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THE ALCAT DIAGNOSTIC SYSTEM

"... it appears to me necessary to every physician to be skilled in nature, and to strive to know, if he would wish to perform his duties, what man is in relation to the articles of food and drink, and to his occupations, and what are the effects of each of them to every one."

- HIPPOCRATES

PREFACE

Recognizing that patients' reactions to foods, molds, chemicals, and drugs follow various pathways, a technologically simple method of measuring the effects of multiple pathogenic mechanisms on cellular populations provides a logical and cost-efficient system for testing such sensitivities. It appears that most, if not all, of the various mediator pathways involved in these sensitivities affect reactions in associated blood cells. The ALCAT Diagnostic System is designed to measure these blood cell reactions. The methodology includes using innovative laboratory reagents allowing accurate cell measurement in their native form. Individually processed test samples, when compared with the "Master Control" graph, will show cellular reactivity (cell count and size) if it has occurred. Scores are generated by relating these effective volumetric changes in white blood cells to the control curve.

THE ALCAT SYSTEM RELATED TO BLOOD CELLS

General Description & Principle of Operation

Whole blood drawn from a subject is collected in a vial containing citrate to prevent clotting. The citrated blood is stable at room temperature for up to 36 hours. The blood is suspended in a neutral solution and is gently agitated. Equal aliquots of the blood suspension are dispensed into multiple vials containing buffer substances, some to serve as controls and the remainder for tests. In the test vials, a test substance in a particular volume is added; in the controls, the same volume of nonreactive buffered incubating solution is used. After an incubation period with gentle agitation, all diluted cell samples are ready for analysis. An electrolytic solution containing an RBC lysing agent is added to the mixture 30 seconds prior to analysis. Using automated apparatus, cells are aspirated from each aliquot using a vacuum pump to insure even flow. The cells are passed through a narrow channel so that information on each cell can be measured at a single portal. An electronic instrument then counts each cell, permitting study of a predetermined number and also instantaneously counts the number of cells in a parallel series of sizes, ranging from the smallest to the largest. The sizes are displayed as either cell diameters (expressed in micra) or as cell volumes (expressed in femtoliters).

Measurements are made using the electronic principle of particle counting and sizing, which is based on changes in electrical resistance (pulses) produced by a particle (in this case a blood cell) suspended in a conductive liquid traversing a small aperture. The particles, or cell pulses, are counted and discriminated by size comparators to produce a histogram. The histogram is displayed by plotting the relative number of counts on the y-axis. The cell size (in femtoliters) is displayed by plotting on the x-axis. Relative number (frequency) will refer to the number of cells of a particular size. The relative number is depicted by the height of a peak or the depth of a valley between two peaks. An interfacing computer permits simultaneous storage of the data on a permanent disk, optical display of the results on a video screen, and printing of the mathematical results on paper as a permanent record. The system has proved to be reproducible, sensitive, and specific.

APPLICATION TO SELECTED BLOOD CELLS

The Leukocytes

As compared to the erythrocytes and platelets, the white blood cells are far less numerous; to analyze them, certain steps are required. In one set of control and test vials, erythrocytes (whose size overlaps that of leukocytes and thus are removed by lysing them with an agent innocuous to the leukocytes). The test is then carried out with the range of cell sizes adjusted to approx. 5 (micra) to 12 . Since the platelets are smaller than 5 , the multichannel display or numbers of cells at each cell size is largely limited to the leukocytes. At the left (smallest cell size) near the ordinate, the amorphous, unreadable residual of platelets and destroyed erythrocyte "ghost" cells will be found. The first leukocyte peak appears to contain the bulk of the lymphocytes. Adjoining it is another peak believed to contain the bulk of phagocytic leukocytes, e.g., the polymorphonuclear neutrophils, monocytes, eosinophils, and basophils. When the height, shape or position of these peaks shifts appreciably in test samples, as compared to the control samples, it is clear that a change in number and/or size has taken place. Such changes in leukocytes appear to reflect activation of the cells or effects secondary to the action of immune factors, mediators, or regulatory substances upon the cells.

The Erythrocytes and Platelets

The test, although not currently performed, can be adapted to include RBC's & platelets. A second set of control and test vials are used to analyze these patterns. No lytic agent is used, because erythrocytes and platelets outnumber the leukocytes so much, the contribution of white blood cells to the overall counts are negligible. The range is adjusted to enumerate first (left) peak ranging in size from 1.5 to 2.9 and erythrocytes are found in the second peak ranging in size from 3.5 to 9 . The zone between the two peaks contains a very small number of cells overlapping in size.

FUTURE APPLICATIONS USING ALCAT

Characterization of Cells Involved in Shifts of Peaks Away from Normal Patterns

To receive the maximum potential from the ALCAT leukocyte system, it is necessary to determine which type of white blood cell is found in each portion of the normal peaks. Ultimately, this knowledge will permit the identification of the type of cell or cell subtype is affected when shifts of any portion of the expected pattern are observed. The cellular "anatomy" of the peaks can be discerned by observing pattern shifts that follow: 1. Use of antibodies (especially monoclonal antibodies) to marker antigens or receptors on cell membranes, and 2. Incubation with substances known to effect the function or metabolism of selected cell types.

In correlation with shifts in patterns, it will be desirable to count the number of each kind of leukocyte remaining after incubation and to use histochemical, metabolic, electron microscopic, fluorescent, or radioactive techniques to assess the metabolic state and viability of persisting cells.

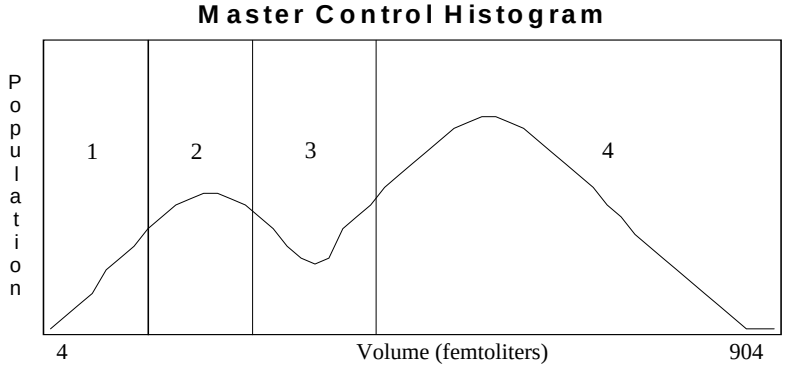
GENERAL INSTRUCTIONS FOR PHYSICIANS

After the careful analysis of thousands of patients' results, it has been observed that tolerance to different foods and other substances varies from patient to patient, and that even in a single patient such tolerance will vary over time, related to the frequency, or ingestion, of exposure or changes in the degree of health. By the same token, if the food being tested is one that the patient has not eaten for a long time, it is possible, but not necessarily the case, that the test will indicate a false negative.

Corticosteroids will influence test results such as to indicate lesser reactivity. Certain blood thinning agents, like Coumadin, have also been seen to have an impact on the results. To the extent possible, the patient should avoid taking these medications prior to blood drawing. If the drugs must be continued the testing can be done in stages whereby the initial results will aid in the construction of an elimination diet that might enable the discontinuation of the drug use followed by additional testing.

Call AMTL at any time during working hours for consultative services. The laboratory staff is prepared to help with interpretation of results as well as other questions.

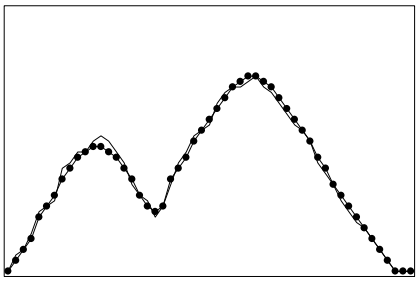
HISTOGRAM INTERPRETATION & SAMPLE RESULTS



Control Cell Count: 4529

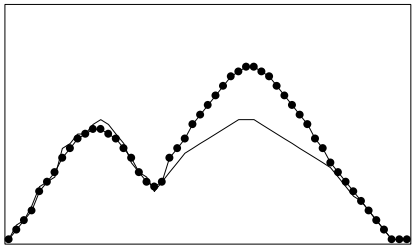
1. *Area of the curve where PLATELET AGGREGATION (if any) can be observed*
2. *LYMPHOCYTE Region*
3. *MIXED CELL DISTRIBUTION Region*
4. *GRANULOCYTE Region*

Negative



Control Cnt : 4529
Sample Cnt : 4552

Loss



Control Cnt : 4529
Sample Cnt : 4012

Granulocyte Loss (Decrease in Number)

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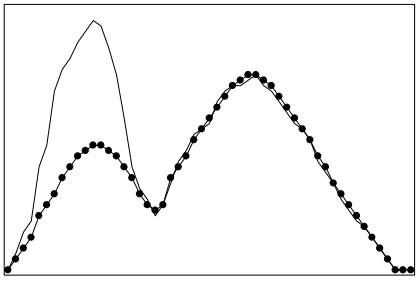
Control Curve

_____
Sample Curve

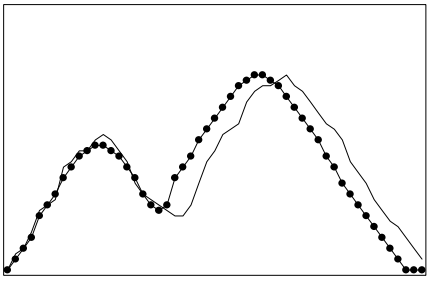
Platelet



Control Cnt : 4529
Sample Cnt : 5439

Platelet Aggregation Reaction

Positive



Control Cnt : 4529
Sample Cnt : 4512

Granulocyte shift (increase in volume/size) can also occur to left indicating decrease

INTERPRETATION OF TEST RESULTS

In addition, please review the Scoring System Update later in this section.

