



Allergenis Peanut Diagnostic Discussion Guide

So you're ready to talk about the Allergenis Peanut Diagnostic with your healthcare provider? Great! Allergenis wants all individuals with a peanut allergy and their caregivers to have clarity on their food allergy. Just print and fill out this discussion guide to make the most out of your conversation with your healthcare provider.

Before talking with your provider

There are several ways to contact your allergist to request testing. Schedule an in-office or telehealth visit.

If you make an appointment,
you can note it here.

date

time

Before speaking to your healthcare provider, answer these questions and share your responses with them:

	yes	no	not sure
Are you currently eating peanuts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you had a recent reaction to peanuts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have anxiety about choosing safe foods to eat due to your peanut allergy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have anxiety about the events you attend due to your peanut allergy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are you interested in what peanut allergy treatments may be right for you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



During the discussion

When determining if the Allergen Peanut Diagnostic may be right for you, here are some questions you can discuss with your healthcare provider:

- How accurate are the current diagnostic tests (Skin Prick and IgE)? Am I really allergic to peanuts? What are my test results?

Skin Prick and IgE blood tests are great rule out tests, if they are negative than you are likely not allergic. However, many diagnostic test results (up to 60%) give a false positive diagnosis when a patient is not truly allergic.

- Will threshold data help me have better clarity and confidence in the daily decisions I make about the foods in my diet? Or about the events I attend?

If allergic, the Allergen Peanut Diagnostic can determine your threshold level by assigning you one of three levels of reactivity. For example, patients that are in level 3 may be able to tolerate one peanut without a reaction.

Once you and your healthcare provider determine the Allergen Peanut Diagnostic is right for you, then it is time to fill out the order form. You can complete the form or your healthcare provider can do it for you.

After the Allergen Peanut Diagnostic is ordered

If your provider is doing an in-office blood draw, we can ship a kit directly to their lab for the draw. If your provider decides to utilize Allergen's mobile phlebotomy service, we will coordinate shipping a blood draw kit to you. You will then receive an email to set up a good time and location for the mobile phlebotomist to come do the draw. All Allergen mobile phlebotomists are trained in pediatric draws.

The following documents may provide additional data and insight for your healthcare provider on the validity of the test. The document has a link that your provider can visit to contact Allergen to order testing.

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laboratory requisition

- 1 Complete all the fields in red before taking to your provider.
- 2 Request your provider complete the fields in blue.
- 3 Email a copy of completed form to orders@allergenis.com

Place specimen label here:

7 Digit Draw & Ship Kit Barcode: _____

Specimen Draw Date: _____ Specimen Volume: _____ Phlebotomist Initials: _____

patient information

Last Name: _____ First Name: _____

Parent/Guardian Name (if patient under 18): _____

Relationship to Patient: _____

Address (to ship draw kit): _____

City: _____ State: _____ Zip Code: _____

DOB: / / Sex: M F

Phone: _____ Email: _____

patient consent

I have provided informed consent for the test ordered above. I authorize Allergenis (AG) to bill my insurer(s) on my behalf for AG's services, and I irrevocably assign my right to payment to AG and my right to appeal any negative coverage decision made by my insurer. I am expressly and knowingly assigning to AG all my rights to pursue ERISA breach of fiduciary duty claims and other legal and/or administrative claims. I am aware that I am responsible for amounts not covered by my insurer(s), including deductibles, copays, or coinsurance. If an insurer pays me directly, I will send the endorsed check to AG within 30 days of receipt. I am aware that AG may refer me to a collections agency if I do not do so.

