How Reliable & Accurate is the Alcat Test?

Analytical Validation | Reproducibility, Specificity, and Sensitivity

The Alcat Test shows correlation between a) a reaction, b) a specific test item, c) the pathogenic inflammatory effect.

Clinical Sensitivity & Specificity

- **83.4%** foods
- **96%** for additives

≥ 80%, which is remarkably high (n=154)

Reproducibility

- **92-96%**
- Reproducibility controls are implemented regularly
- CLIA controlled and licensed lab without any warning letters

State of the Art Methodology

- **Impedance-flow cytometry**

According to the current state of science, impedance-flow cytometry is the international standard used to analyze early cellular responses. Due to its high accuracy it is superior to all other available methods.

Analysis of cellular responses by conventional flow cytometers can miss early adverse cellular responses. We refer to the work of Prof. M. Cooper, a pioneer in label-free technology for "continuous non-invasive real-time cell monitoring."

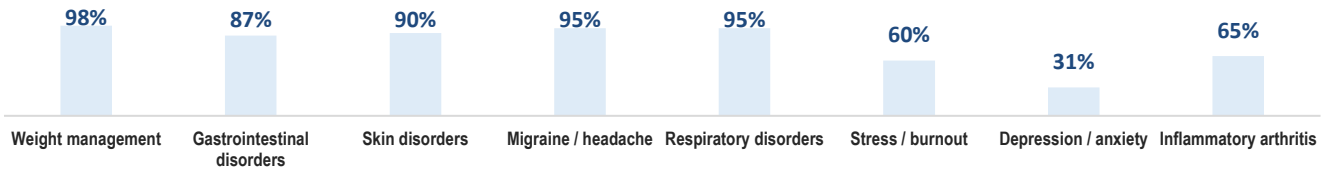
Pathomechanism
Validated and published by Yale University

Proof of Concept: The Alcat test identifies foods that trigger inflammatory cell responses:

- DNA supernatants with reactive Alcat reactions is considered a **specific immune marker**
- Another significant marker was neutrophil elastase (NE). It is associated with **inflammatory processes and increased intestinal permeability**.
- The identified immune path, Protein Kinase C (PKC) is associated with **chronic diseases, metabolic syndrome, autoimmunity and some types of cancer**. A diet based on Alcat results can **significantly reduce symptoms** (IBS)
- **Innate immune cells** were identified as the target cells. Especially eosinophils and neutrophils induce inflammation, a main factor in disease development

Data on file / from double blinded validation only

Health benefits: meta-analysis of data from appr. 1,300 patients



Studies and Research

Alcat / Research Overview reversed chronological order 2018-1988

The following section provides a comprehensive overview of the scientific research conducted to date on the Alcat Test. Studies include double-blind placebo controlled trials, molecular pathomechanism assessment, mechanistic/technical studies, and review papers. Conditions studied include gastrointestinal disorders, skin diseases, respiratory problems, metabolic diseases, autism, migraine and others.

