



IBS-80 Food Patch Testing Informed Consent

What is this testing for?

Food allergy patch testing searches for possible causes for Irritable Bowel Syndrome (IBS) and related symptoms. 80 foods and food additives are placed in contact with the skin (patch testing) for 2 days to look for an allergic response in the skin. Such responses may correlate with similar reactions in the gastrointestinal (GI) tract, which may give rise to symptoms of IBS or other gastrointestinal conditions.

Which foods are being used for the testing?

80 carefully selected common foods and food additives are used. All are safe to eat as normally encountered in the food supply. The food and food additive allergens have been prepared in a form suitable for patch testing by a licensed compounding pharmacy.

Is the testing FDA-approved?

The food allergens used in the testing have not been evaluated by the Food and Drug Administration (FDA) and thus are not FDA-approved. Most medical providers in the United States who perform more than just the most basic patch tests, typically for the purposes of evaluating a rash called “eczema”, use patch test materials that are not FDA-approved.

Is this testing the “standard of care”?

Patch testing is routinely performed in the evaluation of eczema but, because it is so new and is not yet used in a widespread manner for the evaluation of IBS and related symptoms, it is not yet the “standard of care” for these conditions. The usefulness of food patch testing for IBS was discovered in recent years and clinical studies^{1,2,3} support its usefulness:

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.
<https://jofskin.org/index.php/skin/article/view/223>

²Stierstorfer MB, Sha CT, Sasson M. **Food Patch Testing for Irritable Bowel Syndrome.** *J Am Acad Dermatol.* 2013;68(3):377-84.
<https://www.ncbi.nlm.nih.gov/pubmed/23102771>

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.

What will I have to do?

The tests involve 3 visits to the office at Day 1, Day 3 and Day 4 or 5; typically Monday, Wednesday and Thursday or Friday. Individuals who show one or more allergic skin reactions will be advised to avoid eating those foods for one month (and indefinitely if symptoms improve or resolve) and will be asked to complete and return a brief follow-up questionnaire after the one month period.

The tests are conducted as follows:

Day 1: Small amounts 80 foods and food additives will be placed individually under small inert chambers (each slightly less than 1/2 inch wide) and taped with hypoallergenic adhesive tape to your back and/or arm. From the time the patches are placed on your skin until they are removed 2 days later, you must do your best to keep the areas dry by taking a tub bath or sponge bathe to prevent water from getting on the patches while bathing. Swimming and excessive sweating should be avoided for these 2 days to assure the tape remains secure and the patch tests remain in place. Wear loose clothing to help prevent the patches from being pulled off. If the patches start coming loose, you may press on the patches and apply additional tape to the edges of the patches, if needed.

Day 3: The tape and chambers containing the food and food allergens are removed and the first patch test reading is performed by the medical provider and recorded. The sites will be marked with a non-permanent felt-tipped marker. From this point and beyond, you may shower normally except to avoid soap and scrubbing where the patches were placed so you don't wash off the markings until after your third (final) visit.

Day 5: The patch test sites are read by the provider for the final time.

Are there potential side effects if I participate in this testing?

If you are allergic to any of the foods or food additives being tested, you may develop a small red itchy or burning spot or bump at each skin test site where an allergic reaction occurs. A severe reaction could blister or open sore at the test site. The use of a medicated cream may be considered necessary to relieve these itching or burning sensations. On rare occasions, it may be necessary to remove the test strips before the normal 48 hour test time because of severe itching or burning. If pain develops, call your medical provider. Occasionally, a dark or light spot at the test site appears during healing. Healing with or without medication normally takes place within 5 days to 2 weeks, although reactions in some individuals may persist longer, especially dark or light scars which may last for months or rarely be permanent.

Very rarely, anaphylactic (immediate allergic) reactions have been reported to occur with skin patch testing. Should hives, sweating, dizziness, wheezing or shortness of breath occur after application of the test allergens, you should remove the patch tests yourself and inform the provider immediately.

Rarely, this type of allergy testing may cause a person to become allergic to one or more of the substances being tested. A test reaction that appears 10 days or later with no preceding reaction may be a sign of a newly developed allergy. Such an allergy may cause a rash if you touch the substance to which you have become allergic or gastrointestinal symptoms if you eat it. The rash can be treated effectively with over-the-counter or prescription creams, if necessary.

Reactions to the tape or adhesive may occur. The chambers are made of additive-free polyethylene plastic foam.

Who should not participate in this testing?

You should not participate if you:

1. are pregnant or have a severe rash.
2. know you have a severe allergy to adhesive tape.
3. have received by injection or by mouth any cortisone-containing or other immunosuppressive

medications within the week before the testing or plan on doing so during the testing.

If you have any known food or food additive allergies), please report them to our staff prior to the testing so that, if they are among those we are using, we may eliminate them from the testing.

Is my participation in this testing confidential?

Your participation in this testing and your individual results are strictly confidential. We will share results with your other medical providers if you would like us to do so.

What is the cost of the testing?

Fees are \$_____ for the patch tests themselves and standard charges for office visits. The fees include information on how to avoid any foods to which you are found to be allergic and a report to your primary care provider and any other qualified healthcare professionals you may designate. Because patch testing for IBS is new, it may not be covered by your medical insurance.

If you have any other questions, please do not hesitate to ask.

By signing below, you acknowledge that you understand the above information, have been given the opportunity to ask questions, and agree to participate in the testing. You also understand it is possible that no food allergies will be found, and that if any are found, your gastrointestinal symptoms may or may not improve if you avoid eating them.

Patient signature

Date

Provider signature

Date

Patient name (print)

Provider name (print)