T/DM6-A
Vol.17 No.14
Replaces T/DM6-P
Vol. 8 No. 10

September 1997

Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline

This guideline provides technical and administrative guidance on laboratory procedures related to blood alcohol testing, including specimen collection, methods of analysis, quality assurance, and reporting of results.

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- The authorization of a project
- The development and open review of documents
- The revision of documents in response to comments by users
- The acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus–"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialities are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline

Abstract

T/DM6-A, *Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline*, is designed to aid the clinical laboratory in producing timely and accurate blood alcohol results. Its key objective is to address, as comprehensively as possible, recommendations to assure the integrity of the laboratory report on blood alcohol. The document conforms to the objective by addressing specimen collection, methods of analysis, quality assurance, and reporting and significance of results as separate sections. Statutory provisions are included as additional resource information.

The subcommittee recognizes the possible medicolegal impact of blood alcohol testing. The section devoted to the chain-of-custody strives to define the laboratory's responsibility regarding the specimen by outlining specific procedures for the handling and storage of the specimen and subsequent documentation.

[NCCLS. *Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline*. NCCLS Document T/DM6-A (ISBN 1-56238-333-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 1997.]

T/DM6-A
ISBN 1-56238-333-7
ISSN 0273-3099

September 1997

Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline

Volume 17 Number 14

Kurt M. Dubowski, Ph.D.
Patricia H. Field, Ph.D.
Walter Frajola, Ph.D.
Vidmantas A. Raisys, Ph.D.
Robert H. Reeder, J.D.
M. Jeffery Shoemaker, Ph.D.
Vana L. Smith, Ph.D.

Suggested Citation

NCCLS. *Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline*. NCCLS Document T/DM6-A (ISBN 1-56238-333-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 1997.

Proposed Guideline
December 1988

Approved Guideline
September 1997

ISBN 1-56238-333-7
ISSN 0273-3099

Committee Membership

Area Committee on Clinical Chemistry and Toxicology

Basil T. Doumas, Ph.D. **Chairholder**	**Medical College of Wisconsin** **Milwaukee, Wisconsin**
W. Gregory Miller, Ph.D. **Vice Chairholder**	**Medical College of Virginia Hospital** **Richmond, Virginia**

Subcommittee on Blood Alcohol Testing

Kurt M. Dubowski, Ph.D. **Chairholder**	**The University of Oklahoma** **Oklahoma City, Oklahoma**
Patricia H. Field, Ph.D.	WI State Laboratory of Hygiene Madison, Wisconsin
Walter Frajola, Ph.D.	Columbus, Ohio
Vidmantas A. Raisys, Ph.D.	University of Washington Seattle, Washington
Robert H. Reeder, J.D.	Northwestern University Evanston, Illinois
M. Jeffery Shoemaker, Ph.D.	Pennsylvania Dept. of Health Lionville, Pennsylvania
Vana L. Smith, Ph.D.	Abbott Laboratories Abbott Park, Illinois
Sharon S. Ehrmeyer, Ph.D. *Board Liaison*	University of Wisconsin Madison, Wisconsin
Beth Ann Wise, M.T.(ASCP), M.S.Ed. *Staff Liaison*	NCCLS Wayne, Pennsylvania
Patrice E. Polgar *Editor*	NCCLS Wayne, Pennsylvania

ACTIVE MEMBERSHIP (as of 1 July 1997)

Sustaining Members

American Association for Clinical Chemistry
Bayer Corporation
Beckman Instruments, Inc.
Becton Dickinson and Company
Boehringer Mannheim Diagnostics, Inc.
College of American Pathologists
Coulter Corporation
Dade International Inc.
Johnson & Johnson Clinical Diagnostics
Ortho Diagnostic Systems Inc.

Professional Members

American Academy of Family Physicians
American Association of Bioanalysts
American Association of Blood Banks
American Association for Clinical Chemistry
American Association for Respiratory Care
American Chemical Society
American Medical Technologists
American Public Health Association
American Society for Clinical Laboratory Science
American Society of Hematology
American Society for Microbiology
American Society of Parasitologists, Inc.
American Type Culture Collection, Inc.
ASQC Food, Drug and Cosmetic Division
Asociacion Espanola Primera de Socorros
Association Microbiology Clinici Italiani-A.M.C.L.I.
Australasian Association of Clinical Biochemists
Canadian Society of Laboratory Technologists
Clinical Laboratory Management Association
College of American Pathologists
College of Medical Laboratory Technologists of Ontario
College of Physicians and Surgeons of Saskatchewan
Commission on Office Laboratory Accreditation
Institut für Stand. und Dok. im Med. Lab. (INSTAND)
International Council for Standardization in Haematology
International Federation of Clinical Chemistry
International Society for Analytical Cytology
Italian Society of Clinical Biochemistry
Japan Assn. Of Medical Technologists (Osaka)
Japanese Assn. Of Medical Technologists (Tokyo)
Japanese Committee for Clinical Laboratory Standards
Joint Commission on Accreditation of Healthcare Organizations
National Academy of Clinical Biochemistry
National Society for Histotechnology, Inc.
Ontario Medical Association Laboratory Proficiency Testing Program
Sociedade Brasileira de Analises Clinicas
Sociedad Espanola de Quimica Clinica
VKCN (The Netherlands)