Study ref. number / title	Author / publication	Year / study type study subjects	Data points
1) *Effect of Antigen-stimulated Leucocyte Activation Test-Based Diet on Inflammation, Body Composition, and Medical Symptoms*	**Northern Illinois University** Lukaszuk J, Shokrani M, Hoppensteadt J, and Umoren J.; AlternativeandComplementaryTherapies; ArticleID:MNM909073; Minitexon:10/2018 Downloaded by University of Minnesota BIOMEDICAL LIB 325A from https://www.liebertpub.com/doi/abs/10.1089/act.2018.29183.jml	**2018** Clinical study; multiple disorders n=133 **DBPC**	26,600 NEW
2) *A leukocyte activation test identifies food items which induce release of DNA by innate immune peripheral blood leucocytes*	**Yale School of Medicine**; Garcia-Martinez et al.; Yale University; Biomedical Central Nutrition & Metabolism; 4/2018 https://doi.org/10.1186/s12986-018-0260-4	**2018** Molecular patho-mechanism n=20 **DBPC**	*3,000 +1,228 in Aptamer Proteom analysis* NEW
3) *Efficacy of individualized diets in patients with irritable bowel syndrome: A randomized controlled trial*	**Yale School of Medicine**; Ali A, Weiss TR, McKee D, et al; Yale University; BMJ Open Gastro 2017;4:e000164. doi:10.1136/ bmjgast-2017-000164, Accepted 18 August 2017 http://bmjopengastro.bmj.com/content/bmjgast/4/1/e000164.full.pdf	**2017** Clinical study; IBS n=58 **DBPC**	Ca. 12,000 NEW
4) *Individualized Diets in Irritable Bowel Syndrome: A Randomized Controlled Trial*	**Yale School of Medicine:** Ather Ali (1), Theresa R. Weiss (2), Alisa Scherban (1), Sumiya Khan (1), Douglas McKee (1), Damian Apollo (1),Wajahat Z. Mehal (1)**;** online.liebertpub.com/doi/full/10.1089/ACM.2016.29003.abstracts#_OA04.04	**2016/17** Clinical study; IBS 58 patients **DBPC**	ca. 12,000
5) *The Alcat Test Predicts the Release of DNA and Myeloperoxidase by Innate Immune Peripheral Blood Leukocytes Via a PKC Dependent Pathway*	**Yale School of Medicine**: Irma Garcia-Martinez (1), Theresa R. Weiss (2), Ather Ali (2), Wajahat Z. Mehal (1); online.liebertpub.com/doi/full/10.1089/ACM.2016.29003.abstracts#_i106	**2016/17** Molecular patho-mechanism n=20	*3,000*
6) *Effect of Alcat-Based Food Elimination on Inflammatory Markers, Body Composition, and Medical Symptoms*	**Northern Illinois University**; Lukaszuk J, Shokrani M, Hoppensteadt J, and Umoren J. Prof. J. Lukaszuk April 10, 2016, of the University of Miami Miller School of Medicine	**2016/17** Clinical; multiple disorders 133 patients **DBPC**	ca. 30,000
7) *Food Intolerance: Immune Activation Through Diet-associated Stimuli in Chronic Disease.*	**Pietschmann et al.;** Alternative therapies in health and medicine. Jul-Aug 2015;21(4):42-52.; http://www.ncbi.nlm.nih.gov/pubmed/26030116	**2015** Review paper	
8) *Food Reactivity on the ALCAT Leukocyte Activation Test is Associated with Upregulation of CD11b on T Cells.*	**Yale School of Medicine**: Ayaz G, Wajahat M, Ather A. The Journal of Alternative and Complementary Medicine. 2014;20(5):A35-A36. https://www.researchgate.net/publication/262146351_Food_Reactivity_on_the_ALCAT_Leukocyte_Activation_Test_Is_Associated_with_Upregulation_of_CD11b_on_T_Cells	**2014** patho-mechanisms n= 10 **DBPC**	3,000
9) *Evaluation of ALCAT Test results in the non IgE-mediated pathology of the skin.*	**De Amici M, Berardi L**, Castello M, Mantegna G, Giunta V, Ronzi G, Vignini M. Allergy: European Journal of Allergy and Clinical Immunology. 2011;66:226. http://insights.ovid.com/allergy-european-clinical-immunology/algy/2011/06/001/evaluation-alcat-test-results-non-ige-mediated/553/00000381	**2011** Clinical; skin 35 patients	1,750
10) *ALCAT Test results in the treatment of gastrointestinal symptoms.*	**Berardi L,** De Amici M, Castello M, Torre C, Giunta V, Legoratto, Vignini M. Allergy: European Journal of Allergy and Clinical Immunology. 2011.	**2011** Clinical; GI disorders 48 patients	2,400
11) *Rational management of food intolerance in elite soccer club.*	**Angelini F.;** Journal of the International Society of Sports Nutrition 2011;8 (Suppl 1):36. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238170/	**2011** multiple symptoms 8 athletes	800
12) *Utilidad clínica del test ALCAT. Mito o realidad [Clinical utility of the ALCAT test. Fact or fiction?]*	**Ángel San Miguel et al.;** FUEL AND ENERGY ABSTRACTS. 2010;107(1):12-20. https://www.researchgate.net/publication/251563604_Utilidad_clinica_del_test_ALCAT_Mito_o_realidad	**2010** Review paper	/
13) *ALCAT test identifies food intolerance in patients with gastrointestinal symptoms.*	**Berardi L,** De Amici M, Castello M, Torre C, Giunta V, Legoratto, Vignini M. Allergy: European Journal of Allergy and Clinical Immunology. 2009;64:490. https://insights.ovid.com/allergy-european-clinical-immunology/algy/2009/64/001/alcat-test-identifies-food-intolerance-patients/1285/00000381	**2009** Clinical; gastrointestinal 15 patients	750
14) *Food intolerance in patients with cutaneous diseases: diagnostic value of the ALCAT test.*	**Berardi L,** De Amici M, Vignini A, Torre C, Mosca M. Allergy: European Journal of Allergy and Clinical Immunology. 2009;64:490. http://insights.ovid.com/allergy-european-clinical-immunology/algy/2009/64/001/food-intolerance-patients-cutaneous-diseases/1286/00000381	**2009** Clinical: Skin 14 patients	700