ALCAT results are expressed in percent changes in peaks of number of leukocytes in blood aliquots incubated with individual test substances as compared to control blood suspensions. Those results that are scored **POSITIVE** by the computer indicate foods or substances that deserve consideration as being "unsafe," i.e,. potentially causing symptoms upon ingestion, inhalation, or contact.

Those results that are scored **EQUIVOCAL** indicate that some reaction has taken place however, it was not to any significant degree and the score determination of positivity is to be made by the physician reviewing the results. Those with values of 9% or less are considered **NEGATIVE**. Scores of 9% may also be reported as "equivocal" on patients with low overall reactivity. The computer will analyze all the patient results and subdivide the scores accordingly.

Histograms will have different patterns for different patients and disorders. Normal blood distribution will appear as two peaks where the rightmost peak will be either level with or higher than the leftmost peak. (The exception is small children under 3 years old). The histogram represents platelet agglutination (if it occurs) on the far left, a small cell (lymphocyte) peak on the left, a mixed cell type region between the peaks, and, on the far right, the granulocytes. Platelet aggregation may also be depicted as an increased cell count in the lymphocyte peak. When this occurs in the absence of a corresponding decline of cells in the granulocyte fraction (the right peak), it is caused by a platelet reaction.

There are at least five possible reactions:

1. *Cell Enlargement*, the right and/or left peak shifts to the right,
2. *Partial Degranulation*, the right and/or left peak shifts to the left,
3. *Lysis,* the right and/or left peak is lower due to a loss of cells,
4. *Platelet Aggregation*, a peak will appear on the far left area of the histogram, and
5. *No Reaction*, both peaks of the sample and of the control overlay one another.

SCORING SYSTEM UPDATE

A new scoring system for The ALCAT Test is in development where individual scores (percentages) are being evaluated over thousands of subjects in order to determine the mean score for each food/substance. This specific mean score plus standard deviations will then be used to find the reactivity ranges for each specific food/substance. The percent reaction will no longer be used as the cutoff criteria for negative, equivocal or positive.

The reactivity ranges will be divided as follows:

1. Any reaction that falls below or at the mean will be considered negative.
2. Any reaction that is within one Standard Deviation range above the mean will be considered RANGE 1+ and should be treated as an equivocal reactions.
3. Any reaction that is between one and two Standard Deviation range above the mean will be considered RANGE 2+ and should be treated as a positive reaction.
4. Any reaction that is above two Standard Deviations of the mean will be considered MPOS and should be treated as a marked positive reaction.

The release date for this scoring system update is scheduled for Fall 1996.

2

The ALCAT Test for FOOD SENSITIVITIES

Adverse reactions to food have been the subject of a large body of medical and non-medical literature dating back to our earliest recorded history. In modern medical literature, until very recently, most of these records have been discounted as anecdotal and lacking in proof. However, we now see more and more interest in this area of medicine accompanying a resurgence of interest in environmental causes of illness.

It has become clear that IgE mediated immune mechanisms do not explain most food reactions. With increased recognition that other reactions do occur, clinical and laboratory based investigators have actively pursued this problem, thus giving rise to more and more clinical reports of a role for sensitivity to food in both accepted allergic problems like asthma, atopic dermatitis, urticaria, and allergic rhinitis, as well as other disorders, not previously believed to have such a basis, such as vascular headaches, irritable bowel syndrome, Crohn's disease, nephrotic syndrome and lower urinary tract symptoms, arthritis, and neurological problems such as attention deficit disorder and hyperactivity, and obesity.

It is not entirely clear what mechanisms are playing a role in this wide-ranging group of disorders, and most investigators and physicians interested in this challenging and exciting area of medicine believe that multiple mechanisms are involved. The techniques currently used to diagnose adverse reactions to foods can be difficult and tedious, are frequently inaccurate, and often require a high degree of patient compliance.

DIAGNOSTIC TOOLS FOR FOOD SENSITIVITIES

The "*gold-standard*" for diagnosis remains systematic oral challenge following an elimination diet, either with careful single- or double-blind techniques. However, this approach is rather slow and cumbersome for clinical practice and double-blind testing has not been used very much outside of a research setting. Strict elimination diets have been a time-honored approach, but have suffered from a rather arbitrary selection process of "safe" foods or use of a special formula such as the "elements" diet preparation Vivonex. After improvement on the restricted diet, individual foods are reintroduced one at a time and any reactions carefully observed and recorded by the doctor, his assistants, and/or the patient. This technique is quite slow and demanding of the patient, particularly if multiple foods are suspected.

Skin testing has also been used for many years as a diagnostic tool. However, since IgE mechanisms are usually not involved in food reactions, demonstrations of positive prick test wheals are not reliable for the detection of many such reactions. By the same token, a negative skin response does not rule out a sensitivity. Use of provocative skin testing is still considered by many allergists to be an unproven technique, and is such a specialized tool that most physicians could not easily incorporate it into their office routine.

A variety of *in vitro* techniques have been used for diagnosis of food intolerance. These have been primarily directed at immune-mediated reactions. Those evaluating IgE type mechanisms have included IgE RAST or fluorescent antibody methods for measurement of IgE antibodies to specific foods. Basophil degranulation tests essentially measure the same process. Migration inhibition of leukocytes, including macrophages, and the demonstration of *in vivo* and *in vitro* alteration of complement have also been used. Cytotoxic food testing, as developed by the Bryans, has not been supported by adequate clinical correlation and has largely been abandoned. Measurement of IgG antibodies to specific foods has more recently become available and is being used by many physicians.

The IgG antibody techniques have not shown good clinical correlation; the presence of IgG antibodies appears primarily to indicate prolonged exposure to a particular food. One can find increased IgG antibody titers to foods in normals and in children when developing tolerance to that food. So far it has not been possible to demonstrate a relationship between elevated IgG concentrations in serum and presence of specific mediators. Correlation with sensitivity may occur in some instances if gastrointestinal disease exists, which is associated with increased absorption of food.

This page intentionally left This page intentionally left However, this relationship is not close enough to make this test a valuable one as an indicator of sensitivity to foods. In addition, it only measures reactions which putatively involve IgG and is not helpful in other types of food reactions.

As suggested by W.T. Kniker, MD, Professor and Head, Division of Clinical Immunology, Department of Pediatrics, University of Texas Health Science Center, San Antonio, during a symposium on food sensitivity, an ideal diagnostic test for adverse reactions to foods would have certain characteristics:

1. It should be simple, convenient, non-traumatic, and provide rapid results.
2. It should be relatively inexpensive.
3. It should identify food reactive individuals reliably, with few false positive or negative results.
4. It should also identify virtually all major and most minor offending foods.
5. It should preferably not be dependent on a single or limited array of triggering mechanisms, and should be capable of measuring most or all immune and non-immune mechanisms.
6. It should be capable of distinguishing between different triggering or pathogenic mechanisms.
7. It should offer the possibility for study of activation of cellular and non-cellular factors and mediators and their effects on cells or tissue.

The ALCAT Test is an *in vitro* test using whole blood. This has the theoretical advantage that whole blood contains all of the circulating factors and chemical mediators, as well as the leukocytes and other cellular elements that may be involved in various adverse food reactions. Reaction of aliquots of blood with individual food extracts is carried out under carefully controlled conditions and compared with control aliquots identically treated but not exposed to the food extracts. After separation of the white cell fraction, each aliquot is then analyzed using a specially designed cell sizer and counter capable of separating the white cells into 256 of sub-sets based on cell size. The analyzer measures cell number, mean cell size, and size distribution curves. Using computerized analysis, changes in cell number and size, and distribution curves are measured quantitatively and percent change calculated and printed numerically and graphically. The test graph is superimposed on the control graph providing a basis for determining which reactions are indicated by change in cell size (increase or decrease) and/or absolute loss of cells. The primary reactive leukocyte fraction is the subset containing granulocytes and monocytes. Years of testing led to the development of reagents, solutions, and materials which have been demonstrated exhaustively to be unreactive with whole blood and cell suspensions.