Government Members

Armed Forces Institute of Pathology
Association of State and Territorial Public Health Laboratory Directors
BC Centre for Disease Control
Centers for Disease Control and Prevention
China National Centre for the Clinical Laboratory
Commonwealth of Pennsylvania Bureau of Laboratories
Department of Veterans Affairs
Deutsches Institut für Normung (DIN)
FDA Center for Devices and Radiological Health
FDA Division of Anti-Infective Drug Products
Government of Malta Department of Health
Health Care Financing Administration
INMETRO
Instituto de Salud Publica de Chile
Instituto Scientifico HS. Raffaele (Italy)
Iowa State Hygienic Laboratory
Manitoba Health
Massachusetts Department of Public Health Laboratories
Michigan Department of Public Health
National Health Laboratory (Luxembourg)
National Institute of Standards and Technology
Ohio Department of Health
Oklahoma State Department of Health
Ontario Ministry of Health
Ordre professionnel des technologistes médicaux du Québec
Saskatchewan Health-Government of Saskatchewan
South African Institute for Medical Research
Swedish Institute for Infectious Disease Control

Industry Members

AB Biodisk
Abbott Laboratories
ABC Consulting Group, Ltd.
AccuMed International, Inc.
Aejes
Ammirati Regulatory Consulting
Atlantis Laboratory Systems
Avecor Cardiovascular, Inc.
Bayer Corporation - Elkhart, IN
Bayer Corporation - Middletown, VA
Bayer Corporation - Tarrytown, NY
Bayer Corporation - West Haven, CT
Bayer-Sankyo Co., Ltd.
Beckman Instruments, Inc.
Becton Dickinson and Company
Becton Dickinson Consumer Products
Becton Dickinson Immunocytometry Systems
Becton Dickinson Italia S.P.A.

Becton Dickinson Microbiology Systems
Becton Dickinson VACUTAINER Systems
Behring Diagnostics Inc.
Behring Diagnostics Inc. - San Jose, CA
bioMérieux Vitek, Inc.
Biometrology Consultants
Bio-Rad Laboratories, Inc.
Bio-Reg Assoicates, Inc.
Biosite Diagnostics
Biotest AG
Boehringer Mannheim Diagnostics, Inc.
Boehringer Mannheim GmbH
Bristol-Myers Squibb Company
Canadian Reference Laboratory Ltd.
CASCO Standards
Checkpoint Development, Inc.
ChemTrak
Chiron Diagnostics Corporation
Chiron Diagnostics Corporation - International Operations
Chiron Diagnostics Corporation - Reagent Systems
Cholestech
Clinical Lab Engineering
COBE Laboratories, Inc.
Cosmetic Ingredient Review
Coulter Corporation
Cytometrics, Inc.
CYTYC Corporation
Dade International - Deerfield, IL
Dade International - Glasgow, DE
Dade International - Miami, FL
Dade International - Sacramento, CA
DAKO A/S
Diagnostic Products Corporation
Diametrics Medical, Inc.
Difco Laboratories, Inc.
Direct Access Diagnostics
Eiken Chemical Company, Ltd.
Enterprise Analysis Corporation
Donna M. Falcone Consultants
Fujisawa Pharmaceutical Co. Ltd.
Gen-Probe
Glaxo, Inc.
H&S Consultants
Health Systems Concepts, Inc.
Helena Laboratories
Higman Healthcare
Hoechst Marion Roussel, Inc.
Hybritech, Incorporated
Hycor Biomedical Inc.
I-STAT Corporation
Integ, Inc.
International Biomedical Consultants
International Remote Imaging Systems (IRIS)
International Technidyne Corporation
Johnson & Johnson Clinical Diagnostics
Johnson & Johnson Health Care Systems, Inc.
Kimble/Kontes
Labtest Sistemas Diagnosticos Ltda.
LifeScan, Inc. (Sub. Ortho Diagnostic Systems Inc.)
Lilly Research Laboratories
Luminex Corporation
Mallinckrodt Sensor Systems
MBG Industries, Inc.
Medical Device Consultants, Inc.
Medical Laboratory Automation Inc.
MediSense, Inc.
Merck & Company, Inc.
Metra Biosystems
Neometrics, Inc.
Nissui Pharmaceutical Co., Ltd.
Norfolk Associates, Inc.
North American Biologicals, Inc.
Olympus Corporation
Optical Sensors, Inc.
Organon Teknika Corporation
Orion Diagnostica, Inc.
Ortho Diagnostic Systems Inc.
Otsuka America Pharmaceutical, Inc.
Pfizer Canada, Inc.
Pfizer Inc
Pharmacia & Upjohn - Michigan
Pharmacia & Upjohn - Sweden
Procter & Gamble Pharmaceuticals, Inc.
The Product Development Group
Radiometer America, Inc.
Radiometer Medical A/S
Research Inc.
David G. Rhoads Associates, Inc.
Rhône-Poulenc Rorer
Roche Diagnostic Systems (Div. Hoffmann-La Roche Inc.)
Roche Laboratories (Div. Hoffmann-La Roche Inc.)
ROSCO Diagnostica
The R.W. Johnson Pharmaceutical Research Institute (Div. Ortho Diagnostic Systems Inc.)
Sarstedt, Inc.
Schering Corporation
Schleicher & Schuell, Inc.
Second Opinion
SenDx Medical, Inc.
Sherwood - Davis & Geck
Shionogi & Company, Ltd.
Showa Yakuhin Kako Company, Ltd.
Sienna Biotech
SmithKline Beecham Corporation
SmithKline Beecham, S.A.
SmithKline Diagnostics, Inc. (Sub. Beckman Instruments, Inc.)
SRL, Inc.
Streck Laboratories, Inc.
Sumitomo Metal Bioscience Inc.
Sysmex Corporation
TOA Medical Electronics
Unipath Co (Oxoid Division)
Vetoquinol S.A.
Vysis, Inc.
Wallac Oy
Warner-Lambert Company
Wyeth-Ayerst
Xyletech Systems, Inc.
Yeongdong Pharmaceutical Corp.
Zeneca