15) *The effect of the ALCAT test diet therapy for food sensitivity in patients with obesity.*	**Akmal M, Khan SA, Khan AQ**.; Middle East J Fam Med. 2009;7(3). https://www.researchgate.net/publication/268337548_The_Effect_of_The_ALCAT_Test_Diet_Therapy_for_Food_Sensitivity_in_Patient%27s_With_Obesity	**2009** weight loss 27 patients	2,700
16) *Comparison of cellular changes upon exposure to allergens between ROBOCAT II versus FACSCalibur-based methods.*	**Jensen G.;** NIS Labs (Natural Immune System) Oregon USA, 2009	**2009** Method validation	/
17) *The right stuff: Use of ALCAT testing to determine dietary factors affecting immune balance, health, and longevity*	**Deutsch RD**; Anti-Aging-Therapeutics, Volume X; 2007 Conference Year, Chapter 8 https://www.researchgate.net/publication/287020093_The_right_stuff_Use_of_ALCAT_testing_to_determine_dietary_factors_affecting_immune_balance_health_and_longevity	**2007** Review paper	
18) *IMS Health Economics and Outcomes Research- Influence of Food Intolerance in Migraines: Final Report of Statistical Results.*	**Immunological Center of Catalunya**; Version 3, December 28, 2006. http://whatsmyfoodintolerance.com/media/Influence_of_Food_Intolerance_in_Migraines.pdf	**2006** Clinical: Migraine 21 patients	2,100
19) *Technical Study Comparing the Alcat methodology with Activation of Granulocytes Following Challenge with Zymosan*	**Mele C. et al.,** University of Rome, 2002	**2002** Research paper methodology	
20) *Ogni intervento comincia a tavola. [Every intervention begins at the table]*	**Mele C. et al.;** University of Rome; Medici Oggi, Maggio 2002: 210-213.	**2002** Research paper methodology	
21) *The Controversial antigen leukocyte cellular antibody test (ALCAT): a non-specific inhibitory effect of alpha glycoproteins.*	**Kedryna T, Guminska M.;** Med Sci Monit 1999; 5(2):BR193-197.	**1999** Immunol. research paper 37 patients	370
22) *Parexel Medstat Statistical Report- Final Statistical Report: Study of the ALCAT Test in 10 Subjects.*	**Fuglerud P;** Norway, Nov. 1999 Not published	**1999** Reproducibility validation; 10 patients **DBPC**	10,000
23) *Reproducibility of the Antigen Leukocyte Cellular Antibody Test.*	**Neetling WML, Kachelhoffer AM;** University of The Orange Free State in Bloemfontein, South Africa, Jan-April 1998	**1998** Reproducibility validation 10 patients	1,000
24) *Outcome Study in 353 Consecutive Patients Following the Alcat Diet*	**Hoj L.;** Allergy Clinic Charlottenlund Presentation	**1998** 353 patients	
25) *Evaluation of the cytotoxic food test and the ALCAT (antigen leukocyte cellular antibody test).*	**Pasula MJ.;** Pol Merkur Lekarski. 1997 Feb;2(8):154-159. https://www.ncbi.nlm.nih.gov/labs/articles/9538667/	**1997** Review paper method evaluation	