Some major strengths of this method include the fact that a study of a population of normal healthy young adults demonstrated only mild reactivity to an occasional food extract (i.e., few false positive reactions). Separately, repeated studies of the same individual's blood under stable conditions showed only small differences in successive analyses (i.e., good reproducibility for multiple antigens). In addition, the method requires minimal participation by technicians, and computerized measurement and calculations eliminate any error that might have otherwise been introduced by observer bias.

Of course, the utility of The ALCAT Test or any other diagnostic test for food sensitivity depends upon the degree of correlation of its results with results of food challenge to test foods. As already indicated, all of the previously introduced skin tests or *in vitro* tests (including measurement of specific IgG to food) do not have satisfactory reliability or practicality in the diagnosis of non-IgG mediated food sensitivity. Clinical studies using The ALCAT Test have shown a high degree of correlation (83.4%) with Double-Blind Oral Challenge with foods and 96% with Double-Blind Placebo-Controlled oral challenges with food additives.

INDICATION FOR ALCAT TESTING

ALCAT testing can be helpful in identifying potentially offending foods in patients suspected of having food sensitivity, in whom the offending food(s) cannot readily be identified. In some circumstances, ALCAT testing would appear not to be indicated; these include the otherwise healthy individual with serious anaphylactic

reactions to every ingestion of a particular food or infants with presumed food sensitivity, in whom placement on a cow milk substitute and exclusion of all other foods is a convenient and cost-effective diagnostic approach.

On the other hand there are many patients with suspected food sensitivities in whom the possibility of reactions to more than one food exists and in whom the likelihood of pathogenic mechanisms other than exclusively IgE exist. Careful history, the use of diaries and questionnaires, or even the use of immediate skin tests may identify some suspect foods, however, generally these approaches are of limited value.[4,5,6] The ALCAT Test, carried out against a selected panel of foods, is useful in identifying foods which may trigger pathologic reactions, as well as (by negative results) identifying others likely to be safe. Definite diagnosis rests upon elimination of foods identified by history (including diaries) and by ALCAT method and subsequent reintroduction of the individual foods in a provocative challenge.

An ALCAT Test can also be useful in those patients who have attempted elimination diets but were unable, on subsequent challenges, to adequately or clearly identify all the major unsafe foods. In these, the use of an ALCAT Test may help clarify the situation so that an optimal long term elimination diet can be expeditiously constructed.

INTERPRETATION OF FOOD SCORES

The physician may elect to use ALCAT Test results to select those foods (e.g., the equivocals and/or positives) to be eliminated; followed, after a period of symptom remission, by challenge with each. This approach avoids the pitfalls of a routine and arbitrary elimination diet (e.g., Rowe, Rapp, Crook, etc.) in which some common foods are needlessly excluded while other presumed "safe" foods, troublesome in a particular patient, are included. When such a "routine" elimination and challenge procedure leads to confusing results, The ALCAT Test to selected foods may be used to clarify the situation. In either case, a nutritionist or dietician can be quite useful in helping patients go through all the intricacies of dietary manipulation. Telling a patient to eliminate certain foods is not enough; they must be instructed carefully about sources of safe or unsafe foods, hidden forms of unsafe foods in processed products, places to shop, and the importance of varying food recipes. After the diagnostic phase is completed and the need for long-term maintenance of an elimination diet emerges, the nutritionist is invaluable in designing a diet that maximizes compliance, minimizes ingestion of unsafe foods, and maintains optimal nutrition. Medication such as antihistamines, nonsteroidal anti-inflammatory agents, oral cromolyn, or ketotifen (if available) or corticosteroids may also be helpful, but these are always secondary to a carefully planned and followed elimination diet.

EXPECTED VALUES FOR FOOD TESTS

Normal, healthy, allergy-free individuals have characteristically low numbers of positive scores and an overall mean average score of approximately 7%. The right peak of the histogram will be either level with or higher than the left peak, the exception being small children under 3 years of age where the right peak will be significantly lower. Clinically symptomatic patients may have a higher incidence of positive scores and an mean score of approximately 11%. The right peak of the histogram will usually be lower than the left peak.

Positive results almost always indicate a probable association with intolerance or allergic disease such as allergic rhinitis, IBS, migraine headaches, asthma, eczema, atopic dermatitis, etc. To establish ranges, 100 samples were analyzed (50 were from healthy, allergy-free individuals and 50 from an age-matched patient group with suspected allergic diseases) for food sensitivities through The ALCAT Test on 10 different allergens.

PERFORMANCE CHARACTERISTICS

The specificity and accuracy of The ALCAT Test has been found to be 83.4% when correlated with Double-Blind Oral Challenge (DBC). A positive ALCAT score is also positive by DBC 79.3% of the time. A negative ALCAT score is also negative by DBC 87.5% of the time. This data was derived from a study involving 19 patients where a panel of 50 foods was performed on each.

Reproducibility of The ALCAT Test has been demonstrated in studies in which positive and negative results were consistent ($p < .02$) over a three day period.

In another study of 26 patients, 76 oral challenges to common food additives were carried out in double-blind, placebo controlled fashion. Of the 24 positive challenges, 23 were also positive by the ALCAT Test (96%). Of the 26 negative challenges, 24 were also negative by the ALCAT Test (8%). Only 1 reaction occurred out of 26 placebo challenges. Thus, the ALCAT Test was 96% sensitive and 92% specific.

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3

The ALCAT Test for MOLD SENSITIVITIES

Molds grow particularly well in damp environments. There are tens of thousands of different species of molds, but the most common ones are worth testing in allergic patients, particulatly with regard to respiratory and other conditions affecting mucous membranes. Under certain conditions, one particular yeast-like mold, candida albicans, can grow in the warm, moist areas within the body, such as the intestinal or vaginal tracts, and may sensitize an individual.

In The ALCAT Test, the molds are incubated with samples of whole blood in accordance with the same methodology as described for foods, to determine if the presence of the mold causes white blood cells reactivity *in vitro*. Thus, it is more convenient, less expensive, and, because it is not known precisely what biological pathways promote mold sensitivity, it should be more accurate than skin testing or other *in vitro* tests. The ALCAT Test electronically measures any changes in white cell size or number if a particular mold induces such a change.

If a person tests positive to one or more molds, there are basically two options available:

1. Avoidance.

Counter mold growth in the environment by following these steps;

A. *Reduce humidity*

Molds can thrive in moist environments (humidity over 60%).

- Dehumidify and heat moist rooms
- Run an air conditioner
- Ventilate bathrooms, laundry rooms, crawl spaces, and closets
- Vent clothes dryer to the outside
- Reduce the number of plants in the home

B. *Remove sources of mold.*

- Dry laundry as quickly as possible
- Spread out towels and wash clothes
- Avoid carpets as floor coverings
- Remove from the home all items that tend to grow mold such as musty books, mildewed floor coverings, and houseplants: also, check leather items such as clothes, shoes, luggage, and belts regularly for signs of mold growth.

C. *Regularly inspect bathrooms and kitchens for mold and mildew. Clean with Lysol, bleach, or other anti-fungal detergent in areas where mold thrives. Places to check include:*

- Shower stalls
- Shower curtains
- In the tile grout
- Around the commode
- Under and around sinks
- Inside the refrigerator

2. **Therapy.**

Desensitization therapy, in addition to following the procedures listed above, may be helpful.

CANDIDA ALBICANS

The common yeast candida albicans normally lives on the mucous membranes of the digestive tract and genito-urinary tract. The intake of antibiotics (especially prolonged use), birth control pills, the cortisone group of drugs, and high sugar diets may lead to abnormally high concentrations of this yeast. Symptoms that stem from overgrowth include yeast infections, thrush, bloating, constipation, diarrhea, abdominal pain, fatigue and possibly others. Yeast overgrowth in the gut may also play a role in food sensitivities and absorption.

If candida tests positive, a possible course of action is avoiding certain foods which contribute to candida growth in the body, particularly starches and sugars. An anti-fungal treatment may be used in conjunction.

DESCRIPTION OF MOLDS

ALTERNARIA (Air-borne) Colonies:grey, dark green, brown to black. This is an outdoor mold which frequently grows in textiles, foodstuffs, and soils. The black spots seen on tomatoes are usually of the alternaria mold specie. Frequently found on condensed window frames; generally an outdoor mold and appears when the weather is warm.

