

ESTABLISHING A PATCH TEST CLINIC

A RESOURCE MANUAL



DORMER LABORATORIES INC.
North American Distributors

Chemotechnique
Patch Tests & Accessories

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Each Chamber Rim has Adhesive ■ No Leakage, Enhanced Occlusion

Maximum Adhesion ■ Hypoallergenic Surgical Tape ■ No Additional Taping

Inert, Additive-free Polyethylene ■ Maximum Patient Comfort

1 APPLICATION

Size permits maximum units on back.



2 REMOVAL OF UNITS

A rapid diagonal motion will minimize patient discomfort



3 IMMEDIATELY AFTER REMOVAL

Visual chamber imprints, excellent occlusion.



4 ONE HOUR AFTER REMOVAL

Imprints gone, slight erythema from tape.



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PATCH TESTING

Patch Testing has achieved professional recognition and acceptance as a scientific tool in investigating allergic contact dermatitis, an inflammation of the skin developed by some people as a result of their contact with certain substances (allergens).

The advantage of patch testing for suspected allergic contact dermatitis is that the problem allergens can be identified and the patient's rash can be effectively treated.

There are two types of contact dermatitis:

Allergic contact dermatitis which occurs when the skin has become sensitized to a certain substance (allergen) and comes in contact with that substance again. Allergic contact dermatitis symptoms include:

Reddening of the skin (either in patches or all over the body)

Intermittent dry, scaly patches of skin

Blisters that ooze

Burning or itching which is usually intense without visible skin lesions

Swelling in the eyes, face and genital area

Hives

Sun sensitivity

Darkened, "leathery" and cracked skin.

ACD can be difficult to distinguish from other rashes.

Irritant contact dermatitis which occurs when the skin is repeatedly exposed to a mild irritant, such as detergents or solvents, over a long period of time, or a strong irritant, such as acid, alkali, solvent, strong soap or detergent, which can cause immediate skin irritation.

Irritant contact dermatitis symptoms include:

- Mild swelling of the skin
- Stiff, tight feeling skin
- Dry, cracking skin
- Blisters
- Painful ulcers on the skin

Symptoms vary depending upon the cause of dermatitis.

Contact dermatitis can result from normal daily activity or occupational exposure to these substances.

When to Patch Test

- When allergic contact dermatitis is suspected
- When there is evidence of a work related dermatitis
- When there is any "refractory" or unexplained eczema
- When there is exposure to causative substances (jewelry, fragrances, plants, medications, etc)

(It is not recommended to patch test during pregnancy for medico-legal reasons.)

FINANCIAL CONSIDERATIONS of a PATCH TEST CLINIC

This is the abstract of the paper "Building a Patch Test Clinic" presented at the 15 Annual American Contact Dermatitis Society Meeting, February 5th, 2004, at the Renaissance Hotel, Washington, D.C. by Debra D. Fett, M.D.

BUILDING A PATCH TEST CLINIC

Debra D. Fett, Margo Schlewitz, Department of Dermatology, Indiana University, Indianapolis, Indiana

Patch testing is critical to evaluation and treatment of contact dermatitis. Time, expense, and antigen accessibility may even seem prohibitive.

Objective: To develop a patch test clinic which is financially viable and clinically gratifying.

We started by purchasing supplies, hiring a detail-oriented nurse, and ordering antigens through Chemotechnique (CT). Pharmacy prepared additional antigens not available through CT.

We then started our patch test clinic, testing 6 to 8 patients per week.

The initial start-up costs were approximately \$13,000. Antigens comprised most of the expense at \$9,000. At .625 FTE, the average nursing cost with fringe benefits is \$89 a test. The average number of patches per test is 82 for a total direct cost of \$159.00/test. At \$24.00 per patch (comparable pricing), the average charge per test is \$1,968 and the average collection is \$1,144.00/test. Subtracting the direct expenses and allowing 45% of the revenue for indirect expense, the expected profit per test is \$470 or \$124,000 over 44 weeks.