Trade Associations

Association of Medical Diagnostic Manufacturers
Health Industry Manufacturers Association
Japan Association of Clinical Reagents Industries (Tokyo)
Medical Industry Association of Australia
National Association of Testing Authorities - Australia

Associate Active Members

Affinity Health System (WI)
Allegheny University of the Health Sciences (PA)
Allergy Testing Laboratory (TX)
Alton Ochsner Medical Foundation (LA)
American Oncologic Hospital (PA)
Anzac House (Australia)
Associated Regional & University Pathologists (UT)
Baptist Medical Center of Oklahoma
Baptist Memorial Healthcare System (TX)
BC Children's Hospital (Canada)
Bethesda Hospital (OH)
Beth Israel Medical Center (NY)
Bristol Regional Medical Center (TN)
Brooke Army Medical Center (TX)
Brooks Air Force Base (TX)
Broward General Medical Center (FL)
Canterbury Health Laboratories (New Zealand)
Central Peninsula General Hospital (AK)
CENTREX Clinical Laboratories (NY)
Childrens Hospital Los Angeles (CA)
Children's Hospital Medical Center (Akron, OH)
Children's Hospital Medical Center (Cincinnati, OH)
Children's Hospital - New Orleans (LA)
City Hospital (WV)
The Cleveland Clinic Foundation (OH)
Columbia Medical Center (FL)
Commonwealth of Kentucky
CompuNet Clinical Laboratories (OH)
Consultants Laboratory (WI)
Dean Medical Center (WI)
Detroit Health Department (MI)
Dhahran Health Center (Saudi Arabia)
Diagnostic Systems Laboratories, Inc. (TX)
Duke University Medical Center (NC)
Dunn Memorial Hospital (IN)
Dwight David Eisenhower Army Medical Center (Ft. Gordon, GA)
Easton Hospital (PA)
Ellis Fischel Cancer Center (MO)
Elyria Memorial Hospital (OH)
Evanston Hospital (IL)
Federal Medical Center (MN)
Fort Leonard Wood Army Community Hospital (MO)
Frye Regional Medical Center (NC)
Grady Memorial Hospital (GA)
Great Smokies Diagnostic Laboratory (NC)
Hartford Hospital (CT)
Heritage Hospital (MI)
Hopital Saint Pierre (Belgium)
Hunter Area Pathology Service (Australia)
Incstar Corporation (MN)
International Health Management Associates, Inc. (IL)
Jewish Hospital of Cincinnati (OH)
Kaiser Permanente (CA)
Kangnam St. Mary's Hospital (Korea)
Kenora-Rainy River Regional Laboratory Program (Dryden, ON, Canada)
Klinisches Institute für Medizinische (Austria)
Laboratoire de Santé Publique du Quebec (Canada)
Laboratory Corporation of America (NC)
Lancaster General Hospital (PA)
Los Angeles County & USC Medical Center (CA)
Louisiana State University Medical Center
Maine Medical Center
Malcolm Grow USAF Medical Center (MD)
The Medical Center of Ocean County (NJ)
Melbourne Pathology (Australia)
Memorial Medical Center (IL)
Memorial Medical Center (LA)
Mercy Hospital (MN)
Methodist Hospital (TX)
Methodist Hospitals of Memphis (TN)
Montreal Children's Hospital (Canada)
Mount Sinai Hospital (NY)
Mount Sinai Hospital (Toronto, ON, Canada)
National Genetics Institute (CA)
Naval Hospital Cherry Point (NC)
New Britain General Hospital (CT)
New Hampshire Medical Laboratories
New Jersey Department of Health
The New York Blood Center
New York State Department of Health
New York State Library
New York University Medical Center
North Carolina Laboratory of Public Health
North Central Bronx Hospital (NY)
Northwestern Memorial Hospital (IL)
Olin E. Teague Medical Center (TX)
Omni Laboratory (MI)
Our Lady of Lourdes Hospital (NJ)
Our Lady of the Resurrection Medical Center (IL)
Palo Alto Medical Foundation (CA)
PAPP Clinic P.A. (GA)
Pathogenesis Corp. (WA)
Pathology Associates Laboratories (CA)
Permanente Medical Group (CA)
PLIVA d.d. Research Institute (Croatia)
Polly Ryon Memorial Hospital (TX)
Providence Medical Center (WA)
Puckett Laboratories (MS)
Queens Hospital Center (NY)
Quest Diagnostics (MI)
Ravenswood Hospital Medical Center (IL)
Reid Hospital & Health Care Services (IN)
Riverside Clinical Laboratories (VA)
Royal Brisbane Hospital (Australia)
St. Boniface General Hospital (Winnipeg, Canada)
St. Francis Medical Center (CA)
St. John Regional Hospital (St. John, NB, Canada)
St. John's Regional Health Center (MO)
St. Luke's Hospital (PA)
St. Luke's Regional Medical Center (IA)
St. Luke's-Roosevelt Hospital Center (NY)
St. Mary of the Plains Hospital (TX)
St. Paul Ramsey Medical Center (MN)
St. Vincent Medical Center (CA)

