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## Foreword

Tests to identify individuals who are likely to develop serious diseases are being rapidly developed. Some of these tests are directed at diseases for which there are presently no known therapies, thereby raising questions over the social consequences of identifying susceptible persons. Other tests are directed at diseases that are among the foremost causes of morbidity and mortality, such as cardiovascular diseases and cancer, but for which clear-cut relationships between test positivity and a high probability of developing disease have yet to be established. Available tests for identifying persons infected with the AIDS virus are very accurate, but whom to test is a highly controversial issue because of the social consequences of being identified as a carrier of the AIDS virus.

The health status and risk of developing disease of individuals applying for health insurance are routinely evaluated by private health insurers, and applicants may be declined altogether, charged higher premiums, or have certain illnesses excluded from coverage. Medical testing may be included in evaluating the applicant, so wider use of diagnostic and predictive medical tests by insurers is a real possibility as such tests are improved and more tests become available. Many employers—especially large employers—are also foregoing the use of traditional insurers and are self-insuring the health care costs of their employees, so they may have similar incentives to use medical tests when hiring prospective employees.

Such uses of medical tests may lead to substantial costs to government if private insurance becomes too costly or unavailable to selected individuals. Furthermore, approximately 15 percent of the population of the United States do not have health insurance, and an additional 8 to 26 percent of the population under age 65 are underinsured. Thus, use of medical tests in determining insurability and employability not only affects the balance between governmental and private sector financing of health care, but also can aggravate the problem of the uninsured and underinsured.

This assessment examines existing and developing medical tests and their current and potential uses by health insurers and employers. Two related reports have previously been issued as part of this study. *AIDS and Health Insurance: An OTA Survey* was issued in February 1988 and examined health insurance underwriting practices and AIDS claims experience for individually underwritten insurance policies. The *Impact of AIDS on the Kaiser Permanente Medical Care Program (Northern California Region)* was released in July 1988.

OTA was ably assisted in this study by an advisory panel, chaired by Irving Lewis, Emeritus Professor of Public Policy and Community Health at the Albert Einstein College of Medicine. Many individuals and organizations with expertise and interest in these areas also provided information and reviewed a draft of the report. The final responsibility for the content of this assessment rests with OTA. Key staff involved in the analysis and writing were Larry Miike, Jill Eden, Maria Hewitt, Laurie Mount, and Ellen Smith.

  
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NOTE: OTA gratefully acknowledges the members of this advisory panel for their valuable assistance and thoughtful advice. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

