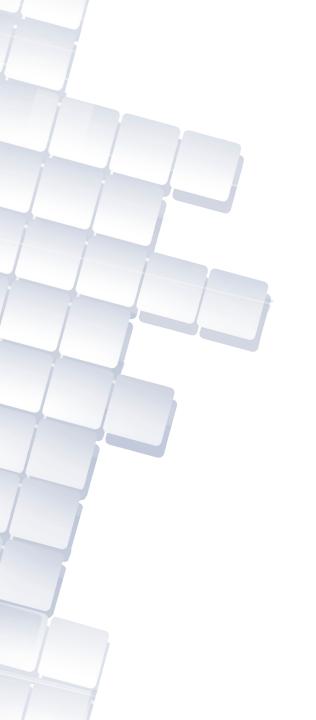


IBS-80® Food Patch Testing

For the Evaluation and Management of Irritable Bowel Syndrome



INTRODUCTION



Irritable Bowel Syndrome (IBS) is a common gastrointestinal disorder affecting 30 to 45 million Americans. Symptoms include abdominal pain accompanied by constipation and/or diarrhea and often excessive gas, bloating and cramping.

The cause of IBS has been unknown, but about 50% of people with IBS report that foods aggravate their symptoms. Recent proof-of-concept studies^{1,2,3} show for the first time that Type 4 food allergies detectable by a tried-and-true dermatologic procedure—patch testing—are the cause of IBS symptoms in many people.

¹Shin GH, Smith MS, Toro B, Ehrlich AC, Luther S, Midani D, Hong I, Stierstorfer M. Utility of Food Patch Testing in the Evaluation and Management of Irritable Bowel Syndrome. Skin. 2018;2(2):1-15.

²Stierstorfer MB, Sha CT, Sasson M. Food Patch Testing for Irritable Bowel Syndrome. J Am Acad Dermatol. 2013;68(3):377-84.

³Stierstorfer M, Toro B._Patch Test-Directed Dietary Avoidance in the Management of Irritable Bowel Syndrome. Cutis. 2021 August;108(02):91-95, E8-E9.



IBS-80®, utilizing skin patch testing to identify Type 4 food allergies, offers potential partial or complete relief of IBS symptoms.

This tutorial presents a brief overview of IBS and the immunology of patch testing followed by a step-by-step tutorial on the art of patch testing with IBS-80®, for primary care providers, allergists, gastroenterologists, dermatologists, and other qualified licensed medical professionals interested in offering this testing.

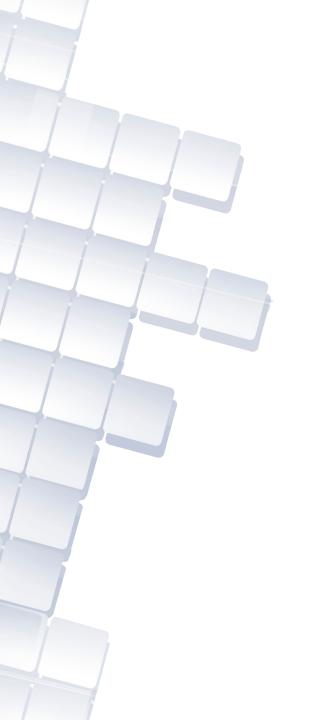
IBS-80® ordering information is included.

Patch Testing

...traditionally performed by dermatologists and allergists

With the discovery of its utility for Irritable Bowel Syndrome, now also a potential procedural skill for medical providers in the fields of:

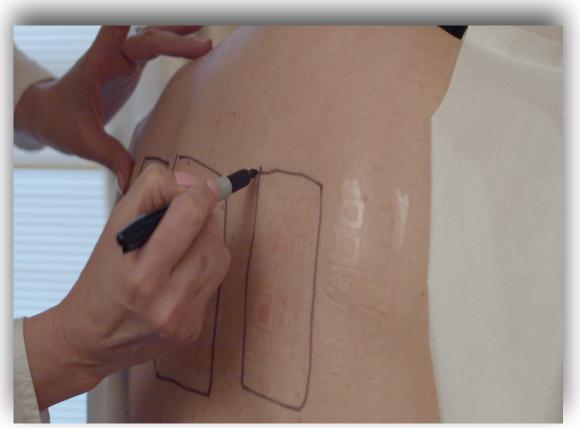
- Primary Care
- Gastroenterology



PATCH TESTING







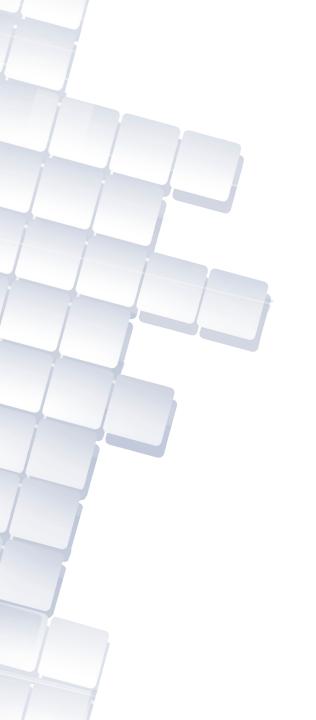
Patch testing traditionally has been used in dermatology to detect causes of allergic contact dermatitis but recently has been shown^{1,2,3} to be useful in identifying food allergies that trigger IBS.