ASPERGILLUS This mold is found in damp conditions where the temperature is approximately 40 degrees celsius, both indoor and outdoor. Optimum growth requirements include a high water activity of the substrate, which is more likely to occur during the winter months. Some diseases associated with the aspergillus are farmers lung, bakers asthma, and malt workers lung. Inhalation of conidia and mycelium of aspergillus can lead to several diseases, the severity of which depends on the host's immune response. It is found in soils, leaf, and plant litter, decaying vegetable and roots, bird droppings, tobacco, and stored sweet potatoes.

BOTRYTIS This world wide mold predominantly occurs in humid and sub-tropical regions. The conidiophores of the mold usually covers the decayed tissues. It is seen as the grey mold on cabbage, red clover, lettuce, sugar beet, beans, barley, wheat, onion, and tomato. It is especially seen in connection with soft fruits, e.g,. strawberries and grapes. In the wine industry, the growth of botrytis on wine grapes has been known to give an added effect to the bouquet of certain wines.

CANDIDA ALBICANS A fermentable white yeast, a gut commensal in at least 50% of humans. Virtually all have delayed immunity to it. Cause of thrush and mucocutaneous candidiasis. Vaginal allergy proved in 1970's. Thought by some to be cause of Dysfunctional Gut Syndrome ("Candida").

CEPHALOSPORIUM It is a mold found in decomposing vegetation, and it is a soil inhabitant. It is also found in dust from textile plants, soil when gardening, bathrooms, and damp old houses. A grey/green color, it is also occasionally found in patients sensitive to candida albicans.

CLADOSPORIUM Of all the molds encountered in the air, this is the most frequent. It is found most commonly on dying and dead plant substrates, especially on leaves and stems of ferns, mosses, and desert and aquatic plants. It is found in various soil types and on food items such as cereals, cucumbers, tomatoes, and peaches. It is also been found in fuel tanks, face creams, paints and textiles. A moist, low damp environment is most suitable for the cladosporium mold (low dense and olive-green to olive-brown in color). Found throughout the year and indoors.

CURVULARIA This mold is dark brown in color with a velvety appearance. It can be found in castor beans, cotton, rice, barley, wheat, and corn. It seems to strive well in most tropical countries. It may cause leaf spots and seeding blight.

EPICOCCUM NIGRUM This mold has worldwide distribution. Found on soil, decaying plants, and fabrics. It has also been isolated from cereals, fruits, polluted fresh water, compost beds, insects, human skin, and sputum. Quite a lot of airborne spores. Some Italian allergists rate it quite highly.

FUSARIUM This mold is a common soil fungus and is widely found on numerous grasses and other plants. It can cause plant diseases and is a major parasite of rice, sugar cane, sorghum, and especially maize grains. Occurs regularly on banana roots and other fruits and vegetable, e.g., tomato and watermelon. Sporulates in warm, wet weather. Shares some of the same allergenic determinants as Penicillium and Aspergillus.

HELMINTHOSPORIUM This mold occurs seasonally and spores are released on dry, hot days. It is a parasite of cereals and grasses. Frequently found on grains, grasses, sugar cane, soil, and textiles.

MUCOR RACEMOSUS This mold has worldwide distribution and is primarily a soil fungus but has been found in horse manure, plant remains, grains, vegetables, and nuts. In the tropics it is found at higher altitudes and often seen on soft fruit, fruit juice and marmalade. Mucor is also the dominating mold found in floor dust in houses.

PENICILLIUM This mold also has a velvety colony which has blue-green centers with pale to bright yellow, vinaceous reverse and yellow exudate. It has a fruity odor, suggesting apples or pineapples. It is found in the soil of citrus plantations and has been isolated from decaying cabbage and barley plants, stored seeds of cereals, grapes, nuts, dried fruits, and fruit juices. It is one of the most dominant and important house molds; the indoor mold can be readily seen on stale bread, citrus fruits, and apples. It is frequently found in wine cellars.

RHODOTORULA Rubra A marginally fermentable red yeast (a group as large as the white yeasts although less well known). Very common on decaying foods. May occur in the gut. Found in pollen counts.

SPOROBOLOMYCES This is a yeast-like fungus which is found on living or dead leaves. It is a pink to red color mold. It is usually an airborne mold released during warm, damp weather, especially in the mornings, and can reach extremely high airborne concentrations.

PHOMA HERBARUM This mold is commonly found in different soils, dead plant tissues, and potatoes. It grows indoors in association with bio-deterioration of wall paints, and produces pink or purple colored spots. This mold has also been isolated from moldy shower curtains.

PULLULARIA This mold is commonly found on dead and decaying leaves, wooden frames, saunas, refrigerator doors, and in the kitchen and bathroom. It is grey in color and has been recorded on wheat seeds, barley, oats, tomato and pecans.

DESCRIPTION OF BACTERIA

BACTERIA MIX This mix contains: Staphylococcus aureus, Streptococcus (viridans & non-hemolytic), Streptococcus (Diplococcus) pneumoniae, Bramhamella (Neisseria) catarrhalis, Klebsiella pneumoniae ,and Haemophilus influenzae. Indicated in recurrent and chronic infections of the respiratory tract and occasionally of the skin. Can play a prominent role in many diseases such as rhinitis, infectious asthma, chronic sinusitis, nasal polyposis, and chronic serous otitis.

4

The ALCAT Test for FOOD ADDITIVES & ENVIRONMENTAL CHEMICALS

This section is a guide to using The ALCAT Test to screen patients' for their susceptibility to commonly encountered food additives, chemicals, and pollutants. It can help practitioners in interpreting the significance of test results for the purpose of initiating a more directed approach to identifying the specific causes of an environmental illness and, thereby, rendering a treatment and avoidance program.

In some cases, this information may also serve as an introduction to understanding the cause(s) of illness for the patients who are interested in taking an active role in their health program. Individuals who undergo this testing most likely will have exhausted other approaches and their need to be informed about the sources of exposure, etc., especially important, since patients must actively participate in their recovery by thoroughly avoiding as many offending agents as possible.

The "Gold Standard" for assessment of chemical sensitivities is double-blind *in vivo* challenge in a controlled environment (Environmental Control Unit) after a period of de-adaptation (de-masking) usually 4 to 6 days, using careful clinical evaluation and, where possible, objective methods of assessing symptom changes. Such an approach is costly and impractical in the majority of cases. Hence the need for a reliable in vitro test.

The white blood cells are a major part of the body's immune system that will very often show effective or afferent changes when the patient is subject to an overload of offending foreign substance, or has an acquired hyper-susceptibility regardless of the underlying mechanism.

The degree of cellular reactivity may not directly correlate with the severity of symptoms; however, a marked shift in cell volumes may reasonably be suspected of being associated with the body's attempt to deal with the substance(s) which situation could, in turn, give rise to symptoms.

THE SCOPE OF THE PROBLEM

Due to complex variables sometimes involving genetic factors or metabolic dysfunction, an individual may be rendered more susceptible to foreign chemicals that are inhaled, contacted, or ingested. Such susceptibility may not manifest in disease provided the primary organs of detoxification are functioning at or near optimum levels. However, even in "normal" patients, a foreign chemical or metabolite might complex with antibody to induce an immune-mediated hypersensitivity reaction.

Non-immune mediated idiosyncratic, toxic, or pharmacologic reactions may also occur. During a period of stress, overload, or lack of adequate nutritional support the liver or kidney, along with enzyme systems, may break down, manifesting symptoms associated with exposure to a particular chemical or group of chemicals.

Virtually any organ system can be the target of an adverse reaction but most commonly it is the skin, respiratory, or CNS. A reactivity pattern has been observed where a large exposure to a foreign chemical may cause what is referred to as "induction," whereby subsequent exposures may then be sufficient to "trigger" reactions, even when the exposure is slight or of minimal amounts. "Spreading" or the development of new sensitivities often occurs, suggesting that the earlier insult may have disrupted a critical metabolic pathway, thus impairing the handling of several chemically related and even other less structurally similar substances.

Clinical observations have documented a wide range of symptoms. Double-blind, placebo-controlled studies have shown hyperkinesis to be associated with food dyes, salicylates, etc. Similarly, asthmatic conditions can be induced by sulfites, aspirin (acetylsalicylic acid), dyes, salicylates naturally occurring in foods, chlorine, and other substances. Eczema and urticarial reactions may be induced by tartrazine, annatto, various drugs, sodium benzoate, aspirin, metabisulfite, and others. The inhaled fumes of several chemicals and substances common in modern buildings has been implicated in a variety of disorders. The so called " Sick Building Syndrome "

implicates chemicals used in building materials, i.e., formaldehyde, cleaning solutions, mold overgrowth in ventilation systems and elsewhere, as well as a preponderance of dust and dust mites.