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## List of Abbreviations

ACLI	—American Council on Life Insurance	MRI	—magnetic resonance imaging (formerly NMR)
ACLU	—American Civil Liberties Union	NAHMOR	—National Association of HMO Regulators
ACS	—American Cancer Society	NAIC	—National Association of Insurance Commissioners
AIDS	—acquired immunodeficiency syndrome	NIDA	—National Institute on Drug Abuse
ALT	—alanine amino transferase (formerly SGPT)	NIH	—National Institutes of Health
AMA	—American Medical Association	NIOSH	—National Institute for Occupational Safety and Health
APS	—attending physician’s statement	NMCES	—National Medical Care Expenditure Survey
ARC	—AIDS-related complex	NMCUES	—National Medical Care Utilization and Expenditure Survey
ASO	—administrative services only	NMR	—nuclear magnetic resonance (former name for MRI)
AST	—aspartate amino transferase (formerly SGOT)	ODPHP	—U.S. Office of Disease Prevention and Health Promotion (PHS)
BC/BS	—Blue Cross/Blue Shield	OPM	—U.S. Office of Personnel Management
BLS	—Bureau of Labor Statistics	OTA	—Office of Technology Assessment (U.S. Congress)
BUN	—blood urea nitrogen	OTC	—over-the-counter
CAD	—coronary artery disease	PHS	—U.S. Public Health Service
CAP	—College of American Pathologists	PMA	—premarket approval
CDC	—Centers for Disease Control	Pro	—preferred provider organization
CEA	—carcinoembryonic antigen	RBC	—red blood cell
CFR	—Code of Federal Regulations	RFLPs	—restriction fragment length polymorphisms
CHD	—coronary heart disease	RIPA	—radioimmunoprecipitation assay
CHIPS	—catastrophic health insurance plans	RNA	—ribonucleic acid
CMPS	—competitive medical plans	SIPP	—Survey of Income and Program Participation
COBRA	—Consolidated Omnibus Budget Reconciliation Act of <b>1985</b>	SGOT	—serum glutamic-oxaloacetic transaminase (former name for AST)
<b>CPS</b>	—Current Population Survey	SGPT	—serum glutamic pyruvic transaminase (former name for ALT)
<b>Cso</b>	—claims services only	STD	—sexually transmitted disease
DHHS	—U.S. Department of Health and Human Services	TPAs	—third party administrators
DNA	—deoxyribonucleic acid	VLDL	—very low density lipoproteins
DOD	—U.S. Department of Defense	WBC	—white blood cell
DOT	—U.S. Department of Transportation		
EIA	—enzyme immunoassay		
EKG	—Electrocardiogram		
ELISA	—enzyme-linked immunosorbent assay		
ERISA	—Employee Retirement and Income Security Act		
ESRD	—end-stage renal disease		
FDA	—U.S. Food and Drug Administration		
FH	—familial hypercholesterolemia		
GAO	—U.S. General Accounting Office		
GC/MS	—gas chromatography/mass spectrometry		
GGT	—gamma-glutamyl transpeptidase		
GHAA	—Group Health Association of America		
HCFA	—Health Care Financing Administration		
HDL	—high density lipoproteins		
HIAA	—Health Insurance Association of America		
HIS	—Health Interview Survey		
HIV	—Human Immunodeficiency Virus		
HMO	—health maintenance organization		
HORL	—Home Office Reference Laboratory, Inc.		
HRA	—health risk appraisals		
IFA	—indirect immunofluorescence assay		
LDL	—low density lipoproteins		
METs	—multiple employer trusts		
MI	—myocardial infarction		
MIB	—Medical Information Bureau, Inc.		

## Glossary of Terms

**Accuracy (“diagnostic accuracy”):** In describing a diagnostic test, diagnostic accuracy is the number of correct test results (i. e., the total of true-positives and true-negatives) divided by the total number of tests performed. Diagnostic accuracy may vary with the prevalence of the disease in the population. See also sensitivity and specificity.

**Acquired immunodeficiency syndrome:** The most severe clinical manifestation of immune dysfunction caused by the human immunodeficiency virus (HIV).

**Adverse selection:** The tendency of persons with poorer than average health expectations to apply for or continue insurance to a greater extent than persons with average or better health expectations. Also known as “antiSelection.”