26) *South African Outcome Study randomized Study on 274 Patients.*	**Geldenhuys J.;** Johannesburg, S. Africa, 1997 **Not published**	**1997** Clinical: Multiple disorders 274 patients **randomized**	13,700
27) *The short term efficacy of the ALCAT test of food sensitivities to facilitate changes in body composition and self-reported disease symptoms: a randomized controlled study.*	**Kaats GR, Pullin D, Parker LK.;** Bariatrician.1996;18-23. https://www.researchgate.net/publication/237241520_The_Short_Term_Efficacy_of_the_ALCAT_Test_of_Food_Sensitivities_to_Facilitate_Changes_in_Body_Composition_and_Self-reported_Disease_Symptoms_A_Randomized_Controlled_Study	**1996** Clinical: weight loss 100 patients **randomized**	10,000-15,000
28) *Diagnostic value of ALCAT test in intolerance to food additives compared with double-blind placebo-controlled (DBPC) oral challenges.*	**Hoj L.;** Journal of Allergy and Clinical Immunology, Vol. 97, No. 1, Part 3, January 1996 https://www.researchgate.net/publication/246090959_616_Diagnostic_value_of_ALCAT_test_in_intolerance_to_food_additives_compared_with_double-blind_placebo-controlled_DBPC_oral_challanges	**1996** Validation chemicals 92 patients **DBPC**	1,840
29) *El test Alcat de Sensibilidad a los Alimentos y su Interés en Medicina Estética* *[Alcat food sensitivity test in Aesthetic Medicine /weight loss]*	**Amigo C,** Moreno Mercer J, Calderon Gomez J, Cabo Soler JR.; 14th Med Day of Esthetical Medicine & Dermatological Survey. Venice, Italy, Sep. 22 – 23, 1995; published in the proceedings. Subsequently published in Estetica Medica Numero 40 - March 1996 (Spanish)	**1995** Clinical: weight loss 30 obese patients	3,000
30) *ALCAT test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system.*	**Mylek D.;** Rocz Akad Med Bialymst. 1995;40(3):625-629. http://www.ncbi.nlm.nih.gov/pubmed/8775317	**1995** Clinical: multiple disorders 72 patients	3,600
31) *Prevalence of Food Allergy and Intolerance in Children Based On MAST CLA and ALCAT Tests.*	**Buczylko K. et al.;** Advances in Medical Sciences 1995;40(3):452-456 http://www.ncbi.nlm.nih.gov/pubmed/8775289	**1995** Clinical Comparison 46 patients; **single-blind**	2,000
32) *Food Intolerance in Patients With Angioedema and Chronic Urticaria: An Investigation By RAST and ALCAT Test.*	**Hoj L.;** European Journal of Allergy and clinical Immunology Supplement 1995; 50:26	**1995** Clinical comparison 56 patients	5,600
33) *Allergie alimentari. Tecniche diagnostiche a confronto [Food allergy: comparison of diagnostic techniques].*	**Mancini S.;** Fierimonte V, Iacovoni R, Spaini A, Viarani P, Pichi A.; Minerva Pediatr. 1995 May;47(5):159-63 [Italian] http://www.ncbi.nlm.nih.gov/pubmed/7643816	**1995** Diagnostic comparison 14 patients	112