San Francisco General Hospital (CA)
Seoul National University Hospital (Korea)
Shanghai Center for the Clinical Laboratory (China)
Shore Memorial Hospital (NJ)
SmithKline Beecham Clinical Laboratories (GA)
SmithKline Beecham Clinical Laboratories (TX)
South Bend Medical Foundation (IN)
Southeastern Regional Medical Center (NC)
Southern California Permanente Medical Group
SUNY @ Stony Brook (NY)
Travis Air Force Base (CA)
UNC Hospitals (NC)
University of Alberta Hospitals (Canada)
University of California, San Francisco
University of Cincinnati Medical Center (OH)
University of Florida
University Hospital (Gent) (Belgium)
University Hospital (Linkoping, Sweden)
University Hospital (London, ON, Canada)
University Hospital (IN)
University Hospital of Cleveland (OH)
The University Hospitals (OK)
University of Medicine & Dentistry, NJ University Hospital
University of Nebraska Medical Center
University of the Ryukyus (Japan)
The University of Texas Medical Branch
University of Virginia Medical Center
U.S. Army Hospital, Heidelberg
UZ-KUL Medical Center (Belgium)
VA (Albuquerque) Medical Center (NM)
VA (Denver) Medical Center (CO)
VA (Long Beach) Medical Center (CA)
VA (Miami) Medical Center (FL)
Venice Hospital (FL)
Veterans General Hospital (Republic of China)
Virginia Baptist Hospital
Warde Medical Laboratory (MI)
William Beaumont Hospital (MI)
Winn Army Community Hospital (GA)
Wisconsin State Laboratory of Hygiene
Yonsei University College of Medicine (Korea)
York Hospital (PA)
Zale Lipshy University Hospital (TX)

Contents

Foreword

This guideline, *Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline*, was developed in response to the frequently expressed need for a readily available information source which addresses the increasingly more frequent involvement of the hospital or independent clinical laboratory in collecting and analyzing blood (and other biological specimens) for ethyl alcohol. The presence of alcohol is frequently associated with trauma, and with a great variety of acute illnesses and chronic diseases. Further, alcohol presence often adversely affects both morbidity and mortality. Therefore, appropriate trauma care and diagnosis and treatment of many medical syndromes and diseases in adults require information about the patient's alcohol status. Demand for blood alcohol testing of patients can, therefore, be expected to continue to increase.