¹Shin GH, Smith MS, Toro B, Ehrlich AC, Luther S, Midani D, Hong I, Stierstorfer M. Utility of Food Patch Testing in the Evaluation and Management of Irritable Bowel Syndrome. Skin. 2018;2(2):1-15. ²Stierstorfer MB, Sha CT, Sasson M. Food Patch Testing for Irritable Bowel Syndrome. J Am Acad Dermatol. 2013;68(3):377-84.

³Stierstorfer M, Toro B._Patch Test-Directed Dietary Avoidance in the Management of Irritable Bowel Syndrome. Cutis. 2021 August;108(02):91-95, E8-E9.

Patch tests are not the same as skin prick and scratch tests, which are used to evaluate conditions such as seasonal allergies, hives and asthma. A comprehensive consensus report from a branch of the National Institute of Health on all aspects of food allergy from 2010 indicates no role for skin prick and scratch tests in the evaluation of irritable bowel syndrome.¹

¹Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Summary of the NIAID Sponsored Expert Panel Report. J Allergy Clin Immun. 2010;126:S1-58.



Food Patch Testing



Before the studies published in 2013¹, 2018², and 2021³, food patch testing (Type 4 food allergy testing) had never been investigated for IBS. The 2018 and 2021 studies showed that a majority of people with IBS who undergo this testing may benefit significantly. When specific food allergies identified by the patch testing are avoided in the diet, over 60% experience moderate to marked improvement or resolution of their IBS symptoms.

¹Shin GH, Smith MS, Toro B, Ehrlich AC, Luther S, Midani D, Hong I, Stierstorfer M. Utility of Food Patch Testing in the Evaluation and Management of Irritable Bowel Syndrome. Skin. 2018;2(2):1-15.

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The Food Allergens



The Patches

IBS-80[®] consists of 8 patches. Each patch (2 x 4.5 inches) consists of a strip of waterproof, hypoallergenic tape containing 10 small wells arranged in 2 columns of 5 wells each, with each well containing a specific food allergen. The position of the food allergen on the patch correlates with its number on the Data Collection Form. The top left well of each patch is labelled #1, 11, 21 and so on. The remainder of the wells are ordered vertically down each column; i.e., the wells in left column for the patch shown here are #1 through #5, and those in the right column are #6 through #10. The patch labelled #11 consists of wells 11 through 15 in the left column and 16 through 20 in the right column, and so on for the remaining patches.



In this figure, "71" corresponds to the well immediately below it, with the remaining wells in the left column being 72 thru 75; the wells from top to bottom in the right column are 76 thru 80. The numbers are written on the clear plastic backing of the the patches during preparation by the pharmacy. In this example, #71 contains salicylaldehyde, naturally occurring in buckwheat, grapes, tomato, cinnamon, milk, coffee and tea.

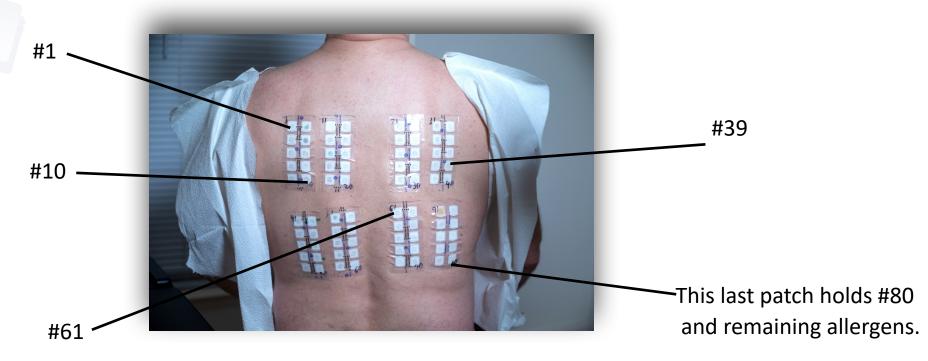




The clear plastic backing is removed from the patches once the patches are applied to the patient.



Thus the patches themselves are unnumbered. Their order is determined by their positioning on the back. If desired, the patches may be renumbered after the clear plastic backing has been removed.