Patient (or Parent/Guardian) Signature: _____

Print Name: _____ Date: _____

billing information

Private Insurance Medicare Patient Self-Pay Medicaid Other: _____

Insurance Information: Attach a copy of front and back of patient insurance card and complete below:

Primary Insurance Carrier: _____ Member ID#: _____ Group ID#: _____

Secondary Insurance Carrier: _____ Member ID#: _____ Group ID#: _____

Name of Subscriber: _____ DOB: / / Relationship: _____

test request Provider please select the test option below.

allergenis peanut diagnostic¹ **NOTE: Patient must NOT be on any food allergy therapy. Test includes both diagnosis and threshold, including threshold for all allergic patients.**

provider information

Ordering Provider Name (s): _____

NPI#: _____

Center Name: _____

Email: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____

Report Delivery Method: (Default is portal.)
 If different than above, please provide alternate below.
 Fax FedEx Portal

provider signature

I have supplied information to the patient regarding testing and the patient has given consent for the testing to be performed. I further confirm that this test is medically necessary for diagnosis of, and the results will be used in the medical management and treatment decisions for, the patient. I confirm I am the person listed in the Ordering Provider space above and am authorized by law to order the test requested herein. I agree that any electronic signatures I provide are the same as handwritten signatures for the purposes of validity, enforceability, and admissibility.

Provider's Signature: _____

Print Name: _____ Date: _____

COMMONLY USED DIAGNOSIS CODES* | ICD-10 CODES (Select all that apply):

- | | |
|---|---|
| <input type="checkbox"/> PEANUT | <input type="checkbox"/> UNSPECIFIED |
| <input type="checkbox"/> Z91.010 Allergy to peanuts* | <input type="checkbox"/> Z91.018 Allergy to other foods* |
| <input type="checkbox"/> T78.01XA Anaphylactic reaction due to peanuts, initial encounter* | <input type="checkbox"/> T78.40XA Allergy, unspecified, initial encounter* |
| <input type="checkbox"/> T78.01XD Anaphylactic reaction due to peanuts, subsequent encounter* | <input type="checkbox"/> T78.40XD Allergy, unspecified, subsequent encounter* |
| <input type="checkbox"/> T78.01XS Anaphylactic reaction due to peanuts, sequela* | <input type="checkbox"/> T78.00XA Anaphylactic reaction due to unspecified food, initial encounter* |
| | <input type="checkbox"/> T78.2XXA Anaphylactic shock, unspecified, initial encounter* |

OTHER ICD-10 CODES: _____

* This is provided for informational purposes only is not intended to be a complete list. Use of these codes is not a guarantee of coverage. It is the provider's responsibility to determine the appropriate codes based on the documented medical record.

1 patient completes

2 provider completes

LABELING

1. Print the patient's name and DOB on each label. Affix one label to the front of this Requisition Form (TRF), one to the EDTA Lavender Top Tube, and one to the specimen tube. Affix extra labels below.
2. Note the 7 digit barcode located on the draw and ship kit box.
3. Draw the patient's blood by performing a standard venipuncture procedure using the EDTA Lavender Top Tube. Fill the tube completely.
4. Mix the blood in the tube by inverting 8-10 times.
5. Centrifuge the EDTA lavender top tube using manufacturer's instructions. Approximately 15 minutes at 1500 RCF.
6. Transfer the plasma into the microcentrifuge specimen tube using the transfer pipette and seal with cap.
7. Ensure at least 200 ul of plasma. Note: 200 ul is approximately the second line on the transfer pipette.

PACKAGING

1. Place both the EDTA lavender top tube and the microcentrifuge specimen tube into the biohazard bag.
2. Remove the excess air and seal the bag along the zippered track.
3. Fold the Test Requisition Form into quarters and place the requisition in the side pocket of the biohazard bag.
4. Activate the temp tag. Fold at the dotted line and firmly pull up. Dispose of the tab.
5. Activate the cold pack by squeezing the middle of the bag.
6. Place the biohazard bag, temp tag, and cold pack into the foil bubble pack.
7. Close the lid of the box and ensure tight. Place box in the provided pre-labeled FedEx bag.

STORAGE

- Ship same day as draw.
- If necessary, store prepped and packaged sample in refrigerator or ambient temperature (40-78°F/4-27°C).