Years of experience have borne out the expectation that the absence, or presence and concentration of alcohol in blood will often have later medicolegal or forensic implications and significance, in addition to its immediate clinical relevance. Some simple and practical measures taken at the outset can greatly reduce the impact of such subsequent legal developments on the clinical laboratory and its personnel. This guideline addresses that issue and the resultant responsibilities of clinical laboratories which are not limited to, but include the collection of blood specimens, quality assurance, records, and reports.

The Subcommittee on Blood Alcohol Testing has endeavored to produce a brief but adequate set of criteria to assist clinical laboratories in meeting the demand for timely and reliable blood alcohol testing for clinical purposes, while minimizing the impact of later medicolegal developments on the laboratory.

Universal Precautions

Because it is often impossible to know which might be infectious, all patient blood specimens are to be treated with "universal precautions." Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention. NCCLS document M29, *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*, deals specifically with all aspects of this issue.

Key Words

Alcohol, blood alcohol, analysis, blood alcohol concentration, chain-of-custody, intoxication.

Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline

1 Scope and Requirements

1.1 Scope of the Problem

The cost of alcohol abuse in our society is extraordinarily high in terms of the loss of human life, its detrimental contribution to the causes of illness and injury, productivity losses in the workplace, and the stress these in turn put on our medical resources and our judicial system. In a series of special workshops on alcoholism and alcohol abuse, the American Society of Clinical Pathologists Task Force on Drug Abuse and Toxicology[1] recognized the magnitude of the problem of alcohol in our society. The title of these seminars was "Alcohol - The Second Great Imitator" because of the medical challenges in the diagnosis of this problem.

1.2 Medical Requirements

Alcohol abuse should be considered one of the most important contributory causes of injury and disease today. The diagnosis of alcohol-use disorders, such as alcohol dependence and alcohol abuse, is a clinical procedure and subject to the problem of inexactness.[2] Diagnosis of the disease may be based not only on the features of alcoholism, with all its signs and symptoms, but on an accurate determination of blood alcohol concentration at the time of examination of a patient.

The use of alcohol acutely affects the central nervous system. Many of the signs and symptoms manifested by the patient are related to the degree of intoxication, as reflected by the concentration of alcohol in the patient's blood. Since many patients with traumatic injuries who are admitted to the emergency department are noncomatose, patient history or initial interview becomes most important. Patients showing direct effects of alcohol—breath odor, released inhibitions, alcoholic facies, toxic amblyopia, possible tachycardia and cardiac arrhythmias, nystagmus, and traumatic injuries of varying degrees—warrant further studies. These studies should include a complete physical examination, clinical laboratory analyses, and determination of the blood or serum alcohol concentration. Other drugs of misuse or abuse should also be considered in the testing procedures. The information in Dubowski's table on the Stages of Acute Alcoholic Influence/Intoxication[3] (Appendix A) and the Guide to Serum-Alcohol Test Results (Appendix B) become important in the evaluation of the patient, for they define possible correlations of blood alcohol concentration with its clinical signs and symptoms.

Because alcoholism can masquerade as many other diseases, vital signs become very important during the physical examination, and the possibility of closed head injury or neurological disorder should be considered. Associated disease diagnoses include neurological disorders; alcohol-induced or nonalcohol-associated cardiovascular disorders; arrhythmias, tachycardias, electrocardiographic alterations; liver disease; fatty liver, alcoholic hepatitis, portal fibrosis, cirrhosis and possible liver carcinoma; blood and blood clotting disorders: anemia, prothrombin elevations and thrombocytopenia; alcoholic pancreatitis; infections; alcoholic myopathies; digestive tract disorders: ulcers, gastritis, esophagitis, esophageal varices and cancer; endocrine disorders; skeletal system disorders: ischemic necrosis of the femoral heads and fractures; skin disorders; and toxic psychoses.

Indicated laboratory studies include analysis for blood alcohol concentration and other relevant clinical laboratory tests.

The evaluation of the *comatose patient* may be more difficult due to the lack of patient history. The physical examination and results of laboratory studies often reveal the diagnosis. These should be combined with radiological studies, particularly of the skull and chest. A proper evaluation of these studies will be valuable for decisions regarding admission to the hospital, proper treatment, and to minimize possible medical and legal complications.

This document necessarily emphasizes certain legal and other nonclinical aspects of blood alcohol testing. It is, therefore, important to recognize at all times that the clinical laboratory's first and primary responsibility is to the patient and to the physician.

1.3 Industrial-Medical Requirements

Alcohol is the most commonly used drug in the United States. It accounts for industrial losses in billions of dollars. For example, productivity losses due to alcohol abuse were estimated at $27 billion in 1985, or 39 percent of the total economic cost of alcohol abuse for that year.[4] Because of the recognition of the economic cost due to alcoholism and alcohol-related injuries, blood alcohol determinations may be required in connection with the following:

- Employment-related (on-the-job) injury
- Workers compensation (federal, state, local) proceedings
- Employee insurance programs
- Pre-employment screening and evaluations
- Employee drug screening
- Alcoholism treatment programs.