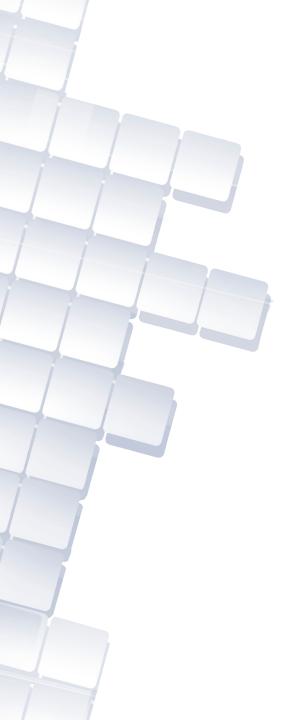


Most of the food allergens are compounded in a petrolatum base and prefilled onto the patches by the pharmacy prior to shipping. These petrolatum-based allergen patches are in ready-to-use form and upon receipt should be stored under refrigeration and used within 10 days from the date of receipt in the office.

The liquid-based allergens must be placed on the wells in the provider's office within one hour of the testing to assure they are still moist when applied to the skin. If dry, they lose some of their potential to elicit an allergic reaction.

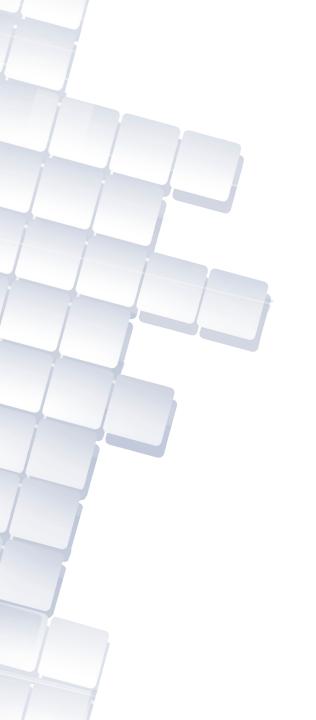
IBS-80® Patch Test Series 80 Type 4 Food Allergens





THE SCIENCE





Allergy Types



There are 4 types of allergic reactions—Types 1 thru 4—each with a different pathophysiology. Types 1 and 4 are the most commonly encountered in the field of medicine.

Immediate-type (Type 1) Hypersensitivity

- IgE antibodies and histamine
- Previously studied and not recommended for IBS

vs.

Delayed-type (Type 4) Hypersensitivity

- T lymphocytes
- Recent studies show usefulness for IBS

Immediate (Type 1) Hypersensitivity

Type 1 allergies, mediated by IgE antibodies and histamine— the type detected by skin prick and scratch tests and RAST blood tests—have been previously investigated and have proven to generally not be involved in IBS. Thus, Type 1 allergy testing is not routinely recommended for IBS.

Delayed-type (Type 4) Hypersensitivity

Patch testing is a test for Type 4 allergies, also known as delayed-type hypersensitivity, a T lymphocyte-mediated process. Food patch testing for Type 4 allergies had never before been investigated for IBS, but recently published studies^{1,2,3} suggest a role for this type of allergy testing in people with IBS.

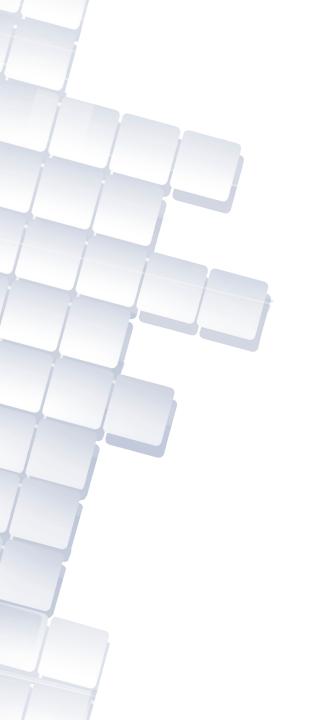
¹Shin GH, Smith MS, Toro B, Ehrlich AC, Luther S, Midani D, Hong I, Stierstorfer M. Utility of Food Patch Testing in the Evaluation and Management of Irritable Bowel Syndrome. Skin. 2018;2(2):1-15.

²Stierstorfer MB, Sha CT, Sasson M. Food Patch Testing for Irritable Bowel Syndrome. J Am Acad Dermatol. 2013;68(3):377-84.

³Stierstorfer M, Toro B. Patch Test-Directed Dietary Avoidance in the Management of Irritable Bowel Syndrome. Cutis. 2021 August;108(02):91-95, E8-E9.

Positive patch test reaction indicating a delayed-type (Type 4) hypersensitivity to the food allergen tested.





THE THEORY

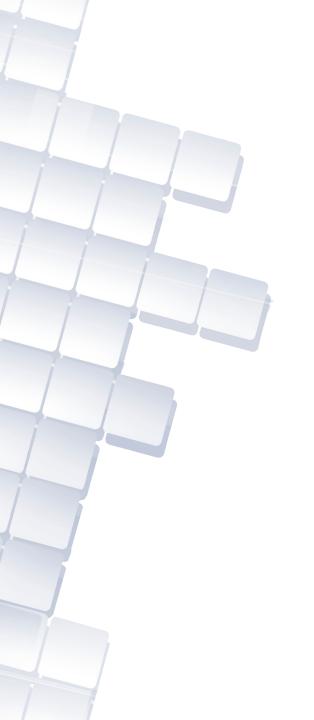


The theory behind the utility of food patch testing for IBS arises from observations of inflammation in the lining of the intestine in IBS patients^{1,2,3} that challenge the long-held view that IBS is a functional disease with no physical or biochemical abnormality. Since the immune system has as much or more access to the lining of the intestine as it does the surface of the skin, it is likely that inflammation similar to that elicited in the skin by food patch testing also occurs in the lining of the intestine when the same foods are eaten. Recent food patch test studies have found that if the foods pinpointed by patch testing are subsequently avoided by the patient, IBS symptoms often improve or completely resolve, thus supporting the theory. Until these studies, a plausible cause for intestinal inflammation in most cases of IBS was unknown.

