C34-A2
Vol. 20 No. 14

Replaces C34-A
Vol. 13 No. 2

Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition

This document addresses appropriate methods of collection and analysis, quality control, and the evaluation and reporting of test results.

A guideline for global application developed through the NCCLS consensus process.

NCCLS...

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 specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition

Abstract

NCCLS document C34-A2—*Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition* is a guideline for the performance of the sweat test for the diagnosis of cystic fibrosis. The primary audience includes laboratory and clinical personnel responsible for collecting, analyzing, reporting, and evaluating sweat test results. Sweat stimulation, collection, and the quantitative measurement of sweat chloride and sodium are described, with an emphasis on avoiding evaporation and contamination. Quality control issues associated with sweat testing are discussed, along with analytical and biological sources of error.

NCCLS. *Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition*. NCCLS document C34-A2 (ISBN 1-56238-407-4). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

C34-A2
ISBN 1-56238-407-4
ISSN 0273-3099

Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition

Volume 20 Number 14

Vicky A. LeGrys, Dr.A., M.T.(ASCP)
Beryl J. Rosenstein, M.D.
Basil T. Doumas, Ph.D.
W. Gregory Miller, Ph.D.
Paul D'Orazio, Ph.D.
John H. Eckfeldt, M.D., Ph.D.
Susan A. Evans, Ph.D.
Gary A. Graham, Ph.D., DABCC
Gary L. Myers, Ph.D.
Patrick J. Parsons, Ph.D.
Noel V. Stanton, M.S.

NCCLS

Suggested Citation

(NCCLS. *Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition.* NCCLS document C34-A2 [ISBN 1-56238-407-4]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.)

Proposed Guideline
March 1993

Approved Guideline
December 1994

Approved Guideline—Second Edition
June 2000

ISBN 1-56238-407-4
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**	**Virginia Commonwealth University** **Richmond, Virginia**
Paul D'Orazio, Ph.D.	Instrumentation Laboratory Lexington, Massachusetts
John H. Eckfeldt, M.D., Ph.D.	Fairview-University Medical Center Minneapolis, Minnesota
Susan A. Evans, Ph.D.	Dade Behring Inc. Deerfield, Illinois
Gary A. Graham, Ph.D., DABCC	Ortho-Clinical Diagnostics Rochester, New York
Gary L. Myers, Ph.D.	Centers for Disease Control and Prevention Atlanta, Georgia
Patrick J. Parsons, Ph.D.	New York State Department of Health Albany, New York
Noel V. Stanton, M.S.	University of Wisconsin Madison, Wisconsin

Advisors

Judith T. Barr, Sc.D.	Northeastern University Boston, Massachusetts
Stanley Bauer, M.D.	Beth Israel Medical Center New York, New York
George N. Bowers, Jr., M.D.	Hartford Hospital Hartford, Connecticut
Robert W. Burnett, Ph.D.	Hartford Hospital Hartford, Connecticut
Mary F. Burritt, Ph.D.	Mayo Clinic Rochester, Minnesota
Kevin D. Fallon, Ph.D.	Instrumentation Laboratory Lexington, Massachusetts

Advisors (Continued)

Carl C. Garber, Ph.D.	Quest Diagnostics, Incorporated Teterboro, New Jersey
Harvey W. Kaufman, M.D.	Quest Diagnostics, Incorporated Teterboro, New Jersey
Jan S. Krouwer, Ph.D.	Bayer Diagnostics Medfield, Massachusetts
Victoria M. Leitz, Ph.D.	International Biomedical Consultants Hilton Head, South Carolina
Richard R. Miller, Jr.	Dade Behring Inc. Newark, Delaware
Robert F. Moran, Ph.D., FCCM, FAIC	mvi Sciences Methuen, Massachusetts
Richard B. Passey, Ph.D.	University of Oklahoma Oklahoma City, Oklahoma
Edward A. Sasse, Ph.D.	Medical College of Wisconsin Milwaukee, Wisconsin
Richard S. Schifreen, Ph.D.	Promega Corporation Madison, Wisconsin
Bette Seamonds, Ph.D.	National Academy of Clinical Biochemistry Swarthmore, Pennsylvania
Beth Ann Wise, M.T.(ASCP), M.S.Ed. *Staff Liaison*	NCCLS Wayne, Pennsylvania
Patrice E. Polgar *Editor*	NCCLS Wayne, Pennsylvania
Donna M. Wilhelm *Assistant Editor*	NCCLS Wayne, Pennsylvania

Acknowledgements

The Area Committee on Clinical Chemistry and Toxicology extends its appreciation to Vicky A. LeGrys, Dr. A., M.T.(ASCP), Chairholder of the former Subcommittee on Sweat Testing, and Beryl J. Rosenstein, M.D., for their help in preparing the second edition of this approved-level guideline, especially their advice on appropriate revisions and responses to the comments.