These numbers reflect our clinic's first 7 months. We anticipate both collections and patient numbers to increase over time.

Conclusion: Developing a viable patch test clinic is possible, challenging and gratifying.

REIMBURSEMENT FOR PATCH TESTING

United States Billing Practices Coding Guide (Patch Testing)

Note: The information provided is believed to be current and correct as of May 1, 2004, however, it is intended to be used only as a guide to the steps required for billing patch testing services rendered by a physician

1. Current Procedural Terminology (CPT) Codes

- a. For the patch test application use CPT Code 95044 (patch or application tests). Specify the number of tests in field 24G of the CMS (formerly HCFA) Form 1500. Each test allergen is a separate billing unit. The total charge is entered in field 24F and is the product of the number of tests and the unit charge per test. In the example shown below, assuming the use of all tests in the North American Series (45 tests), 45 units would be entered in field 24G. Applying a hypothetical unit charge of \$12 per test, a fee of \$540 would be entered in field 24F of Form 1500.
- b. In addition to Code 95044, a separate Evaluation and Management (E/M) code may be billed for the office visit during which the patch test is applied. For new patients, use codes 99201-99205 in field 24D. The CPT modifier 25 (significant, separately identifiable E/M service by same physician) is applied to the E/M code for the visit during which the patch test application occurs.
This is entered in field 24D, as shown in the example.
- c. A separate E/M code is billed for each follow up visit to perform readings (codes 99211-99214). If the reading is taken by a nurse or assistant, use Code 99211; the physician must be available in the office, even if he/she does not see the patient. In the case of the final reading and definitive diagnosis, which may involve a detailed examination, medical decision making of moderate complexity, discussion of results with the patient and counseling on alternative treatments, etc., the appropriate code is related to the time value (*see below*).

E/M Codes

Description	Code	Time
Office visit for evaluation and management of established patient (may not require presence of a physician).	99211	5 min
Office visit for evaluation and management of established patient requiring at least two of the following key components, which must be documented in the patient's file: (a) history; (b) examination; (c) medical decision making.	99212	10 min
	99213	15 min
	99214	25 min
Counseling and coordination of care with other providers or agencies, patient and/or family may also be involved	99215	40 min

2. International Classification of Diseases, (ICD) Codes

692.0	Contact dermatitis from detergents
692.1	Contact dermatitis from oils and greases
692.2	Contact dermatitis from solvents
692.3	Contact dermatitis from topical medication
692.4.	Contact dermatitis from chemical product
692.5	Dermatitis due to food in contact with skin
692.6	Contact dermatitis from plants (except food)
692.8	Dermatitis due to other specified agents
692.9	Dermatitis, unspecified
<i>(Use only when a more specific code is not available)</i>	

3. Form CMS 1500, Field 24 - Example

24	A DATE(S) OF SERVICE						B Place of Service	C Type of Service	D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS I MODIFIER	E DIAGNOSIS CODE	F \$ CHARGES	G DAYS OF UNITS
	MM	DD	YY	MM	DD	YY						
06	01	04				11		99203	25	1	65 00	1
06	01	04				11		99044		1	540 00	45
06	01	04				11		99211		1	20 00	1
06	01	04				11		99214		2	75 00	1

The fees used in this example are for illustration only. They do not reflect values which will apply to all practices; nor are they intended to reflect actual carrier reimbursement levels. Similarly, the choice of E/M codes will depend upon the actual services performed, including complexity and time spent (*see table above*). The number of units entered in field 24G and the charges in 24F depend upon the number of tests performed. The example assumes use of all 45 tests included in the North American Series. Place of Service (POS) Code 11 is used in field 24B to designate office visits. This example shows follow up readings at 48 hours (in the example, performed by nurse or other staff) and a final reading at 72 hours.

Documentation should reflect the level of care, medical necessity, and time spent (see, American Academy of Dermatology; *Coding & Documentation Manual: A Guide for Dermatology Practices*).