¹Chadwick V, Chen W, Shu D, et al. Activation of the Mucosal Immune System in Irritable Bowel Syndrome. Gastroenterology. 2002;122:1778–1783.

²Tornblom H, Lindberg G, Nyberg B, et al. Full-Thickness Biopsy of the Jejunum Reveals Inflammation and Enteric Neuropathy in Irritable Bowel Syndrome. Gastroenterology. 2002;123:1972–1979.

³Sinagra E, Pompei G, Tomasello G, et al. Inflammation in Irritable Bowel Syndrome: Myth or New Treatment Target? World J Gastroenterol. 2016;22(7):2242-2255.



ADMINISTERING IBS-80®



Pre-Patch Test Evaluation



IBS-80 is recommended for individuals who have been diagnosed with IBS by their primary care provider, gastroenterologist, or other provider or who have symptoms suggestive of IBS who previously have been evaluated and found to have no other causes for the symptoms.

Of note, patch testing may be difficult to successfully complete in children less than 12 years old who may have difficulty with the necessary restriction of activities during the testing period.

Ordering IBS-80®

Providers may order IBS-80[®] for appropriate patients by prescription. To order, go to www.IBS-80.com \rightarrow Physicians' Home \rightarrow Order Tests Now!. Download a prescription form.

Fax the completed prescription to The Compounding Pharmacist at (610) 692-8505.

IBS-80® Patch Test Kit

IBS-80® patch test kits will be sent via priority mail after receipt of a patient-named prescription by a licensed medical provider.

Each kit includes:

- IBS-80[®] User Guide
- Patches prefilled with all petrolatum-based food allergens
- Internet access to Material Safety Data Sheets
- Data Collection Forms
- Internet access to a software program for food avoidance information and patient counseling customizable to patients' patch test results after testing is complete
- Internet access to a food avoidance questionnaire to determine patient outcomes after patch test-guided food avoidance for a specified period of time

Insurance Reimbursement/ Diagnosis and Procedure Codes

Currently, food patch testing for IBS is covered by some health care insurers. Many insurers that provide coverage for patch testing restrict coverage to 80 allergens annually. Coverage eligibility and limits should be checked prior to scheduling.

ICD 10 diagnosis codes:

- K58.9 IBS without diarrhea
- K58.0 IBS with diarrhea

CPT procedure code for patch testing:

• 95044, with the number of units = 80.

The Compounding Pharmacist 866-692-8770



Pre-Patch Test Counseling



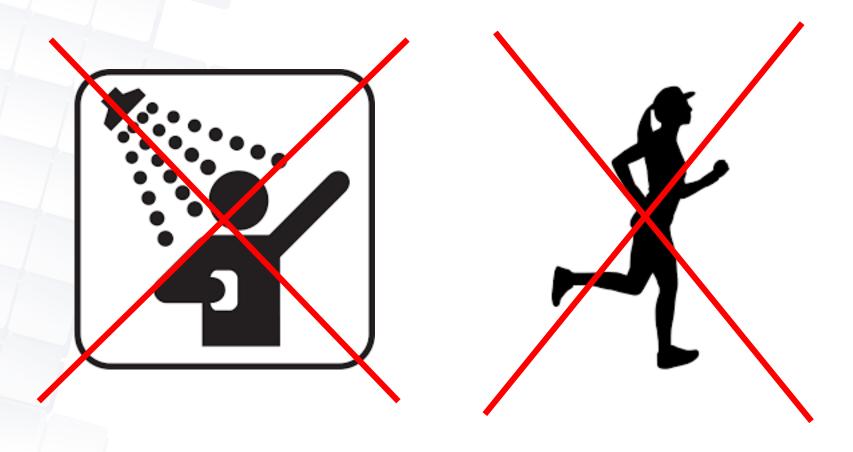
Depending on the extent of pre-test evaluation and counseling, each of the three appointments typically requires 20 minutes or less.