COMMONLY IDENTIFIED CHEMICALS OFF-GASSING FROM 42 MODERN BUILDING MATERIALS

The 10 Most Frequently Identified Compounds	**The 10 Compounds in Highs Average Equilibrium Concentration**
Toluene	Toluene
n-Decane	3-Xylene
1,2,4-Trimethylbenzene	$C_{10}H_{16}$ (Terpene)
n-Undecane	n-Butylacetate
3-Xylene	n-Butanol
2-Xylene	n-Hexane
n-Propyl benzene	4-Xylene
Ethyl benzene	Ethoxy ethyl acetate
n-Nonane	n-Heptane
1,3,5-Trimethyl benzene	2-Xylene

Source: Reprinted with permission from "Indoor Air Pollution Due to Organic Gases and Vapours of Solvents in Building Materials," in Environmental International, 8:117-127 ,122. Molhave, L., Moghissi, A., and Moghissi, B. (eds.) Copyright 1982, Pergamon Press plc., Elmsford, NY.

Tobacco smoke contributes to indoor air pollution. It contains numerous chemicals including the preservatives used during growing, flavor enhancers, and the kerosene fumes from heaters used to warm the leaves while curing. Similarly, the use of natural gas from home cooking and heating can create "smog levels" that exceed that of Los Angeles by three times. Indoor air pollution is typically many times more pernicious than air pollution outdoors.

Sick Building Syndrome includes headaches, fatigue, respiratory problems, mental impairment, nervousness, arthralgia, etc. Recently, workers at the Environmental Protection Agency in Washington, D.C., refused to work in their own building which was contaminated with formaldehyde and latex backing fumes from new carpeting. If symptoms are exacerbated during winter when more time is spent indoors, this cause is implicated.

Another source of health concern is the concentrations of antibiotics found in meats and poultry. They foster the development of resistant strains of bacteria that could infect the system of those that consume the foodstuff. Prolonged indirect exposure on the part of the consumer could also induce a type of hypersensitivity or increased susceptibility. Similarly, growth hormones administered to livestock are of concern as they have also demonstrated adverse reactions to the residue when the tissue is consumed.

Sulfur dioxide has been used by the Romans for 2,500 years to preserve wine. The U.S. FDA has now banned the use of sulfites in meat but not in seafood, and use of these substances is still quite extensive. Commercial corn and potatoes are often soaked in sulfur dioxide and other sulfites are still used as preservatives in salad bars, wines, and other foods, although certain labeling requirements have taken effect. The U.S. government estimates that over one million Americans, especially asthmatics, are sensitive to sulfites, and as of 1987 it attributes 17 deaths directly to sulfite ingestion.

Sulfur dioxide has been implicated in disruption of carbohydrate metabolism and can also negatively impact lymphocyte production of antibody. The enzyme system which metabolizes SO_2, sulfite oxidase, is dependent upon adequate supplies of dietary molybdenum which can be obtained through soybeans and various legumes. Gas contamination represents another factor in food adulteration. Bananas are exposed to ethylene gas for ripening. Most coffee beans are also gas roasted. Each molecule of aspartame consumed causes the release of one molecule of ethanol in the blood. Beet, corn, and cane sugar are also gassed. Honey and sucanat can be good substitutes.

SOCIOLOGICAL PERSPECTIVES

In 1900, 80% of the U.S. population was employed in agriculture. Today that percentage is around 2%. Given the common ownership of much of the world's chemical and agricultural businesses, it is easy to understand the strong bias in favor of using artificial fertilizers, pesticides and other chemicals, and drugs and hormones in the commercial production of crops and livestock. Hence the levels of pesticides have tripled in the two decades from 1965 to 1985 despite the fact that sometimes as little as .1% of pesticide spray reaches its target while approximately 60% of pesticides wind up in the food. Such inefficiency may be economic, but it is certainly not healthful.

Consequently, the average American ingests 6 lbs. of pesticides and artificial compounds per year. As with other environmental chemicals, pesticides will remain stored in the body's adipose fat tissue, thus the fat portion of meat products, apart from posing other health risks, will contain the greatest concentration of chemical residue and should be removed, as much as possible, from the diet. The Public Health Service has conducted a National Adipose Tissue Survey:

COMPOUND	**POSS. SOURCES OF EXPOSURE**	**FREQUENCY IN SUBJECTS**
Styrene	disposable cups carpet backing	100% of people tested had this chemical in their fat
1, 4 Dichlorobenzene	mothballs, house deodorizers	100%
Xylene	gasoline, paints	100%
Ethylphenol	drinking water	100%
OCDD (dioxin)	wood treatment, herbicides auto exhaust	100%
HxCDD (dioxin)	wood treatment, herbicides auto exhaust	98%
Benzene	gasoline	96%
Chlorobenzene	drinking water	96%
Ethylbenzene	gasoline	96%
DDE	pesticide in produce	93%
Toluene	gasoline	91%
PCBs	air, water, food pollution	83%
Chloroform	drinking water	76%
Butylbenzyl phthalate	plastics	69%
Heptachlor	termite control	67%
DDT (banned for use in U.S.-1972)	food and air pollution	55%

Many patients react to a commercial food product but not to the same food when it is grown naturally; a fact that should be taken into account when interpreting ALCAT Test results or challenge testing, and consumption of "organically grown" foods advised accordingly. Other sources of exposure are similarly ubiquitous. Drinking water contains chlorine, apart from a large variety of other contaminants and pollutants; Watson and Kibler reported as early as 1934 that this causes asthmatic problems. Formaldehyde exposure is also common.

SOURCES OF FORMALDEHYDE EXPOSURE

- Industrial Products & Construction Materials
- Urea-formaldehyde foam and fiberglass insulation plywood, paneling, particle board and chip board adhesives and binders
- Molding compounds and laminating veneers protective coatings (water repellents, fire retardants, etc.)
- Preservatives and pesticides
- Leather tanning agents
- Antiseptics, disinfectants, deodorants, mildew prevention products
- Tissue fixatives and embalming fluid
- News print, fabric, and textiles
- Electrical wiring, plastics, and rubber

A sensitive patient must be well advised of its sources and diligent in avoidance. Levels of formaldehyde considered safe by H.U.D. (0.04 ppm) are sufficient to cause any one or more symptoms such as eye irritation, headache, nose and/or throat problems in 90% of the population. Another compound, phenol, is common and is used as a lining of metal food cans. A phenol sensitive patient may react to the phenol from the can the food is stored in and yet be quite unaffected by the food when obtained fresh. It is well known that a patient may react to phenol used to preserve diagnostic allergen solutions used in skin testing.

As with many food sensitivities, abnormal gut status can influence chemical susceptibility. For example, animal studies have shown that a greater proportion of food dyes is excreted if the animal has been pre-treated with antibiotics. Similarly, if tartrazine is administered with the DSS (dioptilsodiumsulphosuccinate), a stool softener, intestinal flora metabolism is inhibited resulting in significantly increased absorption of the dyeand leading to a greater concentration in the blood and brain tissue.

TREATMENTS

When a diagnosis of chemical sensitivity is made the primary treatment is avoidance. The severity of symptoms will determine the extent to which the patient will attempt to clean up his environment. Certain measures are relatively easy to implement, such as wearing clothing made of natural fibers, obtaining fresh organically grown food, avoiding restaurant meals as much as possible, substituting castile soup for other types of detergents, obtaining a water and/or air purification system for home use, etc. Other measures, such as substituting electricity for gas in home heating and cooking, changing one's place of employment, moving to a less polluted environment, and so forth, can be considered.

Nutritional And Dietary Support

In many instances improvement will follow a dietary deficiency connection. For example, many patients who react to MSG will benefit from Vitamin B6 supplementation. Pantetheine, by increasing activity of aldehyde dehydrogenase, has demonstrated usefulness in formaldehyde sensitivity. As mentioned previously, molybdenum is essential to sulfite metabolism. Other important micronutrients are the anti-oxidants Vitamins E and C, beta-carotene, glutathione, and ceruloplasmin; the minerals zinc, copper, iron, manganese, and selenium; B-complex; and the amino acids methionine and cysteine. It is always important that the physician assess the patient's specific needs through dietary evaluation and good laboratory tests where appropriate, and use a qualified nutritionist in developing a custom supplementation program.

Thermal Depuration (Sauna)

Many physicians claim that xenobiotics stored in adipose tissue can be eliminated by the combined use of specific nutritional supplements (to mobilize the fat), exercise and prolonged low temperature sauna. This program should only be use under a physician's close supervision.

DESCRIPTION OF FOOD ADDITIVES & CHEMICALS

ACETALDEHYDE	This chemical is used in perfumes, dyes, plastics, synthetic rubber, silvering mirrors, and hardening gelatin fibers. Large dosages can cause death by respiratory paralysis. Can induce symptoms similar to those of chronic alcoholism
ACID ORANGE	This is a reddish-brown dye which is used in foods, drugs, and cosmetics (FD & C Orange #8).
AFLATOXIN	Found in milk albumin, chili powder, cocoa, corn, hops, goats milk, human milk, peanut, and some mushrooms. A possible carcinogen.