In addition, the area committee would also like to recognize the valuable contributions of the members and advisors of the Subcommittee on Sweat Testing that developed the first approved edition of this guideline.

Vicky A. LeGrys, Dr.A., M.T.(ASCP), Chairholder
Mary F. Burritt, Ph.D.
Lewis E. Gibson, M.D.
Keith B. Hammond, M.S.
Kelly Kraft
Beryl J. Rosenstein, M.D.

Advisors

Wayne K. Barlow, A.S.,B.S.(EE)
Alfred Bracey, M.A.
Warren F. Diven, Ph.D.
Stacey FitzSimmons, Ph.D.
Jody Gorton, M.S., M.T.(ASCP)
James Linn, M.S.
Norbert Mantor, Ph.D.
Samuel Meites, Ph.D.
Robert F. Moran, Ph.D., F.C.C.M., F.A.I.C.
Robert L. Murray, J.D., Ph.D.
Joseph L. Potter, M.D., Ph.D.
Marilyn Presto
M. Narahari Reddy, Ph.D.
Bette Seamonds, Ph.D.

Active Membership
(as of 1 April 2000)

Sustaining Members

Abbott Laboratories
American Association for Clinical Chemistry
Bayer Corporation
Beckman Coulter, Inc.
BD and Company
bioMérieux, Inc.
College of American Pathologists
Dade Behring Inc.
Nippon Becton Dickinson Co., Ltd.
Ortho-Clinical Diagnostics, Inc.
Pfizer Inc
Roche Diagnostics, Inc.

Professional Members

American Academy of Family Physicians
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.
Asociación Española Primera de Socorros (Uruguay)
Asociacion Mexicana de Bioquimica Clinica A.C.
Assn. of Public Health Laboratories
Assoc. Micro. Clinici Italiani-A.M.C.L.I.
Australasian Association of Clinical Biochemists
British Society for Antimicrobial Chemotherapy
Canadian Society for Medical Laboratory Science—Société Canadienne de Science de Laboratoire Médical
Canadian Society of Clinical Chemists
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
Fundacion Bioquimica de la Provincia (Argentina)
International Association of Medical Laboratory Technologists
International Council for Standardization in Haematology
International Federation of Clinical Chemistry
International Society for Analytical Cytology
Italian Society of Clinical Biochemistry
Japan Society of Clinical Chemistry
Japanese Association 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
RCPA Quality Assurance Programs PTY Limited
Sociedade Brasileira de Analises Clinicas
Sociedade Brasileira de Patologia Clinica
Sociedad Espanola de Quimica Clinica

Government Members

Armed Forces Institute of Pathology
BC Centre for Disease Control
Centers for Disease Control and Prevention
Chinese Committee for Clinical Laboratory Standards
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
Health Care Financing Administration/CLIA Program
Health Care Financing Administration
Iowa State Hygienic Laboratory
Massachusetts Department of Public Health Laboratories
National Association of Testing Authorities – Australia
National Center of Infectious and Parasitic Diseases (Bulgaria)
National Institute of Standards and Technology
Ohio Department of Health
Oklahoma State Department of Health
Ontario Ministry of Health
Saskatchewan Health-Provincial Laboratory
Scientific Institute of Public Health; Belgium Ministry of Social Affairs, Public Health and the Environment
South African Institute for Medical Research
Swedish Institute for Infectious Disease Control
Thailand Department of Medical Sciences

Industry Members

AB Biodisk
Abbott Laboratories
Abbott Laboratories, MediSense Products
Accumetrics, Inc.
Amersham Pharmacia Biotech
Ammirati Regulatory Consulting
Asséssor
AstraZeneca
Aventis
Avocet Medical, Inc.
Bayer Corporation - Elkhart, IN
Bayer Corporation - Middletown, VA
Bayer Corporation - Tarrytown, NY

