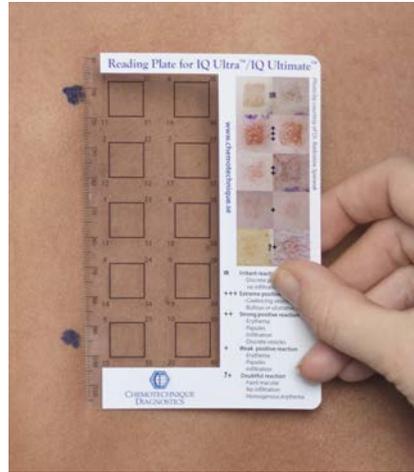


The device is equipped with a special feature facilitating detachment and attachment of the syringe caps without skin contact.

Fixates Patch Test Units



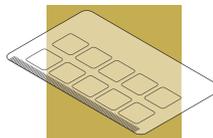
The design prevents the Patch Test Unit from sliding during application of the haptens.



Reading Plate

The **Reading Plate for IQ Ultra™/IQ Ultimate™** facilitates reading and the interpretation of the skin reactions.

Easy Diagnosis



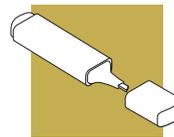
To facilitate visual diagnosis, reference pictures of allergic reactions are printed on the Reading Plate. The images are categorized in accordance with the definition recommended by the **International Contact Dermatitis Research Group (ICDRG)**.



Skin Marking

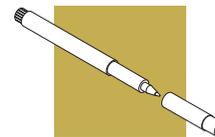
Chemotechnique has developed three different markers to mark the patch test area.

Chemo Skin Marker - Regular™



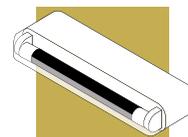
In addition to gentian violet, the Chemo Skin Markers contain silver nitrate for prolonged staining of the skin.

Chemo Skin Marker - Slim™



The **Chemo Skin Marker - Slim™** is a slimmer version of **Chemo Skin Marker - Regular™**.

Chemo Skin Marker - UV™



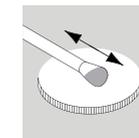
The **Chemo Skin Marker - UV™** paired with the **Ultraviolet Lamp** is suitable for dark skin types or when a non staining marking solution is preferred.



Spot Tests

Chemo Nickel Test™ and **Chemo Cobalt Test™** provide easy ways to detect free nickel or cobalt in metallic objects. The one-component products are easily managed with supplied cotton tips.

Rub & Compare



Rub a moistened cotton tip on the suspected metal object and compare the color result to the supplied reference color.

Patch Testing

Patch testing involves a number of scheduled patient appointments within a one-week time-frame. After the test application on Day 0, two or three appointments are needed for readings.

Preloading



Patch testing can be facilitated by preloading. Non-volatile Patch Test Haptens may be preloaded onto **IQ Ultra™** or **IQ Ultimate™** Patch Test Units and stored for up to two weeks before test application if stored refrigerated, with sealed covers, and kept in air tight bags.

Hapten application

Consider priming each Patch Test Hapten syringes before applying hapten into the Patch Test Chambers. Priming is done by discarding a single dose from the tip of the syringe and thereby possible evaporation/degradation of the active compound is avoided.

Patch Test site preparation

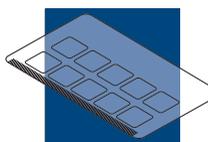
Wiping the test site with ethanol before application is important and will improve adhesion of the Patch Test Unit on patients with oily skin. For patients with very dry or oily skin, additional reinforcing tape might be required. Consider trimming the hair on the test site before patch test application on hairy patients.

Patch Test application

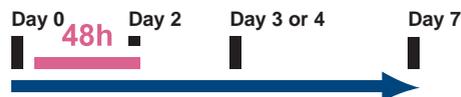


Use the upper part of the patients back if possible. Avoid applying Patch Test Units to the midline and the scapula. Do not put any Patch Test Units under a brassiere which can dislocate the test units. Do not patch test on injured skin.