- Allele:** An alternative form of a gene, or a group of functionally-related genes, located at the corresponding site on the chromosome. Alleles are inherited separately from each parent, and can be dominant, recessive, or co-dominant for a particular trait.
- Antibody:** A blood protein (immunoglobulin) produced by white blood cells in response to the introduction of a specific antigen (usually a protein). Once produced, the antibody has the ability to combine with the specific antigen that stimulated antibody production. This reaction to foreign substances is part of the immune response. At present, five classes of antibodies are distinguishable. Most of the circulating antibodies are immunoglobulin G (IgG); the others are IgM, IgA, IgD, and IgE. See also *immunoglobulin*.
- Antigen:** A substance, usually a protein or complex carbohydrate, which, when introduced into the body of a human or other animal, stimulates the production of an antibody that reacts specifically with it.
- Autoradiograph:** An image produced on an x-ray film by a radioactively labeled substance.
- Biochemical profile:** A battery of twelve or more biochemical blood tests (e.g., calcium, glucose, blood urea nitrogen, total protein) that is conducted using large-volume, automated instruments. Biochemical profiles are sometimes used to screen asymptomatic adults in an effort to identify those with latent disease or those at high risk of developing chronic disease.
- Cholesterol:** An alcohol found in egg yolks, oils, and fats. Cholesterol is used to synthesize cell membranes, is a precursor to steroid hormones, and is a component of bile.
- Chromosome:** A rod-like structure found in the cell nucleus and containing the genes. Chromosomes are composed of DNA and proteins. They can be seen in the light microscope during certain stages of cell division.
- Coinsurance:** A provision in a health insurance contract by which the insurer and insured share, in a specific ratio, the covered losses under a policy. For example, the insurer may reimburse the insured for 80 percent of covered expenses, the insured paying the remaining 20 percent of such expenses.
- Community-rating:** A method of determining premium rates that is based on the allocation of total costs without regard to past group experience. Community rating is required of federally qualified HMOs.
- Conversion privilege:** The right to change insurance without providing evidence of insurability, usually to start individual policy upon termination of coverage under a group contract. Conversion privileges are mandated by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Public Law 99-272).
- Core antigens:** Antigens that make up the internal structure or core of a virus. Compare *envelope antigens*.
- Deductible:** The amount of covered expenses that must be incurred and paid by the insured before benefits become payable by the insurer.
- Deoxyribonucleic acid (DNA):** The substance of heredity; a large molecule which carries the genetic information necessary for the replication of cells and for the production of proteins. DNA is composed of the sugar deoxyribose, phosphate, and the bases adenine, thymine, guanine, and cytosine.
- DNA denaturation:** The separation of DNA into its two strands of nucleotides, for example by exposing it to near-boiling temperatures or to extremely alkaline conditions.
- DNA probe:** A specific sequence of single-stranded DNA used to seek out a complementary sequence in other single strands. The probe is usually made radioactive so that it can be detected.
- DNA sequencing:** The process of determining the nucleotide sequences of DNA.
- Diagnostic test:** A medical test administered to those asymptomatic but high risk individuals identified by a screening test or a test used to identify the cause of abnormal physical signs or symptoms. Compare *predictive test* and *screening test*.
- Direct genetic test:** A DNA-based test capable of identifying a specific disease-causing allele. Compare *linkage test*.
- Direct pay:** See *individual health insurance*.
- Electrophoresis:** A method of separating substances, such as DNA fragments, by using an electric field to make them move through a medium at rates that correspond to their electric charge and size.
- Electrocardiogram (EKG or ECG):** A graphic tracing of the changes of electrical potential of the heart occurring during each heartbeat; usually performed with the patient supine and at rest.
- Envelope antigens:** Proteins that comprise the envelope or surface of a virus. Compare *core antigens*.
- Enzyme immunoassay (EIA):** An assay based on antigen-antibody interactions, which uses enzymes to measure the reaction. For example, in EIAs that are used to measure drugs in urine, a reagent that contains antibodies against a specific drug is first added to the urine specimen. A second reagent containing the specific drug attached to an enzyme is then added, and the enzyme-labeled drug combines with any remaining antibody binding sites. This binding decreases the enzyme activity. The residual enzyme activity relates directly to the concentration of drug in the specimen. The active enzyme converts another substance in the reagent, resulting in an absorbance change that is measured spectrophotometrically. See also *indirect immunofluorescence assay* and *radioimmunoprecipitation assay*.