SETTING UP THE PATCH TEST CLINIC

PHYSICAL ARRANGEMENTS

In addition to the normal medical office layout and arrangements for handling patients, it would be beneficial for the nurse responsible for the patch testing to have:

- a table or counter area available for the preparation of the tests for each patient, (can be prepared in advance or on day of patient visit),
- a refrigerator for the storage of the allergens and the patient tests prepared in advance of the visit, and
- a storage area for patch testing supplies (chambers, reading plates, skin markers, prefilling application plates, plastic bags, etc.).

PATCH TESTING MATERIALS AND ACCESSORIES

Selection of Allergens:

Chemotechnique Diagnostics AB, of Malmo, Sweden, is the world leader in patch test allergens and accessories. Dormer Laboratories Inc., Toronto, Ontario is their North American Distributor. There are 500+ allergens available commercially, as individual allergens or in 33 specific series.



1. Order by series:

The NORTH AMERICAN SERIES (NA-1000) is comprised of 50 allergens selected based upon the current findings, results and conclusions drawn from the continuing research being undertaken in the patch testing field in North America. This is the most widely used screening series. Also available in extended series (NA-65-1000) and (NA-80-1000).

Additionally, there are 29 specialized screening series:

Bakery (B-1000, 19 allergens)	MethAcrylate-Nails (MN-1000, 13 allergens)
Corticosteroid (CS-1000, 8 allergens)	MethAcrylate-Printing (MP-1000, 24 allergens)
Cosmetic (C-1000, 49 allergens)	North American Photo (NAP-1000, 24 allergens)
Cutaneous Adverse Drug Reaction (CAD-1000, 29 allergens)	Oil & Cooling (O-1000, 35 allergens)
Dental (DS-1000, 30 allergens)	Photographic Chemicals (P-1000, 16 allergens)
Dental Materials Patients (23 allergens)	Plant (PL-1000, 13 allergens)
Dental Materials Staff (10 allergens)	Plastics & Glues (PG-1000, 25 allergens)
Epoxy (E-1000, 14 allergens)	Rubber Adhesives (R-1000, 25 allergens)
European Baseline (S-1000, 28 allergens)	Scandinavian Photo (SP-1000, 20 allergens)
Fragrance (F-1000, 31 allergens)	Shoe (SH-1000, 23 allergens)
Hairdressing (H-1000, 27 allergens)	Sunscreen (SU-1000, 20 allergens)
Isocyanate (I-1000, 6 allergens)	Textile Colors & Finish (TF-1000, 33 allergens)
Leg Ulcer (LU-1000, 27 allergens)	Various (individual allergens) - 42 allergens
Medicament (ME-1000, 14 allergens)	
Metal (MET-1000, 42 allergens)	
Meth Acrylate-Adhesive (MA-1000, 15 allergens)	

(To view the allergen composition of each of these series please click on Patch Testing on the Navigation Bar.)

2. Customize your own series to meet the particular needs of your practice.

You can accomplish this by ordering individual allergens or by ordering a series and adding additional allergens to it.

3. Special allergen requirements

If during your patch testing activities you identify allergen requirements that are not in our catalogue (or on our website) just call or fax us your needs and we will determine if we can provide the allergen and the cost.



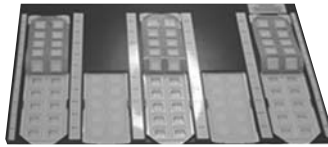
Patch Test Chambers

A small amount of each allergen to be tested is placed into a chamber (there are 10 chambers on each unit) and then placed on the patient's back.

IQ-Ultra patch test chambers are the most advanced patch testing chambers units providing the following features and benefits:

- each chamber has a filter paper used for aqueous allergens incorporated which eliminates the need for loose filter papers;
- the rim of each chamber has an adhesive layer to optimize adhesion to the skin which makes **IQ-Ultra** a closed-cell system enhancing occlusion and eliminating leakage;
- the overall size of the 10 chamber unit is small to allow the application of multiple test units to the patient's back;
- each chamber is made of thin and soft polyethylene foam material maximizing patient comfort;
- highest quality hypoallergenic surgical tape is used reducing the need for additional taping (except with heavy perspiration or excess oil).
- each unit of 10 chambers is attached to a protective recyclable plastic cover which makes it possible to reattach the tape after advance filling of the petrolatum based allergens up to two weeks in advance of need.