Bayer Corporation – West Haven, CT
Bayer Medical Ltd.
BD
BD Biosciences – San Jose, CA
BD Biosciences – Sparks, MD
BD Consumer Products
BD Italia S.P.A.
BD VACUTAINER Systems
Beckman Coulter, Inc.
Beckman Coulter, Inc. Primary Care Diagnostics
Beckman Coulter K.K. (Japan)
Bio-Inova Life Sciences International
Biolog, Inc.
bioMérieux, Inc.
Biometrology Consultants
Bio-Rad Laboratories, Inc.
Biotest AG
Bristol-Myers Squibb Company
Canadian Reference Laboratory Ltd.
Capital Management Consulting, Inc.
CASCO•NERL Diagnostics
Checkpoint Development Inc.
Clinical Design Group Inc.
Clinical Lab Engineering
COBE Laboratories, Inc.
Combact Diagnostic Systems Ltd.
Community Medical Center (NJ)
Control Lab (Brazil)
Copan Diagnostics Inc.
Cosmetic Ingredient Review
Cubist Pharmaceuticals
Cytometrics, Inc.
Dade Behring Inc. - Deerfield, IL
Dade Behring Inc. - Glasgow, DE
Dade Behring Inc. - Marburg, Germany
Dade Behring Inc. - Sacramento, CA
Dade Behring Inc. - San Jose, CA
DAKO A/S
Diagnostic Products Corporation
DiaSorin
Eiken Chemical Company, Ltd.
Enterprise Analysis Corporation
Fort Dodge Animal Health
Gen-Probe
Glaxo-Wellcome, Inc.
Greiner Meditech, Inc.
Health Systems Concepts, Inc.
Helena Laboratories
Home Diagnostics, Inc.
Hycor Biomedical Inc.
I-STAT Corporation
Instrumentation Laboratory
International Technidyne Corporation
Johnson City Medical Center
Kendall Sherwood-Davis & Geck
Labtest Diagnostica S.A.
LifeScan, Inc. (a Johnson & Johnson Company)
Lilly Research Laboratories
Medical Automation Systems
Medical Device Consultants, Inc.
Medical Laboratory Automation Inc.
Medtronic Perfusion Systems
Merck & Company, Inc.
mvi Sciences (MA)
Nabi
Neometrics Inc.
Nichols Institute Diagnostics (Div. of Quest Diagnostics, Inc.)
Nissui Pharmaceutical Co., Ltd.
Nippon Becton Dickinson Co., Ltd.
Norfolk Associates, Inc.
Ortho-Clinical Diagnostics, Inc. (Raritan, NJ)
Ortho-Clinical Diagnostics, Inc. (Rochester, NY)
Oxoid Inc.
Pfizer Inc
Pharmacia & Upjohn
Procter & Gamble Pharmaceuticals, Inc.
The Product Development Group
Quest Diagnostics Incorporated
Quintiles, Inc.
Radiometer America, Inc.
Radiometer Medical A/S
David G. Rhoads Associates, Inc.
Roche Diagnostics GmbH
Roche Diagnostics, Inc.
Roche Laboratories (Div. Hoffmann-La Roche Inc.)
The R.W. Johnson Pharmaceutical Research Institute
Sanofi Diagnostics Pasteur
Sarstedt, Inc.
SARL Laboratoire Carron (France)
Schering Corporation
Schleicher & Schuell, Inc.
Second Opinion
SenDx Medical, Inc.
Showa Yakuhin Kako Company, Ltd.
SmithKline Beecham, S.A.
Streck Laboratories, Inc.
Sysmex Corporation (Japan)
Sysmex Corporation (Long Grove, IL)
The Toledo Hospital (OH)
Trek Diagnostic Systems, Inc.
Vetoquinol S.A.
Vysis, Inc.
Wallac Oy
Warner-Lambert Company
Wyeth-Ayerst
Xyletech Systems, Inc.
YD Consultant
Yeongdong Pharmaceutical Corporation

Trade Associations

Association of Medical Diagnostic Manufacturers
Health Industry Manufacturers Association
Japan Association Clinical Reagents Ind. (Tokyo, Japan)
Medical Industry Association of Australia

Associate Active Members

67th CSH Wuerzburg, GE (NY)
121st General Hospital (CA)
Acadiana Medical Laboratories, LTD (LA)
Advocate Laboratories (IL)
Albany Medical Center Hospital (NY)
Allegheny General Hospital (PA)
Allegheny University of the Health Sciences (PA)
Allina Laboratories (MN)
Alton Ochsner Medical Foundation (LA)
American Medical Laboratories (VA)
Anzac House (Australia)
Asan Medical Center (Korea)
Associated Regional & University Pathologists (UT)
Aurora Consolidated Laboratories (WI)
Baystate Medical Center (MA)
Brantford General Hospital (Brantford, ON, Canada)
Brazileiro De Promocao (Brazil)
Bristol Regional Medical Center (TN)
Brookdale Hospital Medical Center (NY)
Brooke Army Medical Center (TX)
Brooks Air Force Base (TX)
Broward General Medical Center (FL)
Calgary Laboratory Services
Carilion Consolidated Laboratory (VA)