- Enzyme-linked immunosorbent assay (ELISA): A type of enzyme immunoassay; for example, an ELISA is used to test for the presence of antibodies to HIV.
- Exclusion waiver: An agreement attached to an insurance policy which eliminates a specified preexisting condition from coverage under the policy.
- Experience-rating: A method of determining group premium rates based on the actual amount of claim payments made on behalf of the group in a prior period, usually the preceding year.
- False negative: A negative test result in an individual who actually has the disease or characteristic being tested for. The patient is incorrectly diagnosed as not having a particular disease or characteristic.
- False positive: A positive test result in an individual who does not have the disease or characteristic being tested for. The individual is incorrectly diagnosed as having a particular disease or characteristic.
- Familial hypercholesterolemia (FH): An autosomal dominant disease caused by inherited defects in the gene encoding for the low density lipoprotein receptor. The defects disrupt the normal control of cholesterol metabolism.
- Federally qualified HMO: An HMO that is certified as meeting the qualification requirements of the Federal Health Maintenance Act of 1973, as amended (42 U.S.C. Sec. 300e et seq.). Federally qualified HMOs must adhere to certain financial, underwriting, and rate-setting standards and provide specified, medically necessary health services.
- Gas chromatography/mass spectrometry (GC/MS): A method of identifying specific substances (for example, drugs), in which a gas chromatography is coupled with a mass spectrometer. The gas chromatography is used to separate individual substances by the rate they traverse the chromatography column. As these compounds exit the chromatographic column, they may, for example, be bombarded with electrons, with each substance breaking up into characteristic pieces that can be identified with the mass spectrometer. A GC/MS can be calibrated to scan for many substances in a specimen, or to monitor for only a few masses that are characteristic of a particular substance.
- Gene: A unit of heredity; a segment of the DNA molecule containing the code for a specific function.
- Gene expression: The manifestation of the genetic material of an organism as specific traits. Specific gene products are expressed as proteins.
- Genetics: The scientific study of heredity: how particular qualities or traits are transmitted from parents to offspring.
- Genome: The total genetic endowment packaged in the chromosomes. The normal human genome consists of 46 chromosomes.
- Human Immunodeficiency Virus (HIV): A retrovirus that is the etiologic agent of AIDS.
- Huntington's disease: A disease that generally appears in adulthood, producing progressive mental and physical deterioration; it is caused by a dominant gene.
- Hybridization: The placement of complementary single strands of nucleic acids together so that they will stick and form a double strand. The technique of hybridization is used in conjunction with probes to detect the presence or absence of specific complementary nucleic acid sequences.
- In situ hybridization: A method to identify HIV-produced RNA or DNA which involves the use of radioactive-labeled probes.
- Immunoglobulin: Any of the serum proteins with antibody activity. See also *antibody*.
- Incidence: The number of new cases of a disease in a population over a specified period of time. Compare *prevalence*.
- Indirect immunofluorescence assay (IFA): An assay based on antigen-antibody interactions. For example, in searching for viral antigens (such as HIV) in cells, antibodies to the specific viral antigen are first added. Fluorescein-labeled goat antihuman globulin is then added, which binds to antibodies attached to the viral antigen, and these viral antigens are then detected with a fluorescent microscope. See also enzyme *immunoassay* and *radioimmuno-precipitation assay*.
- Individual health insurance: Health insurance that covers an individual and often members of his or her family without any association with an employer or membership group of any kind.
- Individually underwritten groups: Small employee groups that usually include no more than so individuals. Small group underwriting requires that individual group members provide a statement of health and evidence of insurability.
- Linkage: The relationship between two genes, or between an identifiable trait and a genetic disorder. Genes that are located relatively close to each other on the same chromosome are said to be linked and generally are inherited together.
- Lipoprotein: Compounds consisting of lipids (fatty substances such as cholesterol) and proteins. Lipoproteins are classified as very low-density (VLD), low-density (LD), and high-density (HD).
- Locus: The site of a gene on a chromosome.
- Lymphocyte: A white blood cell which is part of the immune system.
- Magnetic resonance imaging (MN): A technique that produces images of the body by measuring the reaction of nuclei (typically of hydrogen protons) in magnetic fields to radiofrequency waves. Formerly known as nuclear magnetic resonance (NMR).
- Monoclonal antibodies (MAbs): Antibodies derived from a single source or clone of cells. MAbs recognize only one type of antigen.
- Multiple employer trusts (METs): A method of insur-