For more **IQ-Ultra** information please click on "**IQ-Ultra**" on the navigation bar.



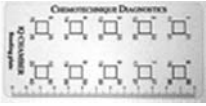
IQ-Ultra Application Plate

Prepare Allergens up to Two Weeks in Advance of Patient Appointment...

Because of the unique design of the **IQ-Ultra** Chamber system (with the recyclable plastic cover) you can now prefill all petrolatum based allergens up to two weeks in advance (aqueous allergens are filled on day of application). Each patient series is placed in a marked plastic bag and refrigerated until the day of application.

This makes the preparation process cost effective and saves nurses/technicians time. For more information on the use of the Application Plate and the pre-filling procedure please click on "**IQ-Ultra**" on the navigation bar.

OTHER ACCESSORIES AVAILABLE TO FACILITATE PROFESSIONAL PATCH TESTING



Reading Plate: to assist in identifying the allergen location on the patient's back after removal of the chamber unit. This is a reusable device.



Skin Markers: for marking the patch test site. This convenient marker contains Methylrosaniline and Silvernitrate for prolonged staining of the skin. For dark skin types or when a non-staining ink is desired a U.V. skin marker if used.



Extra Tape: various widths of hypoallergenic surgical tape (1" and 2" in either roles or dispensers) are available for use with patients where heavy perspiration or excess oil is present.

Other ACD Related Products



Chemotechnique One-Step Nickel Spot Test:

We offer a one-step (dimethylglyoxime) nickel spot test for detection of free Nickel in metal objects. This can be purchased for office use or directly by the patient.

Supplemental Allergens

Mite Patch Testing in Atopic Dermatitis:

Patch Test Mix Dermatophagoides MX21C - 30% petrolatum
50% Dermatophagoide Pharinae
50% Dermatophagoide Pteronyssinus

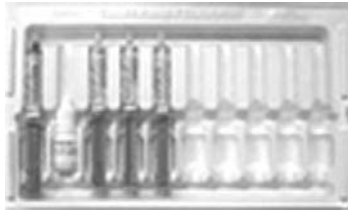
PATCH TESTING & ORDERING INFORMATION

For additional patch testing background and information please browse our web-site. Also to facilitate your ordering or obtaining a quotation please use our online system, on the navigation bar, click on "Patch Testing" and then click on "Order/Quote" and follow the instructions.

You can also fax your orders to **416-242-9487** (or **877-4DORMER**). Our telephone number is **416-242-6167**.

If you would like our latest catalogue please send us an email at info@dormer.com.

PATCH TESTING PROCEDURES



Handling of Allergens

If you order series of allergens you will receive them in plastic storage trays and in proper sequence for application. It is recommended that allergens be stored in these trays and under refrigeration and minimize exposure to light.

To reduce space requirements the trays can be stacked on top of each other.

Each allergen has a label identifying the product and other essential information including an expiry date. The expiry dates vary depending upon the chemical stability with petrolatum based allergens having longer expiry dates (up to 2 years and aqueous and alcohol based allergens shorter periods (up to 9 months). The petrolatum allergens are in syringes and the aqueous/alcohol allergens in bottles.

In order to ensure that you receive allergens with the longest expiry dates we order your allergens directly from Chemotechnique rather than carrying inventory at our facilities. This does require that you allow 4 weeks from the time of order placement for receipt of allergens. We do maintain an inventory of patch test chambers and accessories and ship those upon receipt of your order.

We pride ourselves on our high level of customer service and attention.

Preparation of Allergens

Preparation of allergens (putting allergen in each chamber) for patient application can be handled on the day of the patient's visit or prepared up to two weeks in advance (petrolatum based, aqueous on day of application) and refrigerated.

Complete information on use of the Application Plate for prefilling is found on our website, click on "Patch Testing" and "IQ Ultra".