CB Healthcare Complex (Sydney, NS, Canada)
Central Kansas Medical Center
Centralized Laboratory Services (NY)
Centro Diagnostico Italiano (Milano, Italy)
Champlain Valley Physicians Hospital (NY)
Children's Hospital King's Daughters (VA)
Children's Hospital (LA)
Children's Hospital (NE)
Children's Hospital Medical Center (Akron, OH)
Children's Hospital of Philadelphia (PA)
Clendo Lab (Puerto Rico)
CLSI Laboratories (PA)
Commonwealth of Kentucky
Commonwealth of Virginia (DCLS)
CompuNet Clinical Laboratories (OH)
Consolidated Laboratory Services (CA)
Covance Central Laboratory Services (IN)
Danish Veterinary Laboratory (Copenhagen, Denmark)
Danville Regional Medical Center (VA)
Dean Medical Center (WI)
Delaware Public Health Laboratory
Department of Health & Community Services (New Brunswick, Canada)
Detroit Health Department (MI)
Diagnostic Laboratory Services, Inc. (HI)
Duke University Medical Center (NC)
Durham Regional Hospital (NC)
Duzen Laboratories (Turkey)
Dynacare Laboratories - Eastern Region (Ottawa, ON, Canada)
E.A. Conway Medical Center (LA)
Elmhurst Memorial Hospital (IL)
Elyria Memorial Hospital (OH)
Emory University Hospital (GA)
Fairfax Hospital (VA)
Fairview-University Medical Center (MN)
Foothills Hospital (Calgary, AB, Canada)
Fox Chase Cancer Center (PA)
Franklin Square Hospital Center (MD)
Fresenius Medical Care/Life Chem (NJ)
Fresno Community Hospital and Medical Center
Gambro Healthcare Laboratory (FL)
GDS Technology, Inc (IN)
Grady Memorial Hospital (GA)
Greater Southeast Community Hospital (DC)
Guthrie Clinic Laboratories (PA)
Harris Methodist Fort Worth (TX)
Harris Methodist Northwest (TX)
Hartford Hospital (CT)
Hays Pathology Laboratories, P.A. (KS)
Health Alliance Laboratory (OH)
Health Network Lab (PA)
Health Sciences Centre (Winnipeg, MB, Canada)
Heartland Health System (MO)
Hinsdale Hospital (IL)
Hoag Memorial Hospital Presbyterian (CA)
Holmes Regional Medical Center (FL)
Holy Spirit Hospital (PA)
Holzer Medical Center (OH)
Hospital for Sick Children (Toronto, ON, Canada)
Hospital Israelita Albert Einstein (Brazil)
Hotel Dieu Hospital (Windsor, ON, Canada)
Huddinge University Hospital (Sweden)
Hurley Medical Center (MI)
Indiana University
Instituto Scientifico HS. Raffaele (Italy)
International Health Management Associates, Inc. (IL)
Intermountain Health Care Laboratory Services (UT)
Jacobi Medical Center (NY)
John Peter Smith Hospital (TX)
John Randolph Hospital (VA)
Johns Hopkins Medical Institutions (MD)
Johnson City Medical Center (IN)
Kaiser Permanente (CA)
Kaiser Permanente (NC)
Kantousspital (Switzerland)
Keller Army Community Hospital (NY)
Klinicni Center (Slovenia)
LabCorp (NC)
Laboratoire de Santé Publique du Quebec (Canada)
Laboratório Fleury S/C Ltda. (Brazil)
Laboratory Corporation of America (MO)
Lakeland Regional Medical Center (FL)
Lancaster General Hospital (PA)
Langley Air Force Base (VA)
Lewis-Gale Medical Center (VA)
Libero Instituto Univ. Campus BioMedico (Italy)
LAC and USC Healthcare Network (CA)
Louisiana State University Medical Center
Lutheran Hospital (WI)
Martin Luther King/Drew Medical Center (CA)
Massachusetts General Hospital (Microbiology Laboratory)
Massachusetts General Hospital (Pathology Laboratory)
Mayo Clinic Scottsdale (AZ)
MDS Metro Laboratory Services (Burnaby, BC, Canada)
Medical Center of Southern Indiana
Medical College of Virginia Hospital
Medicare/Medicaid Certification, State of North Carolina
Melrose-Wakefield Hospital (MA)
Memorial Hospital (CO)
Memorial Medical Center (Napoleon Ave., New Orleans, LA)
Memorial Medical Center (N. Jefferson Davis Pkwy., New Orleans, LA)
Memorial Medical Center (IL)
Mercy Health System (PA)
Mercy Hospital (NC)
Methodist Hospital (TX)
Methodist Hospital Indiana
Methodist Hospitals of Memphis (TN)
Michigan Department of Community Health
Montreal Children's Hospital (Canada)
Montreal General Hospital (Canada)
Mount Sinai Hospital (NY)
National University Hospital (Singapore)
Naval Surface Warfare Center (IN)
Nebraska Health System
New Britain General Hospital (CT)
New England Medical Center Hospital (MA)
The New York Hospital Medical Center of Queens