1.4 Medicolegal Requirements

Most blood-alcohol analyses in hospitals and other clinical settings are performed solely for medical diagnostic, treatment-related, or other clinical purposes. In such clinical laboratories there is no requirement for chain-of-custody procedures (see Section 3). In many jurisdictions the results of alcohol analyses may ultimately become evidence in civil or criminal legal proceedings, regardless of their original purpose. There is, however, no rational basis for the mystery and trepidation with which alcohol analyses are often regarded in clinical laboratories.[5] Some simple practices can minimize the extent of involvement of clinical laboratory personnel in subsequent legal proceedings, with respect to the collection and analysis of blood for alcohol for clinical purposes. A frequently updated, comprehensive, written (and/or computerized) protocol which is adhered to as necessary—minimizing the number of people involved in collection, transport, analysis for alcohol, and storage of a given blood specimen; as well as a clear statement on all records and reports that the specimen analyzed was whole blood, serum, or plasma, etc., can significantly reduce the involvement of clinical laboratory personnel in subsequent legal proceedings.

In some institutions, the analysis (or collection only) of blood specimens for alcohol for exclusively legal purposes such as traffic law enforcement or for potential adversarial proceedings such as accident-related workplace alcohol testing[6] is a regular occurrence. In those circumstances, the laboratory can establish a two-option system, in which the full legal requirements such as chain-of-custody procedures and specimen seals and secure specimen storage are reserved for legal-category tests. The investigation of a medico-legal case and the interpretation of the results of analysis in the legal context require good judgment and the assurance that the specimen has been properly collected and processed. If the following factors are appropriately handled, the laboratorian will have far fewer problems with testimony or legal proceedings in a court of law.

1.4.1 Consent

This problem can be dealt with through statutory provisions such as implied consent laws in each jurisdiction, or through legal advice regarding individual consent to obtaining a sample.

1.4.2 Collection Techniques

Knowledge of the statutes of the jurisdiction concerned and implementing national or regional regulations are necessary, for these authorities may designate who may draw the sample, the specimen container to be used, and how it is preserved.

1.4.3 Identification Procedures

For both medical and subsequent legal purposes, if any, a foundational requirement is to establish from whom the blood specimen was collected, by whom, at what date and time, etc. These data provide for "traceability" of the specimen—an aspect as important as specimen integrity (unaltered state).

1.4.4 Chain-of-Custody

This is the documentation discussed in Section 3 that accompanies the specimen if chain-of-custody procedures are used in a given instance. It certifies that: the specimen was obtained from the individual named as the source of the specimen, the specified laboratory was responsible for the analysis, all individuals who had possession of the specimen prior to analysis are listed, as well as the name of the technician who performed the analysis.

1.4.5 Security System

This must be utilized, when appropriate, to maintain the chain of custody and to exclude the possibility of tampering.

1.4.6 Method of Analysis

This must be a recognized method having the requisite reliability, and it must be accompanied by adequate quality assurance procedures. See Section 4.

1.4.7 Interpretations

There are many requirements for interpretation of blood alcohol concentrations and they are both medical and legal in nature. Many of the problems presented in this overview will be addressed in other parts of this document. Certain aspects, however, such as extrapolation of alcohol test results to other times, are beyond its scope.

1.4.8 Checklist of Issues

A checklist of issues that routinely surface during legal proceedings involving the analysis and reported results of a blood alcohol specimen appears as Table 1.

2 Specimen Collection

Recent revisions of motor vehicle codes in many states, in order to combat the problem of driving under the influence of alcohol (DUI) or while intoxicated (DWI) have placed additional responsibilities on hospitals and clinical laboratories. These revisions have created a need for guidance concerning the collection and processing of specimens for blood alcohol analysis. The discussion which follows is intended to assist phlebotomists and laboratory personnel involved with the collection and processing of specimens for alcohol determination.

2.1 Responsibility for Specimen Collection

Several important considerations are involved in decisions made by medical personnel to collect blood specimens from traffic accident victims for alcohol analysis. From a medical treatment viewpoint, it may be desirable, or necessary, to know the patient's blood alcohol concentration before administering anesthetics or medications. Such test results may also be utilized in later legal proceedings to determine whether the person was intoxicated or under the influence of alcohol.

2.2 Types of Specimens

Plasma and serum are physiologically and pharmacologically more appropriate specimens than whole blood. Intravascular alcohol transport involves both the cellular and noncellular components of blood, but alcohol distribution occurs primarily between the circulating plasma and other body tissues and fluids.