Reading



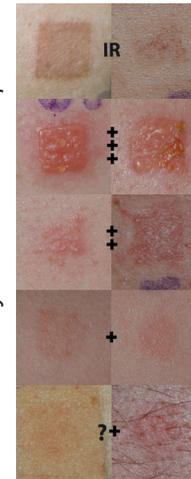
The main reading should be performed within 48h of the removal of the Patch Test Units. A delayed response reading should be performed a full week after the initial test application for haptens that may show delayed reactions.



Day 0: Patch test application (start of 48h hapten occlusion)
Day 2: Patch test removal (optional reading)
Day 3 or 4: Main reading
Day 7: Delayed response reading

The reading criteria for morphologically positive patch test reactions defined by the **ICDRG** is widely acknowledged and used as a reference when diagnosing contact allergic reactions. The reading criteria are visualized below as well as on the **Reading Plate for IQ Ultra™/IQ Ultimate™**.

Pictures courtesy of Dr. Radoslaw Spiewak



IR Irritant reaction

- Discrete patchy erythema without infiltration.

++++ Extreme positive reaction

- Coalescing vesicles • Bullous or ulcerative reaction

++ Strong positive reaction

- Erythema • Infiltration • Papules • Discrete vesicles

+ Weak positive reaction

- Erythema • Infiltration • Papules

?+ Doubtful reaction

- Faint macular • No infiltration • Homogenous erythema

Precautions



Cortisone medication or medications altering the immune system must be avoided prior to and during the test period. The patch test site should not be exposed to UV light during the tests (with the exception of the photopatch series). If using **IQ Ultra™**: Water submersion, showers and exercise should be avoided during the patch test period.

In addition to the visual imprints on the skin from each chamber, a slight erythema from the frames should be visible as a sign of good occlusion. The erythema generally subsides within 30 minutes after removal of the test units but may prevail for up to 24h for patients with sensitive skin. Possible tape irritation generally subsides within 30 minutes of patch test removal.

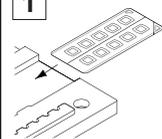
Visit www.chemotechnique.se for a complete list of indications, contraindications, precautions and patch test reactions.

Patch Test Instructions



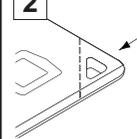
Remove Patch Test Haptens from refrigeration

1



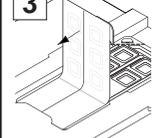
Insert **IQ Ultimate™** or **IQ Ultra™** Patch Test Unit into the **Application Device**

2



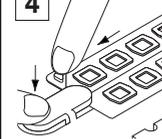
Break the perforation of a preferred corner by folding the corner downwards and upwards

3



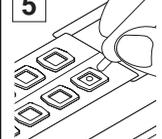
Grip the tape by the detached corner and pull back gently until all chambers are revealed. Do not completely remove the tape from the protective cover

4



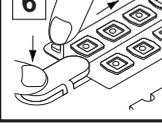
Depress the clip on the **Application Device** and slide the tape underneath - release the clip

5



Apply **25 µl** of hapten in each Patch Test Chamber starting with the 1st hapten of the series in the corresponding chamber

6



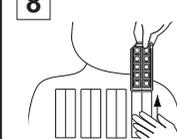
Depress the clip and carefully detach the Patch Test Unit. Remove the Patch Test Unit from the **Application Device**

7



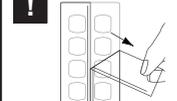
Put haptens (and Patch Test Units if preloading) back in fridge. ! Preloaded Patch Test Units may be stored for < 2 weeks if stored in air tight bags*

8



Position the Patch Test Unit by holding it by its protective cover facing upwards and apply the tape onto the patient. Press your palm on the tape for **5 seconds** to enhance adhesion. Detach the cover and remove the plastic corner. **! Oily skin:** Wipe the test site with ethanol before application to ensure good adhesion

!