AMMONIUM CHLORIDE	This is an ammonium salt added to foods to lighten their texture. It's used in lustering cotton, washing powders, manufacturing dyes, cement for iron pipes, and for slowing snow melt on ski slopes. Therapeutically it's used as a systemic acidifier. An excess intake can cause headaches, loss of energy, acidosis, and menses disturbances.
ASPARTAME	A low-calorie sweetener (*Nutrasweet*) which is about 160 times sweeter than sucrose in aqueous solution. When exposed to heat, aspartame breaks down into the toxic chemical methyl alcohol. Aspartame may change levels of chemicals in the brain that affect behavior.
BENZENE	A component of gasoline, can cause drunken behavior, light headaches, disorientation, fatigue, and loss of appetite. Used in the production of rubber and plastics such as polystyrene and nylon, and present in many organic solvents.
BENZOIC ACID	A food preservative. It occurs naturally in berries, prunes, tea, cinnamon, and cloves. It will cause temporary distress through gastrointestinal irritation.
BRILLIANT BLACK	Is used as a dye in food, drugs, cosmetics and clothing.
CAFFEIC ACID	Is ubiquitous in nature. It can be found in beans, artichoke, apple, carrot, cauliflower, grape, lettuce, and olive.
CHLORINE	Drinking water, bleach, and disinfectants contain chlorine. It induces pain and inflammation of mouth, throat, and stomach. It can also cause confusion, delirium, respiratory tract irritation, pulmonary edema, skin eruptions, and vomiting. Exposure to chlorine has been linked to an increase in blood pressure, diabetes, anemias, heart disease, gastrointestinal and urinary tract cancer, and asthma.
CHLOROGENIC ACID	This pharmacoactive chemical is found in allspice, coffee, squash, apple, apricot, peach, cherry, and potato.
COUMARIN	This chemical has a pleasant odor like that of vanilla beans. It is found in tonka beans, lavender oil, woodruff, and in sweet clover. It is primarily used as a pharmaceutic aid (flavor).
CRYSTAL PONCEAU	This orange-red dye is used in dyeing wool , coloring food, drugs, and cosmetics (FD&C Red #1).
DOPAMINE	A neurotransmitter naturally occuring in avocado and banana. It is used as an anti-hypotensive adrenergic.
ERYTHROSINE B	Used as a color additive and as a biological stain; a red dye used in the coloring of foods and drugs (FD & C Red #3).
ETHYLENE	Used in anti-freeze, in heating and cooling systems, and in paint and plastic solvents. It is also found in ink pads, ink for ball point pens, and is used as a softening agent for cellophane, stabilizer for soybean foam, and to extinguish oil and gasoline fires. It is also used in the synthesis of elastomers, plasticizers, and synthetic fibers and waxes.
FLUORIDE	Is commonly found in toothpaste and water. Clinical studies have shown that fluoride contributes to osteoporosis and long-term exposure produces osteosclerosis.
FORMALDEHYDE	Is found in household detergents and cleaners, and is also used in photographic chemicals, paint and rubber production, textile finishes and conditioners, pesticides and vermicides, diesel exhaust, toilet paper, paper towels, glues, disinfectants and pharmaceutics preservatives. It can also be produced by burning charcoal and cigarette smoke. It may produce such symptoms as irritability, disorientation and depression.
GALLIC ACID	Has been used as an intestinal astringent. It is used to manufacture inks, to develop photographics, and in tanning and dyeing. The esters are used as an antioxidant. It is found in fruits, beans, milk, egg, hops, olive, potato, and yeast mix.
GLUTEN	This is a protein component of cereal grains. It is also used to fortified cereals and to improve the texture in baked goods. It will irritate the intestinal lining in gluten sensitive patients and may interfere with normal absorption of nutrients in the diet. It may also cause diarrhea, distress, weakness, weight loss, and small intestinal damage.

HISTAMINE	This is a potent vasodilator found in normal tissues and blood. It stimulates the secretion of pepsin in the stomach. Eating stimulates the release of histamine from gastric mucosa. It has been used as a diagnostic aid (gastric secretion, pheochromocytoma) and for hypo-sensitization therapy. Naturally occuring in beer, black bass, catfish, chicken, cocoa, codfish, flounder, halibut, cow's milk, lobster, oyster, salmon, trout, tuna, turkey, and yeast mix.
MALVIN	This chemical is found as diglucoside in wild malve. It is basically found in albumin (cow's milk), most fruits, cinnamon, cashew, beans, potato, and egg.
MSG	Monosodium Glutamate is used in food preparation to enhance taste. It can cause numbness, heart palpitation, cold sweat, headache (Chinese Restaurant Syndrome) and could be a factor in obesity.
NICKEL SULFATE	An alloy ingredient in precious metals. Found in costume jewelry, eyeglass frames, silver and white gold jewelry, hairpins, braces, chairs, knives, forks, coins, and medical instruments. It may also be included in bleaching agents, dyes for hair, mineral oil products, and chemical fertilizers.
NICOTINE	This chemical is a byproduct of the tobacco industry, obtained from the dried leaves of Nicotiana Tabacum and is combined with citric and malic acids. It's been used in insecticides and fumigants. Symptoms of nicotine toxicity includes extreme nausea, vomiting, convulsions, mental confusion, and twitching. It produces vasoconstriction and slight central nervous system depression. Nicotine has been found in banana, malt, cow's milk, potato, tomato, and yeast mix.
NITRATES	Nitrates are converted to nitrites in the body which may decrease in blood pressure, headache, vertigo, palpitation, nausea, vomiting, and diarrhea. It can also turn into nitrosamines, which are possible carcinogens.
OCTOPAMINE	This pharmacoactive agent is found in ham, lobster, cow's milk, mutton, and pork.
ORRIS ROOT	a semisolid fatty substance which is primarily used in perfumes and cosmetics.
PATENT BLUE	A blue dye used in coloring of clothes, and in food, drugs, and cosmetics (FD & C Blue #1).
PHENOL	Allergen extracts are often diluted in phenol. Also used in the linings of tin cans as a general disinfectant for toilets, cesspools, floors, and drains; in many medical and industrial compounds; and as a topical anesthetic and antipruritic. It can cause skin eruptions, peeling, swelling, hives, vomiting, numbness, cold sweats, convulsions, and circulatory collapse.
PHENYLALALINE	A naturally occurring amino acid, a precursor of other chemicals such as dopamine, and melanin. Patients with phenylketonuria are usually treated by low phenylalanine diet. This chemical which is ubiquitous, found in barley, cocoa, codfish, egg, gelatin, grape, hops, potato and yeast mix.
PHENYL-ETHYLAMINE	This chemical is prepared by the reduction of acetophenone in liquid ammonia. It is used as a resolving agent and as a chiral intermediate.
PIPERONAL	This chemical is used in cherry and vanilla flavors, in organic syntheses, and in perfumery. It can be found in cinnamon, clove, cucumber, honey, cow's milk, mustard, peach, pineapple, walnut, and yeast mix.
POLYSORBATE	A sorbitan derivative, it is used in foods and in flavor 80 compositions as an emulsifier. It is employed in shortenings, dressings, baked goods, dairy products, beverages, coffee whitener, meat, and fish.
POTASSIUM NITRATE	Is used in fireworks, fluxes, pickling meat, treating tobacco so that it burns evenly, and matches. Prolonged exposure can lead to anemia, ethemoglobinemia, and nephritis. Vomiting and diarrhea may also occur upon ingestion.
PYRIDINE	This chemical is a nitrogen analog of benzene. It can be derived from tobacco and various other organic matter. It is a weak basic liquid which is often used in histology as a solvent and to extract lipids from tissue.

RUTIN A bioflavonoid (coumarin derivative) which is extracted from buckwheat. Rutin has been shown to inhibit histamine release from both peritoneal mast cells and mucosal mast cells. It is found in other sources such as milk, beans, vegetables, chicken, cocoa, egg, pork, and potato.

SACCHARIN Used as a sweetener in low calorie soft drinks, dietetic ice cream, and other low calorie foods.

SEROTONIN Found in asparagus, avocado, cocoa, pineapple, plum, tomato, and yeast mix. It is a powerful neurotransmitter.

SODIUM META-BISULFITE Used as a pharmaceutic aid (antioxidant) to reduce and prevent spoilage by bacteria. It minimizes browning and discoloration. It can cause asthmatic reactions.

SODIUM NITRATE Used to manufacture nitric acid; also used in manufacturing glass, enamels for pottery, in matches, pickling meat, in treating tobacco for even burning, as a color fixative for meats, and in fertilizers.