Motor Vehicle Codes or other laws may state that breath, blood, or urine may be analyzed for alcohol content. Of these fluids, blood, serum, or plasma are usually analyzed in clinical laboratories, since breath-alcohol testing equipment is generally not available in the clinical laboratory, and since urine alcohol concentrations are not well correlated with blood alcohol concentrations.[5,7,8]

When the term "blood" is used in motor vehicle statutes, *whole blood* is the universal meaning. Most regional laws define the alcohol element of drinking/driving offenses wholly or partly in terms of blood-alcohol concentrations; and may specify whole blood as the required specimen when “blood” is analyzed. Hence, if blood rather than breath is to be analyzed for alcohol, either exclusively or primarily in connection with traffic law enforcement, it is best to analyze whole blood.

Table 1. Checklist of Issues Commonly Arising in Legal Proceedings Involving Blood-Alcohol Analysis Results

Laboratory and Personnel

- Identity, status, and qualifications of the person giving testimony
- Name, status, and location of laboratory
- Identity, status, and qualifications of the analyst(s) and phlebotomist
- Identity, status and qualifications of the laboratory director
- Licensure and accreditation of laboratory and personnel

Specimens

- Information and documentation on identity of the specimen donor; and on the nature, integrity, and security of specimens
- Authority for ordering the test and for procurement of the specimens
- Appropriateness and validity of specimen selection
- Details of specimen collection, handling, storage
- Time, date, location of specimen collection; and bodily sampling site
- Chain-of-custody of specimens, and evidence to establish absence of irregularities or tampering; seals, labels, etc.
- Details of specimen containers, anticoagulants, preservatives, etc.
- Present location and condition of specimens or residues

Analysis

- Analysis protocols and standard operating procedures; literature references
- Details of the analysis actually performed; including apparatus, equipment, devices, and procedures involved
- Analytical “raw” data and final results and findings, and their derivation
- Details of instrument or system calibration
- Method characteristics, especially with respect to accuracy, precision, linearity, sensitivity, specificity, interferences
- Validity and reliability of the analysis scheme

Quality Assurance

- Overall quality assurance/quality control schemes
- Control specimens; nominal concentrations, actual results
- Standards, and their origin and validation
- Replicate analyses of the unknown specimens
- Laboratory performance in external alcohol analysis proficiency testing programs and surveys

Interpretation of Results

- Scientific validity of the test results
- Pharmacological, toxicological, or clinical significance and meaning of the results
- Relevance or significance of the results to the legal issues
- Relevant patient history, clinical care and treatment details; effects on results of fluid(s) administration, medications, shock, trauma or other details of patient status or medical conditions
- Compliance with applicable statute law, case law decisions, and rules and administrative procedures

Documentation

- Records, laboratory requisitions and requests, reports, manufacturers’ literature and other source documents pertaining to any of the foregoing matters

Alcohol, at equilibrium, is generally distributed throughout the body in proportion to the water content of various fluids, tissues, and organs. In particular, the alcohol concentration of whole blood is not identical to that of plasma or of serum. However, the alcohol concentration of either serum or plasma is, in practice, the same. Both theoretical calculations, based on water content, and experimental data yield typical mean ratios of 1.12/1 to 1.18/1 in normal subjects for serum/whole blood alcohol concentrations, with typical experimental ranges of 1.05/1 to 1.25/1.[9,10]

The specimen type analyzed should be identified. Results of alcohol analysis on serum or plasma specimens should not be converted to whole blood concentrations. If courts require the interpretation of serum alcohol concentrations or the conversion of serum concentrations to whole blood concentrations, experts can be retained to perform these functions. It is a complex issue.[11]

2.3 Specimen Collection, Handling, and Preservation

The blood collection procedure for *forensic* alcohol determinations must be conducted so that no doubt exists as to the authenticity and validity of the specimen. In this regard, several points should be emphasized.

2.3.1 Time of Collection

The time of collection is critical information which must be recorded and should appear on the report of results.

2.3.2 Site of Venipuncture

The site of the venipuncture is usually the median cubital or one of the other superficial veins of the forearm. Veins in the lower extremities can also be used if the forearms are not accessible because of injuries or for other reasons. During the early phases of alcohol absorption, peripheral venous blood concentrations lag behind arterial blood concentrations, particularly in the lower extremities.