34) *Autism - A Multidisciplinary Approach to Treatment.*	**Kotsanis CA**, Dart L, Harjes C, Miller R.; American Academy of Otolaryngic Allergy	**1994** Clinical: autism 12 patients	600
35) *Reproducibility of the ALCAT Test.*	**Steinman H.;** Potter P.; University of Cape town; Johannesburg, South Afrika 1994	**1994** Reproducibility validation 12 patients	600
36) *The ALCAT test: in vitro procedure for determining food sensitivities.*	**Pasula MJ.;** Folia Med Cracov. 1993;34(1-4):153-157. http://www.ncbi.nlm.nih.gov/pubmed/8175054	**1993** Review paper	?
37) *The ALCAT Test- A Guide and Barometer in the Therapy of Environmental and Food Sensitivities.*	**Solomon B.;** Environmental Medicine. 1992;9(1 & 2).	**1992** Clinical: multiple disorders 172 patients	17,200
38) *Cellular responses to food in irritable bowel syndrome - an investigation of the ALCAT test.*	**Fell PJ, Soulsby S, Brostoff J;** Journal of Nutritional & Environmental Medicine; 1991;2(2):143-149. https://www.researchgate.net/publication/237626374_Cellular_Responses_to_Food_in_Irritable_Bowel_Syndrome_-_an_Investigation_of_the_ALCAT_Test	**1991** Clinical: IBS 22 patients **DBPC**	1,000
39) *Pilot Study into the Effect of Naturally Occurring Pharmacoactive Agents on the Alcat Test.*	**Fell PJ.** Annual Meeting of the American Otolaryngic Allergy Association, September 27, 1991; Kansas City. https://www.researchgate.net/publication/237648208_PILOT_STUDY_INTO_THE_EFFECT_OF_NATURALLY_OCCURING_PHARMACOACTIVE_AGENTS_ON_THE_ALCAT_TEST	**1991** Validation biogenic amine 24 patients	336
40) *Pharmacoactive Compounds in Foods – The effect on the Alcat Test in Healthy volunteers and patients suffering from Migraine.*	**Fell PJ, Brostoff J, Pasula M.;** AAOA News 9:2:29.	**1990**	
41) *Gastrointestinal Complaints related to diet.*	**Sandberg DH**.; Int Pediatr 1990; 5:23-29.	**1990** Clinical: gastrointestinal 3 patients	40
42) ALCAT® - "A New Cellular Test For Food Sensitivity".	**Fell PJ, Brostoff J., Soulsby S.;** American In-Vitro Allergy & Immunology Society August 1990 Toronto Canada; https://www.researchgate.net/publication/242123352_ALCATR_-_A_NEW_CELLULAR_TEST_FOR_FOOD_SENSITIVITY?_sg=RrhUY_2693tFb-qwhSBFW5AgXmyz0QIYQ4Z4QZR0sNRCPAJsNVB2GOuIDkjVo3rd	**1990** Clinical: gastrointestinal 80 patients **DBPC**	4,000
43) Inhibitory Effect of Sodium Cromoglycate on Granulocyte Response to Food Antigens In Vitro.	**Fell PJ, Sandberg DH, Pasula MJ.;** ACAI 45thAnnual Meeting, Nov. 10 – 14, 1990, San Francisco. published in the proceedings	**1990** Immunological study 10 patients	100
44) Multiple Pathogenic Mechanisms in Food Sensitivity Reactions In-Vitro.	**Pasula MJ, Puccio S.;** 4th International Symposium on Immunological and Clinical Problems of Food Allergy. Milan, Italy: November 5-9, 1989. published in the proceedings	**1989** Immunological study 9 patients	54
45) Influence of Food Antigens on Volumes of Circulating White Blood Cells and Platelets Aggregation.	**Brostoff, Fell, et al.;** 4th International Symposium on Immunological and Clinical Problems of Food Allergy. Milan, Italy: November 5-9, 1989. published in the proceedings	**1989** Immunological study 9 patients	54
46) High Correlation of the Alcat Test Results with Double Blind Challenge (DBC) in Food Sensitivity.	**Fell PJ, Brostoff J, Pasula MJ.;** ACAI 45thAnnual Meeting, L.A. Nov. 12-16, 1988, published in Annals of Allergy.	**1988** Clinical: gastrointestinal 179 patients **DBPC**	8,950
47) A Comparison of the Alcat Test for Food Reactions Amongst 2 Population Sub-Groups.	**Sandberg DH, Pasula MJ.;** ACAI 45thAnnual Meeting, L.A. Nov. 12-16, 1988, Published in Annals of Allergy	**1988** Clinical: multiple disorders 50 patients	450
48) ALCAT- "A New Test for Food Induced Problems in Medicine?"	**Fell PJ, Brostoff J, O'Donnell H, O'Connor A, Charig E.** Annual Meeting of the American Academy of Otolaryngic Allergy, 1988; Washington, D.C.	**1988** Clinical: multiple disorders; 53 patients **DBPC**	2,650