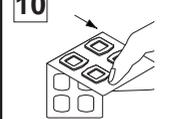
IQ Ultimate™ only:
When all test units have been applied, remove the top-liners with a gentle diagonal motion

9



Mark the 1st and the 5th chamber using a **Chemo Skin Marker**.
! Register the sites location in a Patch test record form**

10



After 48 hours:
Remove the Patch Tests with a rapid diagonal motion to minimize patient discomfort

How much is 25 µl?



25 µl equals approximately to a 5 mm string of petrolatum or a single drop of liquid.

Video Instructions



Visit www.chemotechnique.se for detailed step-by-step video instructions

* Volatile haptens cannot be preloaded.

** Patch Test record forms are available at www.chemotechnique.se

IQ Patch Test Instructions



For more information on patch testing and to access all of our useful patch testing services, please visit www.chemotechnique.se*

Online resources:

- **Patch Test product search**

We have detailed information on all haptens easily available in our product database, useful for physicians and patients alike.

- **Video instructions**

Our detailed patch test video instructions and tutorials are great for first time and long term users alike.

- **Web shop**

We have a web shop service available for all of our users practicing patch testing in areas without local distribution.

- **Patch test record form**

Our user friendly patch test record forms facilitate the patch testing process.

- **Patient information sheet**

Our printer friendly Patient information sheet is a great way of introducing the patch test procedure to your patients.

About Chemotechnique



Chemotechnique - The trusted name in Patch Testing



Chemotechnique has provided Patch Test solutions since 1981 and is proudly recognized as the Trusted name in Patch Testing. Chemotechnique is a Sweden based company with global reach through world-wide distribution.

Research and Development



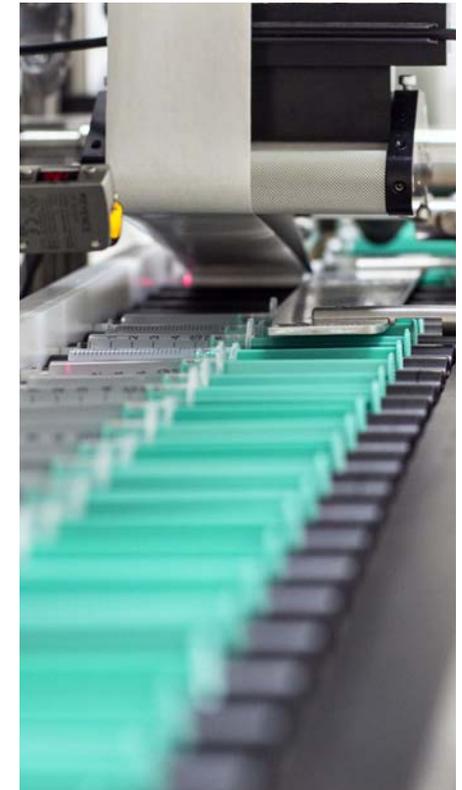
With emphasis on R&D and working in close cooperation with contact dermatitis research groups such as the International Contact Dermatitis Research Group (**ICDRG**), the European Environmental and Contact Dermatitis Research Group (**EEDCRG**) and the North American Contact Dermatitis Group (**NACDG**), Chemotechnique ensures an ideally composed product line-up.

Highest quality products



Chemotechnique offers a complete range of high quality Patch Test Products including haptens, Patch Test Units as well as Patch Test Accessories and Spot Tests. Our haptens are produced in Sweden under strict pharmaceutical control following the **GMP** quality management system audited by the Swedish Medical Products Agency. Certified by the **ISO 13485** and **ISO 9001**

Quality Management systems the Chemotechnique high quality products and reliable service will aid you in the diagnosis of contact allergy in your patients.





CHEMOTECHNIQUE DIAGNOSTICS

DISTRIBUTOR

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