Applying the Patch Test Chamber Units to the Patient

The ideal application site is the upper back. Mid-back can also be used if necessary. The test chambers should be applied neatly, leaving a gap of approximately 5cm between units and either side of the spine. They should not be applied directly under brassiere straps. A record indicating the order of placement of each allergen must be kept.



INITIAL PATIENT INSTRUCTIONS

Proper explanation to the patient of the patch test procedures will ensure greater patient compliance. Providing the patient with a Handout (sample below) can be helpful.

You are being patch tested to determine if your eczema is caused by an allergic reaction to any specific substances. This will involve several visits to the clinic.

On your first visit an examination and evaluation of potential causes will be undertaken so we can identify potential suspect substances.

On your next visit you will have strips of chambers filled with the suspect antigens placed on your back. This may occasionally feel uncomfortable, and you may develop itching under one or more of the chambers. Try to avoid scratching as itching is normally an indication of a positive reaction and scratching might alter the test results. If pain occurs call the clinic. It is recommended that you keep the area dry during this time period while avoiding heavy and physical exercises that could cause excessive perspiration and detachment of the test unit. We also recommend that you wear loose clothing, and a tshirt in bed as this helps to prevent the patches from peeling or loosening from the skin. (If you notice such a loosening have someone pressure the adhesive onto the skin. If necessary, you can also apply additional tape to the edges of the chamber units.) Abstain from taking cortisone containing medications, and avoid prolonged sun exposure.

The chamber units will be removed in 48 hours with the first reading being done 20-30 minutes after removal. Your physician will advise you if additional readings are necessary over the next 5 to 7 days.

Upon completion of this procedure you will be provided with the results, advised of any allergies you may have and how to minimize possible reoccurrence.

READING THE RESULTS

Exposure Time

Most clinics advocate an exposure time of 48 hours (day 2) after application to the patient's back and again at 96 hours (day 4). If late reactions are suspected a third reading could be scheduled on day 7 or 10. Between readings the patient can take a bath but not wash the back.

Removing the Chamber Units

Before removing the chamber units from the patient's back mark the edges with a skin marker (either the regular or the U.V. marker). Some transient erythema may be present after the removal caused by the occlusive effect of the allergens and adhesive.

It is recommended that the first reading be taken 15 to 30 minutes after the chamber units has been removed. This will allow the erythema to settle.

Reading and Interpreting Results

This phase of patch testing is, of course, the most critical...determining the relevance of any reactions to the allergens and their significance to the patient.

The result of the reading of each allergen is noted on the Record Sheet (click on "Patch Testing" and "Test Forms" for a copy) using the standard scoring system:

- Negative - no reaction
- ? Doubtful reaction
- + Weak reaction
- ++ Strong reaction
- +++ Extreme reaction
- IR Irritant reaction
- NT Not tested

It is suggested that reading of the various Contact Dermatitis reference and resource books can be very helpful in gaining an understanding of this aspect of patch testing. This listing can be found by going to the navigation bar and clicking on "Patch Testing" and clicking on "Reference & Resources".

Patient Information

Once positive reactions are noted and relevance determined advise the patient about sources of exposure, cross reactions, avoidance, etc. It is suggested that the patient be provided with written information specific to their allergies. The dormer.com website provides basic information (click on "Patch Testing" and "Patient Info") that can be added to from other sources.

REFERENCE AND RESOURCE SOURCES

A listing of professional journals and reference books related to contact dermatitis and its practice, internet web-sites, and how to contact the American Contact Dermatitis Society.