It is important that the patches remain in close contact with the skin for the entire 48 hours after placement on the skin and that nothing suppresses the patient's immune system during the testing. Prior to scheduling and in preparation for the first visit, patients should be counseled on the following:

- Informed consent* may be completed prior to or at the first visit, with any questions answered by the provider.
- Do not expose the back to the sun for four weeks prior to the patch testing as ultraviolet light suppresses the immune system in the skin.
- Any back hair should be shaved two days prior to the day of patch application.
- Avoid application of ointments or lotions to the test areas on the day of patch application.
- Medications that suppress the immune system may affect test results (see "Medications During Patch Testing" later in this presentation).
- When the patches are in place, no showering, swimming, sweat-inducing activities or excessive bending of the back for the 48 hours that the patches are in place. Tub baths are okay but the back must be kept dry. Women may wear undergarments after patch placement and patients do not need to alter sleeping position while the patches are in place.

^{*}A model informed consent is available upon request.





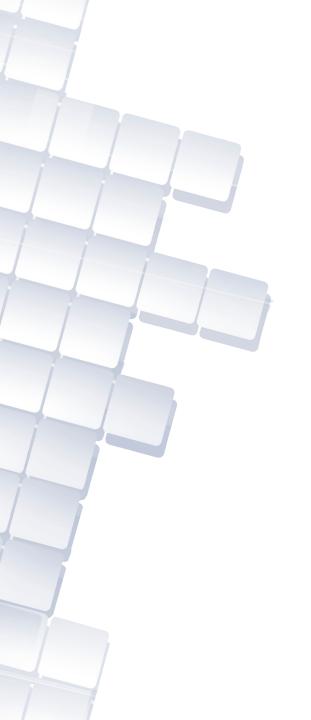


Medications During Patch Testing

Recent literature^{1,2} addresses which immunosuppressive medications may by used during patch testing without causing false negative results:

- Antihistamines okay
- Short term Prednisone okay to patch test after off for 2 to 3 days
- Chronic Prednisone try to reduce to 10 mg or less for a few weeks prior to patch testing
- Methotrexate probably okay
- Anti-TNF inhibitors probably okay
- Cyclosporine, tacrolimus, azathioprine, mycophenylate mofetil probably not okay
- Dupilumab uncertain

¹Fowler JF, et al. Effects of Immunomodulatory Agents on Patch Testing: Expert Opinion 2012. Dermatitis. 2012;23(6):301-303. ²Hoot JW, et al. Patch Testing in a Patient on Dupilumab. Dermatitis. 2018;29(3):164.



Day 1 Patch Application Day



Preparing the Patches

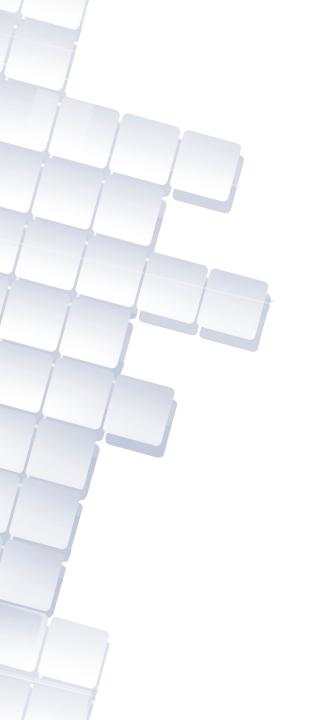
All petrolatum-based food allergens are prefilled on the patches prior to shipping. They should be stored under refrigeration until the day of the testing.

*Note: Prior to testing, the patient should be asked whether he/she has any known food allergies. If so, those foods should be listed on the prescription and will be excluded from the prefilled panels if any are among the foods in the patch test series being used. Alternatively, if not determined until the day of testing, the corresponding wells containing those foods should be cut out and removed from the panel prior to testing. When testing is completed, avoidance information for those foods should be included in the patient counseling.

First Visit Counseling

Repeat some of the pre-test counseling:

- It is essential for the patches to remain firmly adherent to the back for the 48 hours the patches are on the skin. Advise against showering, swimming, sweat-inducing activities or excessive bending of the back during that time. Tub baths are okay as long as the back remains dry. Women may wear undergarments and patients do not need to alter sleeping position while the patches are in place.
- Medications that suppress the immune system may lead to false negative results (see previously shown "Medications During Patch Testing" slide) and should be avoided leading up to and during the testing.
- Advise the patient to wear old and/or dark clothing for the next (48 hours later) visit at
 which time the patches are removed. After the patches are removed, the back is marked
 with a dark marker which may stain clothing.

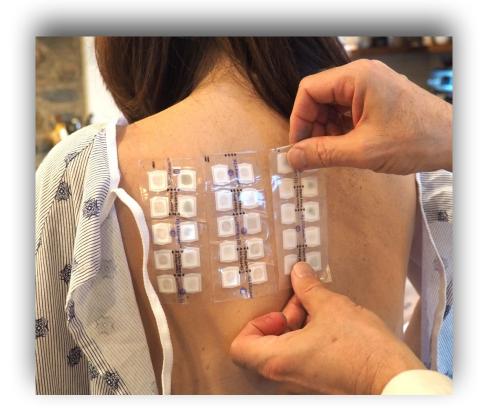


Patch Testing Procedure



Patch Test Application

At the first visit, gently wipe the upper and mid-back (and upper inner arm, if necessary) with an alcohol prep pad ("rubbing alcohol") to remove any excess oil. When the back is dry, apply the vertically oriented patches in order (i.e., 1 thru 10, 11 thru 20, etc.) to the upper and mid back.