- ance in which small employers band together and act as a large employer to create a larger risk pool so that premiums can be lower compared to premiums based on each employer's smaller risk pool.
- Myocardial infarction (MI): Necrosis (death) of tissue in the myocardium (heart muscle) that results from insufficient blood supply to the heart.
- Nuclear magnetic resonance: See magnetic *resonance imaging (MRI)*.
- Nucleic acids: DNA and RNA, the molecules that carry genetic information.
- Nucleotide: A building block of DNA or RNA. It includes one base, one phosphate molecule, and one sugar molecule (deoxyribose in DNA, ribose in RNA).
- Oligonucleotide: A short string of nucleotides.
- Oligonucleotide probe: A short DNA sequence which is synthesized from a known gene or segment of a gene that can be either normal or mutant.
- Oncogene: A gene of which one or more mutant forms is associated with cancer formation.
- Oncolipid: Alterations of the lipid moieties of lipoprotein particles found in the plasma of patients with cancer.
- Open enrollment: A health insurance enrollment period during which coverage is offered regardless of health status and without medical screening. Open enrollment periods are characteristic of some BC/BS plans and HMOS.
- Penetrance: A term used to refer to the frequency with which the effects of a gene (whether dominant or recessive) known to be present are actually seen in the individuals carrying it.
- Phenylketonuria (PKU): An autosomal recessive genetic disorder of amino acid metabolism, caused by the inability to metabolize phenylalanine to tyrosine. The resulting accumulation of phenylalanine and derived products causes mental retardation, which can be avoided by dietary restriction of phenylalanine beginning soon after birth.
- Polymorphism: A single gene trait (e.g., red blood cell surface antigens) that exists in two or more alternative forms (such as types A, B, AB, and O blood). A genetic variant would be considered a polymorphism if its frequency exceeded 1 percent, but would be considered a rare mutation if found in less than 1 percent of the population.
- Predictive test: A medical test generally applied to asymptomatic individuals to provide information regarding the future occurrence of disease. Compare *diagnostic test* and *screening test*.
- Predictive value: The proportion of individuals with positive test results that have (or will have) the condition in question.
- Preexisting condition: A condition existing before an insurance policy goes into effect and commonly defined as one which would cause an ordinarily prudent person to seek diagnosis, care, or treatment.
- Prevalence: The number of existing cases of a specified disease or condition divided by the number of people in the total population at a point in time. Compare *incidence*.
- Radioimmunoprecipitation assay (RIPA): An assay method based on antigen-antibody interactions, based on principles similar to enzyme immunoassay but using radioisotopes to measure the interactions. See also *enzyme immunoassay* and *indirect immunofluorescence assay*.
- Rated premium: A premium with an added surcharge that is required by insurers to cover the additional risk associated with certain medical conditions. Rated premiums usually range from 25 to 100 percent of the standard premium.
- Recombinant DNA: The hybrid DNA produced in the laboratory by joining pieces of DNA from different sources.
- Recombinant DNA technology: The techniques for cutting apart and splicing together pieces of DNA from different sources.
- Reliability: The consistency of measurement or degree of dependability of a measuring instrument.
- Restriction enzyme (or restriction endonuclease): An enzyme that recognizes a specific base sequence (usually four to six base pairs in length) in a double-stranded DNA molecule and cuts both strands of the DNA molecule at every place where this sequence appears.
- Restriction enzyme recognition site: The DNA site where a specific restriction enzyme cuts the DNA molecule.
- Restriction fragment length polymorphisms (RFLPs): The presence of two or more variants in the size of DNA fragments from a specific region of DNA that has been exposed to a particular restriction enzyme. These fragments differ in length because of an inherited variation in a restriction enzyme recognition site. See also *polymorphism*.
- Retrovirus: A virus that contains RNA, not DNA, and that produces a DNA analog of its RNA through the production of an enzyme known as "reverse transcriptase." The resulting DNA is incorporated in the genetic structure of the invaded cell in a form referred to as the "provirus."
- Reverse transcriptase: An enzyme that produces a DNA analog of its RNA counterpart, reversing the usual process of gene expression during which the RNA analog of DNA is produced.
- Risk classification: The evaluation of whether an insurance applicant will be covered on a standard or substandard basis, or not at all.
- Screening test: Generally, a test used to sort out apparently well persons who probably have disease from those who probably do not. A screening test is not

