

patient

NAME:
DOB:
GENDER:
MEDICAL RECORD/ID#:

provider

PROVIDER:
NPI:
CENTER:
ADDRESS:
PHONE:
ACCOUNT:
OTHER PROVIDER:

specimen

SPECIMEN ID#:
COLLECTION DATE:
REPORT DATE:
SPECIMEN TYPE:
RECEIVED DATE:



allergenis peanut diagnostic

Bead-Based Epitope Assay (BBEA)¹⁻²

allergy status

likely allergic

description

Patient is likely allergic:

- Post test probability of patient being allergic to peanuts is greater than or equal to 91%.¹
- Results should be considered in conjunction with patient’s history and other applicable information.

epitope reactivity level

level 1

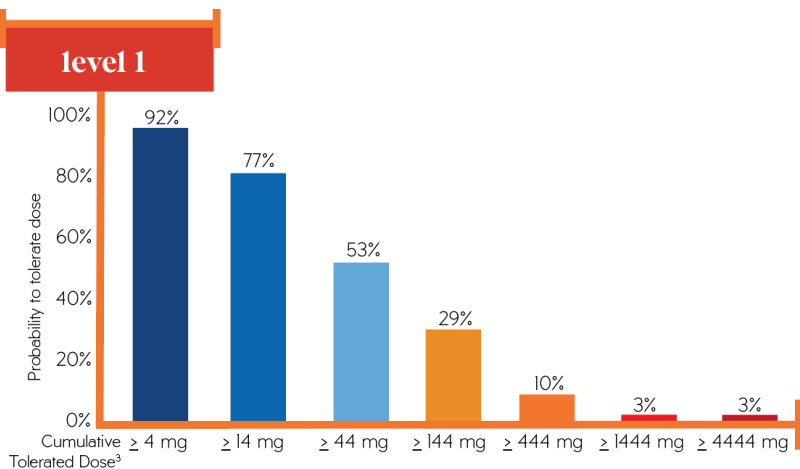
level 2

level 3

description

A level 1 patient is a low dose reactor, meaning the patient may react to even low levels of peanut protein. The higher the level, the more peanut that a patient can consume before having a reaction.

level 1



description

Cumulative Tolerated Doses (CTD) shown for a Level 1 peanut allergic patient. A CTD of at least 14 mg would be tolerated by 77% of patients in this level, as determined by a standardized oral food challenge.²⁻³

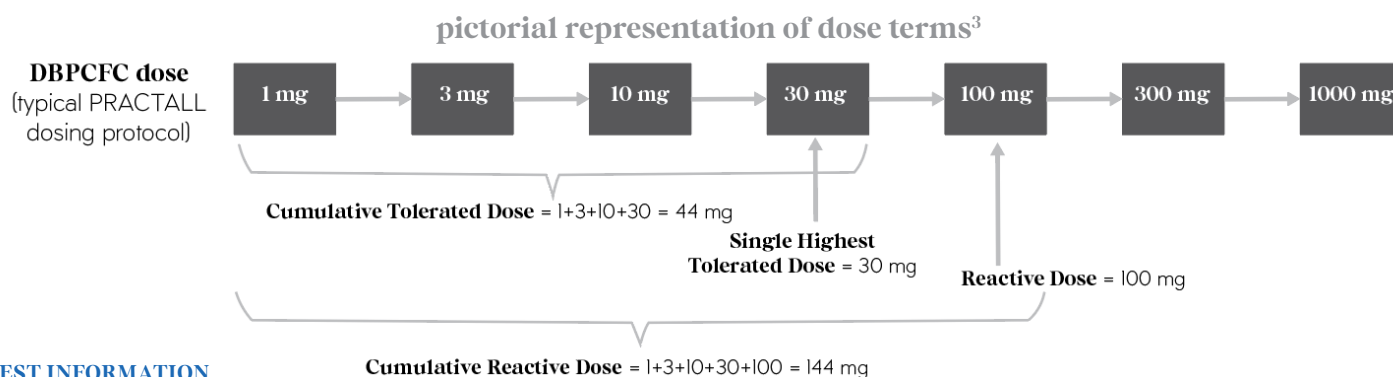
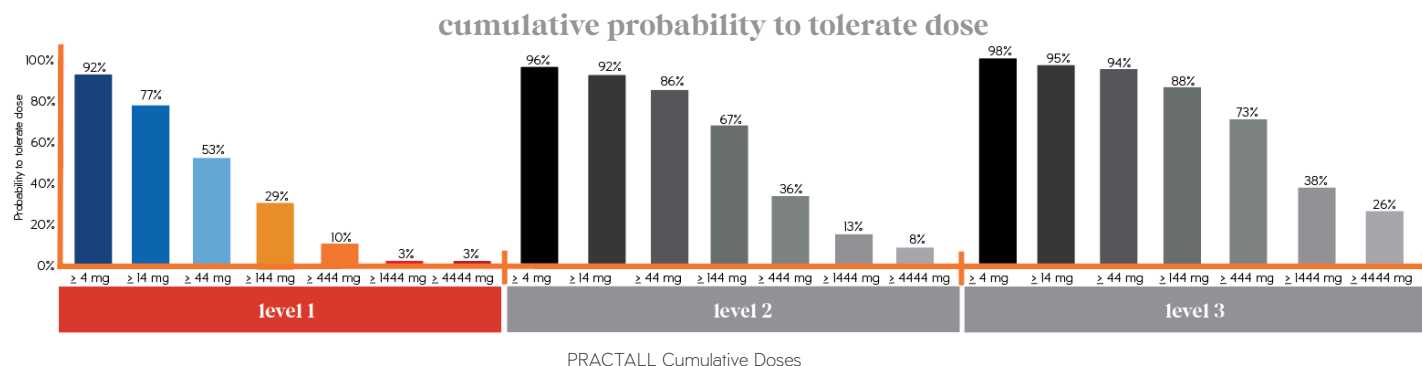