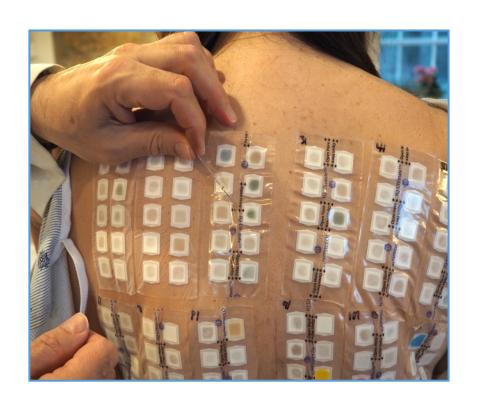


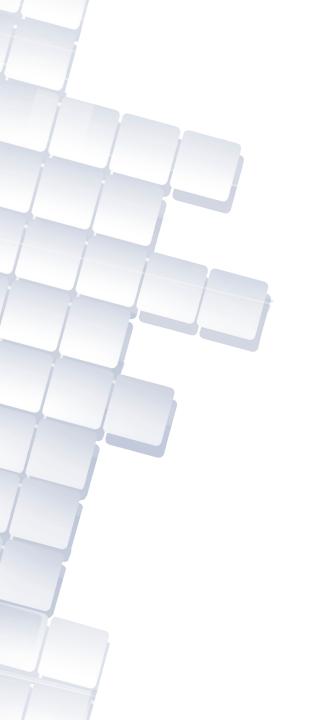
The Data Collection Form lists each food allergen in the order of its numbered position on the patch; i.e., 1 to 80. Be sure to appropriately space the panels so they all fit on the upper and mid-back but do not overlap. Avoid placement directly over the spine.



Representative Data Collection Form for food allergen #'s 1 thru 20.

Next, peel off the clear plastic backing from each patch, taking care not to peel the patch itself from the skin. Finally, press each patch for a few seconds to enhance adherence.





Day 3—2nd Visit



Patch Test Removal, 1st Patch Test Reading

At the second appointment, two days after placement on the skin, the patches are removed. Remove each patch with a rapid diagonal motion to minimize patient discomfort. After removal, use an alcohol prep pad to gently remove any residual patch test allergen debris from the skin test sites. Then mark the back with an indelible black felt tip pen to outline the test sites. Alternatively, just the corners of each patch may be marked. The marks need to be visible at the third appointment, one or two days later, so that any late reactions can be correlated at that time with the correct numbered position of the allergen. Refer to the Data Collection Form for the numbered position of each allergen.

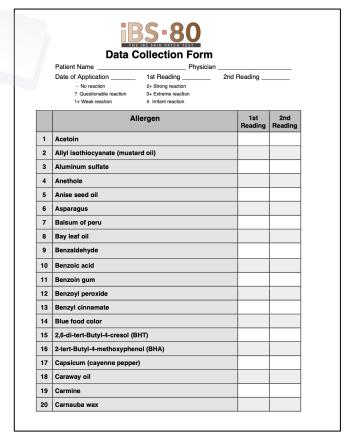


Good lighting and accurate patch test readings are crucial for the success of the testing. It is important that each of the 80 test sites is closely inspected for a reaction at 48 and at 72 or 96 hours and that the food allergen of each reactive site is accurately determined.

Wait at least 15 minutes after patch removal before performing the first reading as transient erythema from occlusion may interfere the reading. In some patients, the entire back where the patches were just removed is red, making it impossible to complete the reading. This generalized redness almost always clears by the next visit/reading at 72 or 96 hours.

Data Collection Form

The 48-hour patch test readings are recorded on the Data Collection Form at this time. The final (72 or 96-hour) reading will be recorded at the next (and usually last) visit.



First page of the 4 page Data Collection Form.

Patch Test Interpretations ("Readings")

Readings are as follows:

Negative (-): Normal appearing skin

Irritant reaction (IR): follicular papules or pustules, erosions, necrosis or burn-like reactions

Uncertain reaction (?): Flat light red area under test chamber

Weak positive reaction (+): Redness, slight infiltration (slight epidermal edema), possible papules

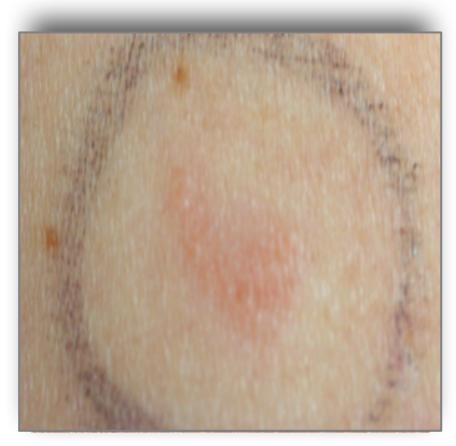
Strong positive reaction (++): Infiltration (epidermal edema), more elevated red papules, vesicles

Extreme positive reaction (+++): Intense redness, infiltration (epidermal edema), coalescing vesicles

Reactions usually approximate the size of the corresponding well on which each food allergen is placed.