SODIUM NITRITE & POTASSIUM NITRATE Found in drinking water and used to cure food products to produce a pink color in meat and extend the shelf life. They also add to characteristic flavor. When nitrates are converted through biological processes to nitrosamine it could lead to cancer.

SODIUM SULFITE Reduces and prevents spoilage by bacteria. It minimizes browning and other discoloration. Sulfites are used in dehydration, freezing, and brining of fruits and vegetables. It is used in fruit juices and purees, syrups, and condiments and in wine making. It can cause a decrease in vitamin B1 or destruction of thiamine in the body and can cause asthmatic reactions.

SOLANINE This chemical is found in the potato family.

SORBIC ACID Used in preservatives to inhibit bacterial yeast-mold growth. Used in cheeses, wine, chocolate syrups, margarines, and fruit-juice drinks.

TOLUENE A volatile organic compound found in gasoline. It is used in manufacturing dyes and other organic compounds. Also used as a solvent for paints, lacquers, gums, and resins.

TRYPTOPHAN This amino acid is found in pork, shellfish, and other sources. It is a precursor of serotonin.

TYRAMINE This amino acid is found in milk, banana, black bass, cashew, cocoa, egg, oyster, green pea, perch, plum, potato, prune, raisin, spinach, tomato, walnut, and yeast mix.

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5

The ALCAT Test for DRUG SENSITIVITIES

Reactions to medications are frequent enough to limit optimum treatment for many medical disorders.[3,9,28-30,32,33,37,47] Although most drug reactions involve the skin,[5] almost any organ of the body may be involved in reactions to medications. In some instances, the reactions mimic other disorders and recognition is delayed; particularly, since there are no adequate diagnostic tools in most instances to confirm diagnosis.[16,19,22,45] In other situations (e.g., reactions which appear to be typically allergic), it's difficult to identify the offending substance.[6]

The range of drugs for treating certain illnesses is restricted. It is often necessary or desirable to treat specific diseases with multiple medications. It is also common to have patients suffering from more than one illness; frequently this requires use of multiple drug therapy. In the elderly population, it is not unusual to have patients simultaneously being treated with a dozen different medications.[13]

As the number of drugs proliferates, so does the number of associated reactions. Commonly, reactions are caused by antibiotics, non-steroidal analgesic and anti-inflammatory medications, chemotherapeutic agents such as the group of sulfonamides, and radio contrast agents.[21,23,28-30] However, other drugs are also common causes of reactions, including local and general anesthetics.[7,8,12,18] Further, uncommon reactions to medications occur as these drugs are used more often; particularly when they are given to individuals who are reactive to multiple medications or who have unusual problems involving their immune system.[14,16,46] These are often expressed in a bewildering variety of manifestations.[2,22,25,26,34,46,48] These problems are confounded further by the common occurrence of pseudo-allergic reactions.[10,35,44]

Often when an apparent reaction to medication occurs, it is highly desirable to identify that a true reaction did happen, and further to determine which drug was responsible. It is also possible that an individual may react to one of the ostensibly inert components of a medication; elucidation of such reactions is ordinarily very difficult. Separation of such true reactions from subtle alterations in bioavailability and any resulting toxic effects may be difficult. There may be as many as 15 to 20 individual components in a tablet or capsule in addition to the active principle. Many of these ingredients are now listed in the PDR for specific products.

Precise identification of the above reactions is difficult principally because of the lack of a test capable of determining specific causes, except for the area of anaphylactic reaction to penicillin and to a lesser extent for other types of allergic reactions to penicillin.[20,24,41]

EXISTING TESTING METHODS FOR DRUG SENSITIVITIES

Those tests which are available and useful for penicillin hypersensitivity include immediate skin tests with various fractions of penicillin; P-K reactions with passive transfer; RAST Tests for IgE antibodies; and basophil histamine release.[27,43] At this time, both skin tests and RAST are the most commonly used, and do have predictability when the last contact with penicillin was not too far in the past.[36] There is enough difference in the minor determinants to allow for some individuals to react only to certain of the haptens.[42]

There also appears to be some validity for the use of RAST for IgG and IgM antibodies in some cutaneous reactions to penicillin and possibly for some rare dyscrasias such as agranulocytosis or hemolytic anemia. It's also possible to demonstrate delayed hypersensitivity to penicillin. However, so far, this has been only of limited clinical usefulness; cellular hypersensitivity may play a role in some dermatitis. Lymphocyte transformation, or blastogenesis, has also been used to try to demonstrate some allergic reactions to drugs.[40] These reactions have usually been evaluated morphologically or by rate of incorporation of thymidine. This is a rather cumbersome, expensive method and has had limited clinical use. Even more elaborate methods are under investigation.[4,31] Results have been mixed and patients clearly allergic to a drug may not show transformation in the presence of the drug *in vitro*. There are a number of possible explanations of such discrepancies.

As for immunologically-based reactions to other drugs, these immunologic tests have not been very helpful in evaluation. This is in part related to the lack of isolation of haptens responsible for the reactions. There are a few scattered reports in the literature of apparent IgE mediated reactions to a variety of drugs.[17,18,39,48] There have been some reports of use of such tests as the basophil degranulation test or migration inhibitory factor assays for evaluation of drug allergy, but only on an occasional basis.[1,2,15,38] In addition, other mechanisms for reactions, other than immunologic, do not have adequate testing procedures available.

There is a great need for a simple, rapid method of broad applicability for such determinations Such tests would greatly increase our understanding of drug reactions as well as provide information regarding frequency of reactions to specific "inert" components. This knowledge would allow more enlightened formulation of medications to minimize such reactions. In addition, reduction of the number of drug reactions occurring in hospitalized patients would significantly reduce hospital stays and result in lowered healthcare costs.

THE ALCAT TEST FOR DRUG SENSITIVITIES

There exists a great opportunity to use the ALCAT blood test to assist in the identification of drug reactions as well as reactions to other components of medications. Such capability would be of immense clinical value for physicians in all specialties of medicine and surgery.

The ALCAT blood test has the multiple virtues of an *in vitro* test, technical simplicity, excellent reproducibility, reasonable cost, and high probability that it will become a major tool for testing individuals for food, mold, chemical and other sensitivities. Its capability for identifying active sensitization to foods in a group of patients with multiple symptoms related to various organ systems has recently been demonstrated convincingly. [11] Since most drugs are carried through the circulation bound to plasma proteins, carrying out this test in an environment of whole blood is most appropriate. If use of the ALCAT for identifying drug reaction is shown to be feasible, it is unlikely that another method will be found in the near future with the same broad capability without great technical complexity and cost.

DESCRIPTION OF DRUGS

ACETAMINOPHEN This is used for its therapeutic effect as an analgesic and antipyretic characteristic. It is used in many over-the-counter pain relievers. Found in Tylenol and Datril.

ANTIBIOTICS These compounds have been known to induce anaphylaxis, asthma, and urticaria. Other possible effects are less documented.

ASPIRIN Acetylsalicylic acid is the most commonly used antipyretic analgesic drug. Used extensively as a prophylaxis of stroke due to its blood thinning properties. Aspirin can induce an asthmatic reaction.

NON-STEROIDAL ANTI-INFLAMMATORY These chemicals (NSAID) can cause urticaria and asthmatic reactions. Highly cross-reactive among themselves,.Cyclo-oxygenase blockers especially cross-react (and cross-desensitize) with aspirin.

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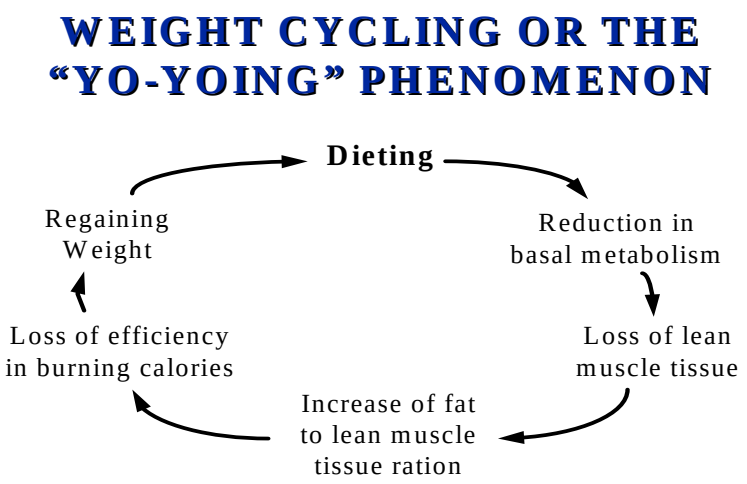
6

The ALCAT Test for WEIGHT MANAGEMENT & PERFORMANCE

Obesity is on the rise. In fact, Americans are heavier now than at any time before. Thirt- four percent of the adult population and 25% of teenagers are more than 20% above their ideal body weight. Health professionals are concerned by these developments as expressed by former U.S. Surgeon General, C. Everett Koop, who has stated that obesity is the number two cause of death in the United States, right behind smoking.[1]

Being overweight is not due to a lack of willpower as much as it is due to an imbalance in biochemistry. Recent research has shown that the majority of overweight people have a biochemical imbalance which impairs essential fatty acid metabolism and insulin sensitivity; and that this imbalance will remain even after the person achieves his or her desired weight. Genetic defects encoding for certain proteins (e.g., leptin, glucagon like protein 1) and their receptors have recently been associated with obesity. The macro-nutritional composition of food may also influence hormonal secretions and determine the metabolism of carbohydrates and impact whether they are efficiently converted to energy or stored as fat.