BOOKS

- Fischer's Contact Dermatitis, 4 Edition, Rietschel th & Fowler Williams & Wilkins
- Contact & Occupational Dermatology, 2nd Edition, Marks & DeLeo Mosby
- Practical Contact Dermatitis, Guin, McGraw Hill
- Textbook of Contact Dermatitis, 2nd Edition, Rycroft, Menne, Frosch, Springer-Verlag
- Occupational Skin Disease, 3rd Edition, Adams, Saunders
- Patch Testing, 2nd Edition, DeGroot, Elsevier
- Patch Testing, Prick Testing, A Practical Guide, Lachapelle, Maibach, Springer-Verlag
- Management of Positive Patch Test Reactions, Wahlberg, Elsevier, etc. Springer-Verlag

PERIODICALS

- American Journal of Contact Dermatitis, Saunders - The Voice of the American Contact Dermatitis Society
- Contact Dermatitis, Munksgaard - Official publication of European Contact Dermatitis Society

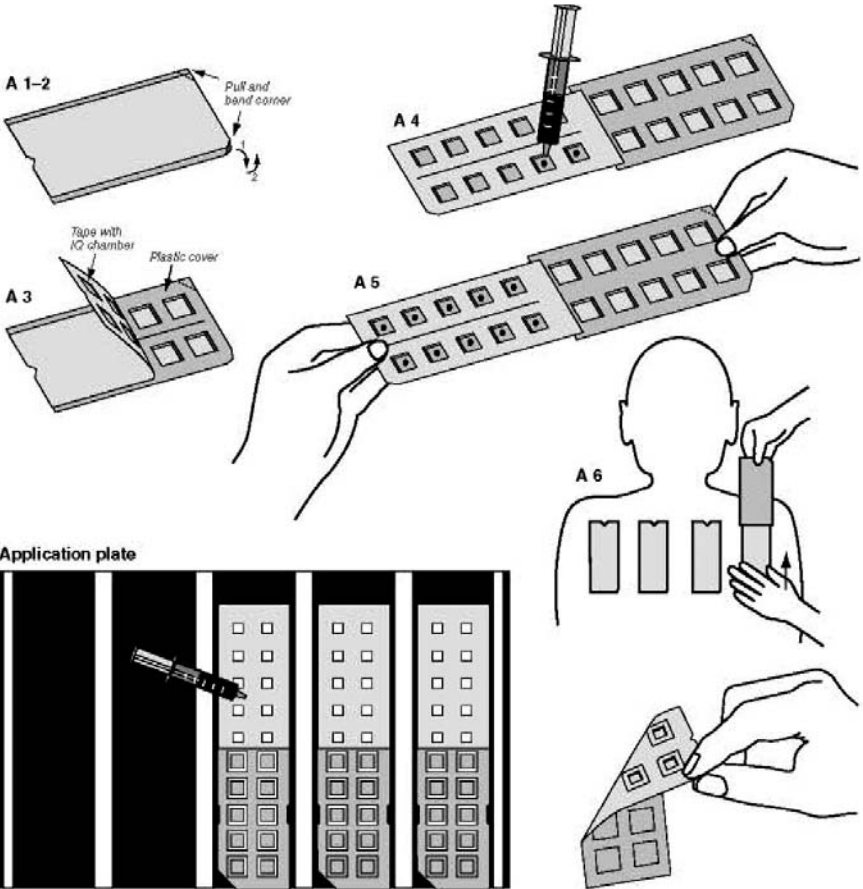
WEB-SITES

- American Contact Dermatitis Society - **www.contactderm.org**
- Dörner Laboratories Inc. (North American Distributor for Chemotechnique Diagnostics AB, Malmö, Sweden) - **www.dorner.com**
- Chemotechnique Diagnostics AB, Malmö, Sweden - Leader in Patch Testing **www.chemotechnique.se** (Requires registration)

PROFESSIONAL SOCIETY

- American Contact Dermatitis Society (section of American Academy of Dermatology) membership and general information - **www.contactderm.org**
Telephone: **847-330-9830** • Facsimile: **847-330-1135**

PREPARATION STEPS



ORDER ON LINE

Place an order / Obtain a quotation for
**CHEMOTECHNIQUE ALLERGENS
& ACCESSORIES**

@

www.dormer.com

Click "Physicians Enter Here"

Click "Patch Testing" Click "Order/Request Quote"

Also available on this site are Patient Information Sheets

DORMER LABORATORIES INC.
North American Distributors

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Toll Free Fax: **1 877 436 7637**

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