EXTRA SPECIMEN LABELS

Please affix any extra labels below.



a NEW way to diagnose peanut allergy patients

stratify your patients in a way never been done before

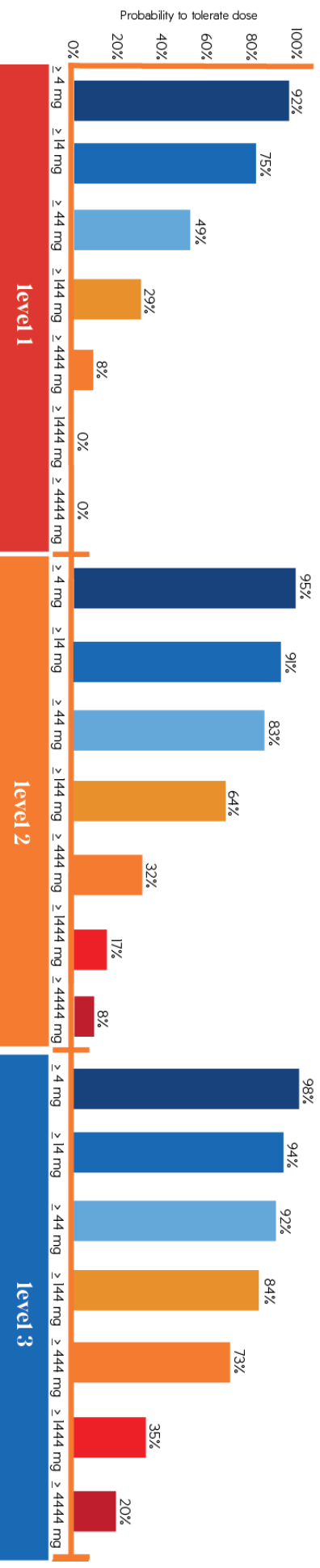
The new Allergenis Peanut Diagnostic provides additional, highly accurate insight into your allergic patients that you have never received before in a blood test. The new testing can now:

- give over 93% accurate diagnosis.¹⁻³
- provide threshold levels for each allergic patient.²⁻³
- inform probability of risk of an in-office oral food challenge.²
- Increase insight into the appropriate patients for immunotherapy.²
- advise appropriate starting eliciting doses (so you can potentially shorten the escalation period).²
- provide guidance on the risk of reaction to cross contamination, which may reduce patient and/or caregiver anxiety during accidental ingestion.

the only test that provides over 93% accuracy and epitope reactivity level⁵⁻⁶

epitope reactivity level for every allergic patient

The Allergenis Peanut Diagnostic is an accurate blood based test which predicts a patient's allergy status and the epitope reactivity level.⁴⁻⁶ If a patient is allergic, the diagnostic provides an epitope reactivity level of 1-3 which aligns with the PRACTALL dose guidelines used in an oral food challenge.¹⁻³ This gives insight into what level of peanut protein ingestion your patient may likely tolerate which may help you and your patient plan next steps, such as an oral food challenge or allergy immunotherapy.⁶⁻⁷