York State Department of Health
NorDx (ME)
North Carolina Laboratory of Public Health
North Carolina School of Veterinary Medicine
North Mississippi Medical Center
Northridge Hospital Medical Center (CA)
Northwestern Memorial Hospital (IL)
Olin E. Teague Medical Center (TX)
O.L. Vrouwziekenhuis (Belgium)
Ordre professionnel des technologists médicaux du Québec
Ottawa General Hospital (Ottawa, ON, Canada)
Our Lady of Lourdes Hospital (NJ)
Our Lady of the Resurrection Medical Center (IL)
Pathology and Cytology Laboratories, Inc. (KY)
Pathology Associates Laboratories (CA)
The Permanente Medical Group (CA)
Pocono Hospital (PA)
Presbyterian Hospital (NC)
Presbyterian Hospital of Dallas (TX)
Providence Health System (OR)
Providence Seattle Medical Center (WA)
Queen Elizabeth Hospital (Prince Edward Island, Canada)
Queensland Health Pathology Services (Australia)
Quintiles Laboratories, Ltd. (GA)
Regions Hospital
Research Medical Center (MO)
Rex Healthcare (NC)
Riyadh Armed Forces Hospital (Saudi Arabia)
Robert F. Kennedy Medical Center (CA)
Royal Columbian Hospital (New Westminster, BC, Canada)
Saint Mary's Regional Medical Center (NV)
St. Alexius Medical Center (ND)
St. Anthony Hospital (CO)
St. Barnabas Medical Center (NJ)
St. Boniface General Hospital (Winnipeg, Canada)
St. Elizabeth Hospital (NJ)
St. John Hospital and Medical Center (MI)
St. John Regional Hospital (St. John, NB, Canada)
St. Joseph Medical Center (MD)
St. Joseph Hospital (NE)
St. Joseph Mercy – Oakland (MI)
St. Joseph's Hospital - Marshfield Clinic (WI)
St. Luke's Hospital (PA)
St. Luke's Regional Medical Center (IA)
St. Mary Medical Center (IN)
St. Mary of the Plains Hospital (TX)
Salina Regional Health Center (KS)
San Francisco General Hospital (CA)
Santa Cabrini Hospital (Montreal, PQ Canada)
Santa Clara Valley Medical Center (CA)
Seoul Nat'l University Hospital (Korea)
Shanghai Center for the Clinical Laboratory (China)
Shands Healthcare (FL)
SmithKline Beecham Clinical Laboratories (GA)
SmithKline Beecham Clinical Laboratories (WA)
South Bend Medical Foundation (IN)
Southern California Permanente Medical Group
South Western Area Pathology Service (Australia)
Speare Memorial Hospital (NH)
Speciality Laboratories, Inc. (CA)
Stanford Health Services (CA)
State of Washington Department of Health
Stormont-Vail Regional Medical Center (KS)
Sun Health-Boswell Hospital (AZ)
Sunrise Hospital and Medical Center (NV)
Sutter Health (CA)
Tampa General Hospital (FL)
Tripler Army Medical Center (HI)
Tulane Medical Center Hospital & Clinic (LA)
UCSF Medical Center (CA)
UNC Hospitals (NC)
Unilab Clinical Laboratories (CA)
University of Alberta Hospitals (Canada)
University of Chicago Hospitals (IL)
University of Florida
University Hospital (IN)
University Hospital (Gent) (Belgium)
University Hospital (London, Ontario, Canada)
The University Hospitals (OK)
University of Massachusetts Lowell
University of Medicine & Dentistry, NJ University Hospital
University of Michigan
University of the Ryukyus (Japan)
University of Virginia Medical Center
University of Washington
UPMC Bedford Memorial (PA)
USAF Medical Center (OH)
UZ-KUL Medical Center (Belgium)
VA (Dayton) Medical Center (OH)
VA (Denver) Medical Center (CO)
VA (Martinez) Medical Center (CA)
VA (San Diego) Medical Center (CA)
VA (Tuskegee) Medical Center (AL)
VA Outpatient Clinic (OH)
Vejle Hospital (Denmark)
Via Christi Regional Medical Center (KS)
Virginia Department of Health
Viridae Clinical Sciences, Inc. (Vancouver, BC, Canada)
Walter Reed Army Institute of Research (MD)
Warde Medical Laboratory (MI)
Warren Hospital (NJ)
Washoe Medical Center (NV)
Watson Clinic (FL)
Wilford Hall Medical Center (TX)
William Beaumont Hospital (MI)
Williamsburg Community Hospital (VA)
Wilson Memorial Hospital (NY)
Winchester Hospital (MA)
Winn Army Community Hospital (GA)
Wishard Memorial Hospital (IN)
Womack Army Medical Center (NC)
Yan Chai Hospital (P.R. China)
Yonsei University College of Medicine (Korea)
York Hospital (PA)
Zale Lipshy University Hospital (TX)