- intended to be diagnostic. Compare diagnostic test and *predictive test*.
- Self-insurance:** Usually refers to the practice of employers, particularly large employers, of assuming the risks for the health care expenses of their employees instead of purchasing health insurance through insurance companies. Such employers often continue to contract with insurance companies or other organizations for claims processing and administrative services, as well as purchasing stop-loss insurance to limit the amount of their liability for medical claims. Similar arrangements exist in other lines of insurance; e.g., liability insurance.
- Self-pay:** See *individual health insurance*.
- Sensitivity:** One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all those who actually have the condition being tested for who are correctly identified as positive by the test. Operationally, it is the number of true positive test results divided by the number of patients that actually have the disease (true positives divided by the sum of true positives plus false negatives). Compare *specificity*.
- Sickle-cell disease:** A potentially lethal recessive blood disorder caused by the mutation of a single nucleotide in the gene for beta-globulin, one of the protein chains that make up adult hemoglobin.
- Southern blotting:** A procedure for transferring DNA fragments from an agarose gel to a filter paper without changing their relative positions.
- Specificity:** One measure of the validity (or accuracy) of a diagnostic or screening test: the percentage of all specimens that do not have the condition being tested for that are correctly identified as negative by the test. Operationally, it is the number of negative test results divided by the number of specimens that actually do not have the condition (true negatives divided by the sum of true negatives plus false positives). Compare *sensitivity*.
- Standard risk:** A person who, according to an insurer's underwriting criteria, is entitled to purchase insurance coverage without extra premium or special restrictions.
- Substandard risk:** A person that does not meet the normal health requirements of a standard health insurance policy and whose coverage is provided with a higher premium and/or exclusion waiver.
- Tay-Sachs disease:** An autosomal recessive genetic disease resulting in developmental retardation, paralysis, dementia and blindness, usually fatal in early childhood. The defective gene codes for hexosaminidase A, an enzyme that is involved in certain chemical pathways in the brain.
- T4/T8 cell ratios:** The ratio of T4 cells (helper cells) to T8 cells (suppressor cells). Individuals with AIDS have a deficiency of T4 cells and a reversal of the usual ratio of T4 and T8 cells.
- Thalassemias:** Recessively inherited blood disorders caused by various mutations which reduce the synthesis of one of the protein chains that make up hemoglobin. The victims of severe thalassemia require frequent blood transfusions and often die in their teens or early twenties.
- Third party administrators (TPAs):** A term originally used in the Taft-Hartley legislation of 1947 to designate an entity that is neither union nor management but administers joint labor-management welfare and pension funds. In self-insured health plans, TPAs typically provide administrative services such as medical claims processing, utilization and charges review, and data processing and reporting.
- Tumor marker assays:** Assays (e.g., immunoassay) that detect tumor-produced proteins.
- Underwriting:** The process by which an insurer determines whether or not and on what basis it will accept an application for insurance.
- Western Blot:** An assay designed to differentiate among several proteins present in the specimen, using electrophoresis and antigen-antibody interactions. Electrophoresis is used to separate proteins by their molecular weights, and each protein is subsequently identified through combining with their respective antibody or antigen. For example, in Western blot testing for HIV antibodies, the protein components of HIV are first separated electrophoretically, transferred to blots, then mixed with sera suspected of containing HIV antibodies. The presence of antibodies to specific proteins of HIV are revealed by the combination of antibodies with their specific protein components of HIV.