PRACTALL Cumulative Tolerated Dose Levels⁸

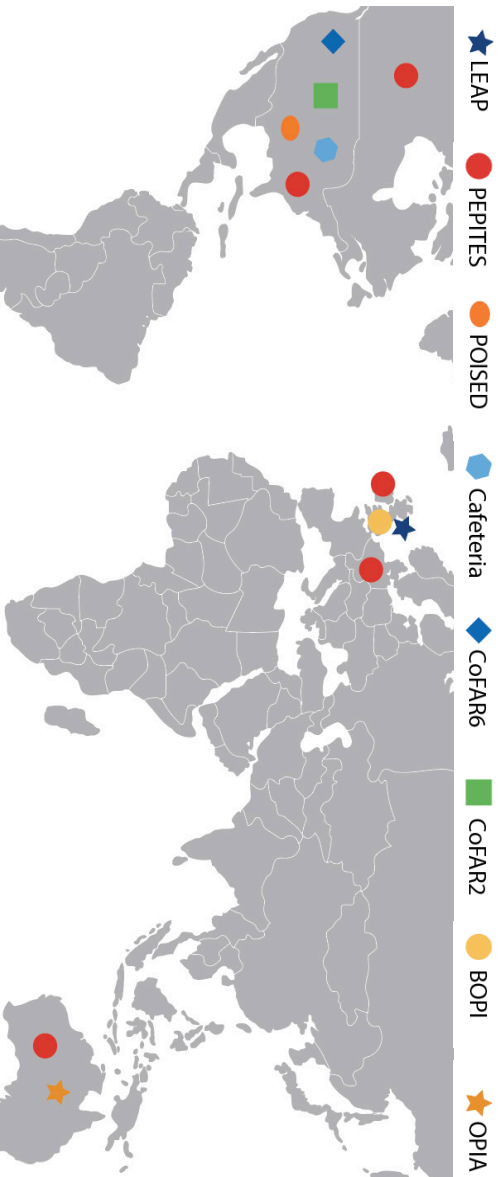
diagnostic utilizes epitope mapping technology⁴⁻⁵

Epitope mapping subdivides allergenic proteins in foods into smaller peptides, or epitopes, and then measures the reactivity of a patient's blood IgE and IgG4 levels to these epitopes. The results are put through our machine learning algorithm which has been rigorously validated to the gold standard, a PRACTALL double-blind placebo controlled oral food challenge.



extensive, diverse, multi-cohort validation

Allergens currently holds the largest repository of peanut allergy oral food challenge confirmed cases in the world. The peanut diagnostic was validated across international, well-characterized and diverse cohorts. Only cohorts using a double-blind oral food challenge result were included in the validation of the test.



ready to order?
Scan the below code to get started. You can also visit allergenis.com.



references

1. Suarez-Farinas M, Suprun M, Kearney P, Getts R., Grishna G., Hayward C., Lita D., Porter A., Wimmer M., du Toit G., Lack G., Chinthrajah R., Gallil S., Nadeau K., Sampson H. Accurate and Reproducible Diagnosis of Peanut Allergy Using Epitope Mapping. 15 May 2021. **Allergy.** 2. Data on file, available upon request. 3. Sampson H., Genth van Wilk R., MD, Bindsev-Jensen C., Sicherer S., Teuber S., Burks W., MD, Dubois A., Beyer K., Eigenmann P., Speigel J., Werfel T., Chirchilli V. PRACTALL consensus report. 2012. *JACI*, 130:6 4. Lin J, Bardina L, Shreffler WG, Andreae D, Yongchao G, Wang J, Burni F, Fu Z, Han Y, and Sampson HA. Development of a novel peptide microarray for large-scale epitope mapping of food allergens. *J Allergy Clin Immunol*. 2009;124(2):315-322. 322.e1-3 5. Suprun M, Getts R, Raghunathan R, Grishna G, Wimmer M., Gimenez G., Sampson HA., and Suarez-Farinas M. Novel Bead-Based Epitope Assay is a sensitive and reliable tool for profiling epitope-specific antibody repertoire in food allergy. *Scientific Reports*. 2019. : 18425. 6. Crevel R., Ballmer-Weber B., Holzhauser T., Hourihane J., Krusi A., Macke A., Timmermans F., Taylor S. Thresholds for food allergens and their value to different stakeholders. *Allergy*. 2008;63:597-609. 7. Hourihane J, Allen K., Shreffler W., Dunnington G., Nordlee J., Zurzolo G., Dunnington Z., Gurrin L., Baumert J. and Taylor S. Peanut Allergen Threshold Study (PATSt): Novel single-dose oral food challenge study to validate eliciting doses in children with peanut allergy. *J Allergy Clin Immunol* 2007; 139:1583-90.

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