Questionable reaction (?) (Macular Erythema)



Weak reaction (+) (Red slightly elevated papule)



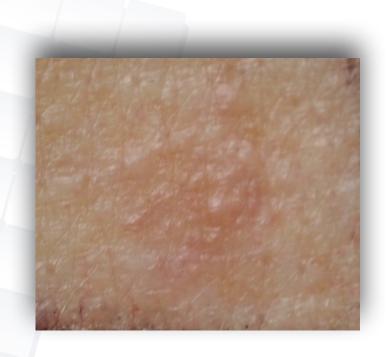
Strong Reaction (++)
(Red moderately elevated papules)

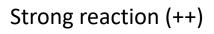


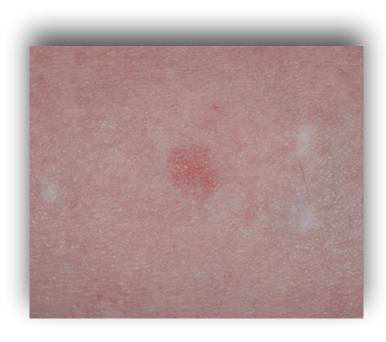
Extreme Reaction (+++) (Vesicular)



Irritant Reaction (IR) (burn-like)



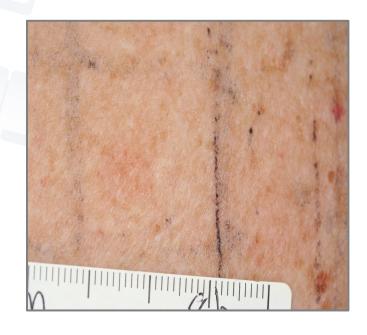




Weak reaction (+)



Questionable reaction (?)



Questionable reaction (?)



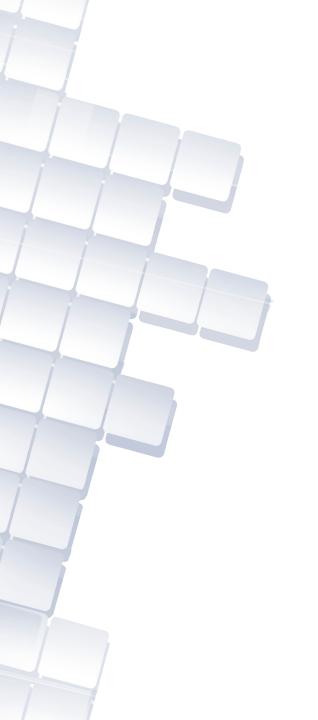
Questionable reaction (?)) (above) Weak reaction (+) (below)



Questionable reaction (?)



Weak reaction (+)

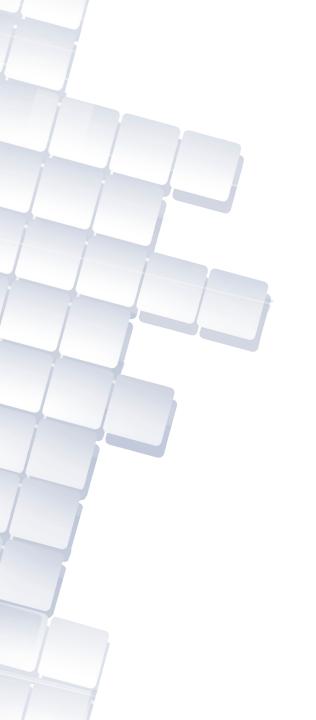


Search Google Images "Patch Test Images" for other examples of patch test reactions



Second Visit Counseling and Beyond

- A shower may be taken as long as not much water gets on the back (face the shower head and do not wash the back) to prevent the skin markings from washing off. The markings need to be visible at the final visit at 72 or 96 hours.
- The patient may arrange for someone to re-mark the test site markings with an indelible felt tip marker if the markings are fading.
- After the final visit at 72 or 96 hours, the patient may shower normally. The back markings will slowly disappear or can be gently washed off with alcohol prep pads to hasten their removal.



Day 4 or 5—3rd Visit

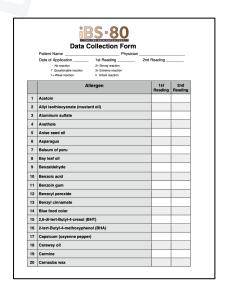


2nd (72 or 96-Hour) Patch Test Reading

It is at this 72 or 96-hour reading that the reading is more significant and more indicative of a true allergic reaction, although irritant reactions sometime remain at these readings as well.

Closely inspect each test site again for a reaction at 72 or 96 hours. Be sure that the food allergen of each reactive site is accurately determined by its position within the marked patch grid.