Actions and management of food allergies are best managed by a board certified allergist, or those licensed providers with extensive training in food allergy.

references

1. Suarez-Farinas M, Suprun M, Kearney P, Getts R., Grishina G., Hayward C., Luta D., Porter A., Wimer M., du Toit G., Lack G., Chinthrajah R., Galli S., Nadeau K., Sampson H. Accurate and Reproducible Diagnosis of Peanut Allergy Using Epitope Mapping. 15 May 2021. *Allergy* . <https://doi.org/10.1111/all.14905>
2. Suprun M, Kearney P, Hayward C, Butler H., Getts R., Sicherer S., Turner D., and Sampson H. Predicting probability of tolerating discrete amounts of peanut protein in allergic children using epitope-specific IgE antibody profiling. *Allergy*. 2022;00:1-9. doi: 10.1111/all.15477
3. Sampson H., Gerth van Wijk R., MD, Bindslev-Jensen C., Sicherer S., Teuber S., Burks W., MD, Dubois A., Beyer K., Eigenmann P., Spergel J., Werfel T., Chinchilli V. PRACTALL consensus report. 2012. *JACI*, 130:6

notes:



TEST INFORMATION

Allergenics peanut diagnostic is a Laboratory-Developed blood-based test service offered by prescription to licensed health care providers. The test uses a Bead-Based Epitope Assay (BBEA) and is clinically validated on multiple cohorts. Allergenics peanut diagnostic monitors the reactivity of patient IgE with multiple epitopes (linear peptides) from the peanut allergen Ara h2.

TEST PERFORMANCE

Development of Allergenics peanut diagnostic followed the National Academy of Medicine’s established guidelines with discovery performed on 133 subjects from the non-interventional arm of the LEAP trial (NCT00329784) and an independent clinical validation performed on 166 subjects (65 allergic, 101 non-allergic) from the CoFAR2 (NCT00356174) and POISED (NCT02103270) cohorts. All subjects in the clinical validation had allergy status confirmed by oral food challenge (OFC) and ranged in age from <2 to 49 years. In the clinical validation, Allergenics peanut diagnostic showed 93% concordance with an OFC.

Reactivity threshold determination was developed using 75 samples from the BOPI (NCT02149719) and OPIA (ACTRN12617000914369) studies where cumulative reactive doses (CRD) ranged from 3 mg of protein to >4443 mg protein. Independent clinical validation was performed on 237 samples from 4 cohorts, BOPI, OPIA, Cafeteria (NCT03907397) and CoFAR6 (NCT01904604) where patient CRDs ranged from 1 mg to >9043 mg. Predicted reactivity values correlated with log(CRD) levels with a Pearson correlation p-score of 3.49E-13.

The test uses epitope mapping to characterize a patient’s allergen reactivity levels. The test results are then calculated from the reactivity levels. The test results are independent of the patient’s age, gender, or the presence of other allergen sensitivities. For additional information please contact Allergenics Customer Support.

LABORATORY INFORMATION

The Laboratory is regulated under the Clinical Laboratory Improvement amendments of 1988 as qualified to perform high complexity clinical testing (CLIA Laboratory License #39D2178580). Allergenics Peanut Diagnostic was developed and its performance characteristics defined by Allergenics. It has not been cleared or approved by the US Food and Drug Administration; the FDA does not require this test to go through premarket FDA review. The laboratory-developed test is indicated in the clinical assessment of peanut allergy and is used for clinical purposes. It should not be regarded as investigational or for research use only.

Disclaimer

Assumes Allergenics peanut diagnostic is being ordered and threshold values are being applied from publication. The Allergenics peanut diagnostic test is not validated for patients who are currently taking omalizumab or any immunotherapy and test results may not be reliable. For additional information please contact Allergenics Customer Support.

references

1. Suarez-Farinas M, Suprun M, Kearney P, et al. Accurate and Reproducible Diagnosis of Peanut Allergy Using Epitope Mapping. 15 May 2021. *Allergy*. <https://doi.org/10.1111/all.14905>
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