Blood should not be removed from veins into which intravenous fluids or other medications are being administered at the time. The dilution effect can lower the alcohol concentration. Even when the presence of such parenteral fluids would not be expected to significantly affect the alcohol concentration of the blood, it is better to select a venipuncture site remote from the location of fluid administration in order to ensure a specimen representative of the true alcohol concentration of the specimen. If possible, it is best to collect the specimen before any treatment is begun. Ideally, venipuncture should be performed in accordance with applicable procedures described in the NCCLS document H3, *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture.*[12]

2.3.3 Disinfectant

The disinfectant used for cleansing the venipuncture site should not contain alcohol or other volatile organic substances. The most frequently employed disinfectants for this purpose are aqueous benzalkonium chloride or aqueous povidone-iodine.[13] Studies by Dubowski and Essary[13] have revealed that blood specimens can be significantly contaminated if alcohol containing sponges are used to cover the venipuncture site at the time when the needle is withdrawn from the vein while attached to the vacuum tube. Therefore, to avoid the possibility of contamination and legal challenges to the acceptability of the specimen collection procedure, only nonalcoholic disinfectants should be employed, and sterile dry sponges should be used to cover the venipuncture site. Further, if evacuated collection tubes are used, the tube should be removed from the multisample collection needle and holder before withdrawing the needle from the puncture site.

2.3.4 Specimen Container

The specimen container is important and will vary depending on whether serum, plasma, or whole blood is to be analyzed. If serum is required, the blood should be collected in a container without a preservative or anticoagulant and allowed to clot. The serum can be sent directly to the laboratory without further processing if the specimen is to be analyzed for alcohol content within four hours. If the analysis will be delayed, the serum should be transferred to another container and treated with sufficient sodium fluoride to produce a minimum concentration of 10 mg/mL (0.24mmol/ml).

For whole blood or plasma specimens, the type and amount of anticoagulant present is not important if the specimen is analyzed within four

hours of collection. It is only necessary that the anticoagulant not interfere with the alcohol determination and that a sufficient quantity is present in the specimen to prevent clotting. If the analysis is to be delayed, additional safeguards must be instituted to prevent changes in the alcohol content of the blood. For this purpose, potassium oxalate monohydrate (5 mg/mL of blood; 2.7μmol/mL) and sodium fluoride (1.5 mg/mL of blood; 3.6μmol/ml) are an appropriate anticoagulant and preservative combination for storage at 5 °C of initially sterile blood specimens for up to 48 hours.[14] Blood alcohol specimens stored at -20 °C or below are stable indefinitely.

Specimens that are to be transported or mailed in an unrefrigerated condition, or stored for more than 48 hours should be preserved with higher concentrations of sodium fluoride (10 mg/mL of blood; 0.24mmol/mL).[8] However, it has been documented that changes produced by contaminating microorganisms can affect alcohol concentrations in blood specimens even in the presence of preservatives. Blume and Lakatua[15] reported that various organisms isolated from contaminated blood specimens were capable of producing ethanol when inoculated into bank blood. *Candida albicans* was particularly active in this regard, producing significant quantities of alcohol even in the presence of sodium fluoride. These investigators recommended that fluoride (10 mg/mL; 0.24mmol/ml) be used as a preservative and that care should be taken to assure that microbial organisms are not introduced into the specimens.

Winek and Paul[16] reported that alcohol analyses of blood obtained under sterile conditions from living humans can be delayed as long as 14 days without a significant change in alcohol content. They state that this holds true whether the blood sample is refrigerated or not, or whether a preservative is added to the sample. Nevertheless, the question can still arise as to how the phlebotomist could know with certainty, even if aseptic collection techniques were employed, that no micro-organisms entered the specimen and produced changes in the alcohol concentration. For this reason, it is advisable to employ preservatives and to refrigerate specimens as additional safeguards against changes in alcohol content.

2.3.5 Size of Sample

The size of the sample should be sufficient to permit retesting, if necessary.

2.4 Specimen Handling

To ensure complete dissolution of the fluoride in the blood, the closed container of blood should be gently inverted several times immediately following specimen collection.

The laboratory request form for alcohol analysis should be completed legibly and should contain the following information:

- Patient's full name
- Identification number
- Time and date of specimen collection
- Site of venipuncture
- Phlebotomist's name
- Name and address of facility where specimens were collected.

Collection kits designed to facilitate the sampling process are available from commercial sources. Potential purchasers should determine that the kits meet their needs and comply with local laws concerning blood alcohol analysis.

Additional special specimen handling considerations are addressed in Appendix C.

2.5 Replicate Blood Specimens

When it is known at the outset that alcohol analysis results will be required for legal purposes as well as for immediate clinical patient care, it may be practical and appropriate to collect replicate blood specimens in parallel and with consideration for the required kind of specimen, e.g., unpreserved serum for immediate analysis for clinical purposes, and a preserved anticoagulated whole-blood specimen for separate medicolegal analysis. Different documentation and handling may be required in such instances.

3 Chain-of-Custody Procedures[17,18]

3.1 Purpose

The established relationships between alcohol, trauma, and litigation ensure that the results of many medically-indicated blood-alcohol analyses