Record the 72/96 hour reading on the Data Collection Form. The final (72 or 96 hour) reading is the most important and the one upon which patient counseling is based. If a red mark was observed at 48 hours but not at the final reading, it likely was of an irritant nature and not relevant—allergic contact skin reactions should persist beyond 48 hours.



First page of the 4 page Data Collection Form.

Post-Patch Test Patient Counseling Food Avoidance

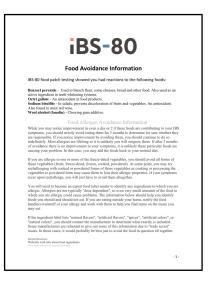


At the third visit, review patch test results with the patient. If there are any positive and/or questionable results, distribute and review food avoidance information. Many patients have reactions of varying degrees and all foods, including those with questionable reactions, should be included in the avoidance counseling.

To generate food avoidance information,

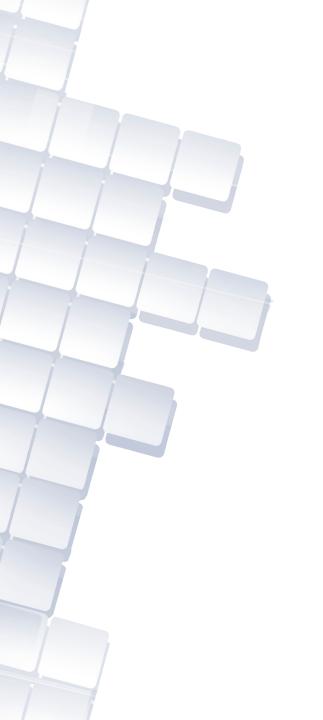
go www.IBS-80.com → Physicians' Home → How to Administer/Patient Counseling, and

scroll down to Food Avoidance.



Advise the patient that if the foods are relevant to the IBS symptoms, improvement should occur within one month of patch test-directed avoidance, often much sooner. If there is no improvement by one month, it is unlikely that the foods being avoided are playing a role in the patient's symptoms and the patient may resume his/her normal diet.

If there are no reactions, inform the patient that nothing was found, meaning that he/she does not have any Type 4 allergies to the comprehensive panel of foods that were tested. There may be other foods contributing to the patient's IBS symptoms, but the foods tested are unlikely responsible.



Post-Patch Test Follow-up



A food avoidance questionnaire and a pre-addressed, stamped envelope with your address may be distributed to the patient at the last visit or mailed to the patient three months after completion of testing. (The latter of these options usually yields higher response rates.) Instruct the patient to complete and return the questionnaire three months after avoiding the foods in question so that you receive follow-up on the outcome of the patch test-directed food avoidance. Utilize copies of the completed questionnaire to provide follow-up information to any of the patient's other providers.

To access the food avoidance questionnaire, go to www.IBS-80.com → Physicians' Home → How to Administer/Patient Counseling → Food Avoidance Questionnaire.

RESOURCES

For more information on the science behind food patch testing for IBS and on administering the testing, please use the following resources:

- www.IBS-80.com
- Clinical Studies:

¹Shin GH, Smith MS, Toro B, Ehrlich AC, Luther S, Midani D, Hong I, Stierstorfer M. Utility of Food Patch Testing in the

Evaluation and Management of Irritable Bowel Syndrome. Skin. 2018;2(2):1-15.

²Stierstorfer MB, Sha CT, Sasson M. Food Patch Testing for Irritable Bowel Syndrome. J Am Acad Dermatol. 2013;68(3):377-84.

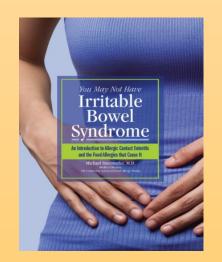
³Stierstorfer M, Toro B. Patch Test-Directed Dietary Avoidance in the Management of Irritable Bowel Syndrome. Cutis. 2021

August;108(02):91-95, E8-E9.

 You May Not Have Irritable Bowel Syndrome—An Introduction To Allergic Contact Enteritis and the Food Allergies that Cause It. ©2014, ©2019, ©2021 by Michael Stierstorfer, MD.

Free download from www.IBS-80.com

FREE BOOK DOWNLOAD



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Fax 610-692-8505
contact@IBS-80.com

Disclaimer

This educational tutorial (Tutorial) is an informational resource for qualified medical providers (Providers) interested in performing IBS-80® patch testing. The Tutorial is intended to assist Providers by teaching or reviewing basic principals of skin patch testing as it relates specifically to Type 4 food allergen patch testing for individuals with Irritable Bowel Syndrome (IBS) or symptoms suggestive of IBS. Principals and practice vary among experts and this Tutorial presents just one approach to patch testing and its use in the evaluation and management of IBS.

The Tutorial serves only as an informational tool for Providers and does not establish a physician-patient or other relationship with any person.

If you have any questions about this Tutorial, please let us know. Email contact@IBS-80.com.