It is also observed that when one diets the body naturally defends itself from the perceived threat of starvation by lowering metabolism in order to conserve body mass. Thus, weight lost through dieting results primarily in lean muscle loss; the very tissue that burns calories most efficiently. Consequently, when one reverts to his previous diet he will gain back the weight that was lost or, most likely, gain back even more weight. This "yo-yoing" effect then further increases their risk of heart attack, other cardio-vascular disorders, osteoarthritis, diabetes, certain cancers, and other disorders. Socially, obese women are 20% less likely to marry than their thinner counterparts, have a lower household income by an average of $6,710 per year; and are 10% more likely to live in poverty. It also has an obvious depressing effect upon self-esteem.

As dieting rarely achieves any lasting benefits and often results in a worsening of the condition, other approaches are often tried, including drugs. Appetite suppressant drugs have improved safety profiles as compared with the amphetamines commonly prescribed in the sixties and seventies; and, newer serotoninergic drugs, such as fenfluramine and other anorectics, are often effective in the short-term; yet, long term use has not been proven to be safe.

FOOD SENSITIVITIES & WEIGHT GAIN

For years, a small number of doctors and other healthcare professionals have been aware that foods can cause adverse reactions, including immunologic problems and imbalances in bio-chemistry, which can result in weight gain or the inability to lose weight. Any food can cause the problems and it is often the very food or foods that one craves the most which do so. What we take for granted as a "normal diet" is a relatively recent cultural development which, in many instances, has outstripped biological mechanisms of adaptation. For example, members of certain racial groups who, by virtue of their geography and culture have not had a historic exposure

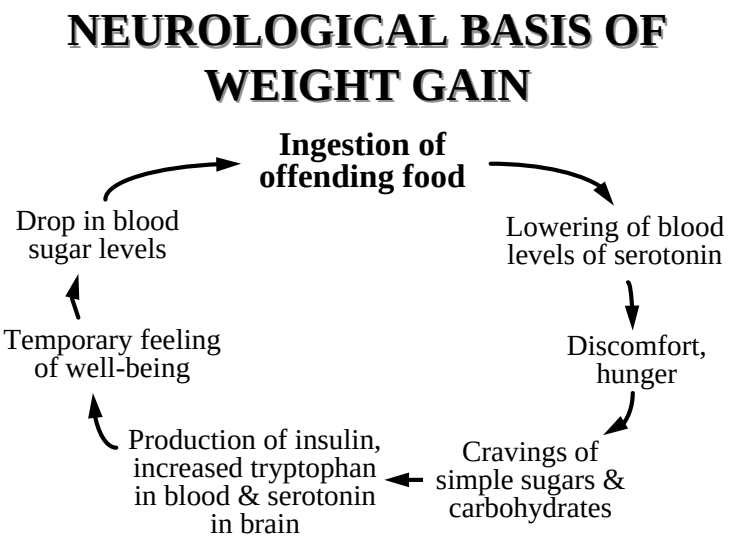
to milk, will not have developed the genetic disposition to digest milk proteins efficiently and may experience an adverse reaction to ingestion of milk or foods that contain it. Nonetheless, dairy products are heavily advertised and have become a major component of a modern American diet.

In addition, "advances" in food technology, as regards to methods of processing, preserving, and flavoring, including the use of dyes, pesticides, and fertilizers, has altered food to the point that these additives, in addition to food's natural components, can cause a disruption to the immune system. Further complication may arise from the overuse of antibiotics coupled with an increased consumption of simple sugars and refined flours (very common in a food sensitive patient's diet) thus causing an imbalance in the flora of the intestinal tract and an overgrowth of yeast (candida). This overgrowth of yeast in the gut can effect the mucosal lining of the intestines, contributing to a condition known as, "leaky gut syndrome" which then allows non-fully digested food proteins to enter the blood where they can trigger immune reactions and the release of chemical mediators of inflammation.

One outcome of this process, for many people, is damage to the structure of the blood capillaries, causing them to leak fluid into the surrounding connective tissue. This condition is known as edema, which it makes one look bloated and is directly associated with what in common parlance is referred to as "cellulite."

NEUROLOGICAL BASIS OF WEIGHT GAIN

Some obesity specialists have put forth another theory to explain brain chemistry's effect on hunger and weight gain. It has been demonstrated that after eating an offending food, blood levels of the neurotransmitter serotonin go down. Ingestion of highly refined carbohydrates and sugar cause a rapid release of insulin, increasing blood levels of tryptophan, a pre-cursor of serotonin. Thus, in order to compensate for lower brain levels of serotonin (caused by eating offending foods) food sensitive people may tend to crave foods which will increase serotonin in the brain (i.e., simple sugars and refined flours). This sets up a vicious cycle which, according to this theory, can only be broken when the foods that initiate the process are accurately identified and duly eliminated from the diet.[2]



SUMMARY

To summarize, any food can be incompatible with one's physiology, because: a) One does not have the necessary genetic experience with that food and therefore lacks the enzymes necessary to digest it properly, b) The food may contain naturally occurring pharmacoactive chemicals that directly trigger cellular responses to it, c) The condition of the gut wall may be too permeable (by virtue of an allergy that attacks the gut wall itself, thus creating an imbalance in the gut's natural protective functions, and/or damage resulting from an imbalance in gut flora). This condition then allows for the "perfusion" of food macromolecules into the bloodstream. Non-fully digested food proteins then enter the blood and cause the cells to release toxins that induce damage and inflammations; and, in many instances, water retention. Secretory IgA deficiency can also cause the same effect, d) Due to dietary insufficiency or another defect in one of the body's detoxification systems, any one or more of the artificial additives, or naturally occurring pharmacoactive agent in a food may cause a similar disruption to the immune system and metabolic function. Therefore, in order to sustain weight loss, it is important to regain balance in the body's metabolic functions which is promoted by the elimination of incompatible foods.

APPLYING THE RESULTS OF THE ALCAT TEST

Two recent studies have demonstrated the effectiveness of using The ALCAT Test for weight management.[3,4] Both studies have shown that subjects following a diet based on the results of The ALCAT Test, overall, lost scale weight and fat and improved body composition as compared with the control group, or their own pre-treatment phase. The study groups also experienced reduced hunger and improvement in other food sensitivity related conditions.

When the test is completed on a patient, the report provides the graphic test results, and a personalized, easy-to-follow diet plan which excludes test positive foods and rotates the test negative foods in addition to providing other relevant dietary information.

After following the diet for some days (usually about one to two weeks), the patient should notice improvement. However, there are some principles about food sensitivities and a phenomenon called "masking" that can relate to withdrawal-like symptoms. Suddenly eliminating an offending food may, in some cases, create temporary discomfort for a period of about 3 or 4 days. This is most likely to occur if it involves food(s) that were eaten every day or if there was a craving for the particular food(s). It is very important during this time for the patient not to succumb to the desire for the food(s), keeping in mind that the discomfort will pass very shortly, at which time the patient should feel much better than before the change in diet. "Masking" refers to the fact that eating moderate portions of the food frequently will induce chronic but low grade symptoms thus masking the fact that it is an offending food. The craving for the food exists because it will temporarily stop the discomfort associated with withdrawal of the food.

It is also necessary to be aware that processed foods contain a large combination of other foods. For example, corn exists in: corn syrup, corn starch, corn oil, corn chips, pop corn, etc. Also, milk is contained in cheeses, yogurt, sour cream, some baked goods, and so forth. It is also important to be aware to read labels in order to fully avoid problem foods. Sometimes reactions occur not so much to the foods themselves, but rather to the chemicals that are added to them. The ALCAT Test can be used for many of the more common food additives and the results applied in exactly the same way; i.e., avoid the offending substance(s).

Usually the process is very simple. However, in rare instances a patient may test positive to a very large number of foods. In such cases, it is especially important that careful advise is given to maintain adequate nutrition while restricting the diet overall. However, often, after a period of avoiding the offending foods (perhaps 3 to 6 months), a tolerance to many of the previously problematic foods may be achieved and they can then be eaten again in moderation. To determine this, challenge the patient's system by adding back each food, one by one, and noting reactions, or re-test the patient.

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