Contents

Contents (Continued)

Foreword

The quantitative measurement of chloride in sweat (commonly called the “sweat test”) is used to confirm the diagnosis of cystic fibrosis (CF). With an approximate incidence of 1:3,200 in the United States, CF is the most common lethal genetic disease within the Caucasian population. It is an autosomal recessive disorder characterized by viscous secretions that affect the exocrine glands, primarily in the lungs and pancreas. Patients with CF have an increased concentration of sodium, chloride, and potassium in their sweat. The criteria for the diagnosis of CF include: the presence of one or more characteristic phenotypic features, or a history of CF in a sibling, or a positive newborn screening test result; and an increased sweat chloride concentration by pilocarpine iontophoresis on two or more occasions, or identification of two CF mutations or demonstration of abnormal nasal epithelial ion transport.[1]

The sweat test has been reported to have unacceptably high false-positive (up to 15%) and false-negative (up to 12%) rates attributable to inaccurate methodology, technical error, and patient physiology.[2-7] Comprehensive guidelines addressing the collection of sweat and the quantitative measurement of electrolytes in sweat are needed. Improvement in the performance of such tests can only occur when laboratory scientists and clinicians are aware of appropriate methods of collection and analysis, quality control, and evaluation of results. This document describes, in detail, the quantitative pilocarpine iontophoresis test for the determination of sweat chloride, including techniques to minimize the potential for false-positive and false-negative test results. Because some laboratories analyze sweat sodium in addition to chloride, a procedure for sodium is found in Appendix F. Nonselective screening methods, such as conductivity and osmolality, are also mentioned; such methods measure other analytes in addition to chloride. Other methods for measuring sweat electrolytes after pilocarpine iontophoresis exist but are not included in the guideline. Some of these methods are documented as having significant analytical problems.[2-7]

The Cystic Fibrosis Foundation requires that, at accredited Cystic Fibrosis Care Centers, sweating be stimulated by pilocarpine iontophoresis and collected in either gauze or filter paper, or microbore tubing followed by quantitative measurement of chloride. At alternative sites, as a screening procedure, conductivity may be measured (see Section 8.3.1). Patients with a sweat conductivity value of 50 mmol/L (equivalent NaCl) or above should have a quantitative measurement of sweat chloride.[8]

Key Words

Chloridometer, iontophoresis, sweat chloride, sweat testing

Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline—Second Edition

1 Introduction

Because the sweat test has been reported to have unacceptably high false-positive and false-negative rates attributable to inaccurate methodology, technical error, and patient physiology,[2-7] comprehensive guidelines addressing the collection of sweat and the quantitative measurement of electrolytes in sweat are needed. Improvement in the performance of such tests can only occur when laboratory scientists and clinicians are aware of appropriate methods of collection and analysis, quality control, and evaluation of results. This document describes, in detail, the quantitative pilocarpine iontophoresis test for the determination of sweat chloride, including techniques to minimize the potential for false-positive and false-negative test results.

2 Scope

The following procedures are described: the stimulation and collection of sweat and the quantitative measurement of chloride; sweat stimulation by pilocarpine iontophoresis (specific precautions are noted); and sweat collection in filter paper, gauze, and microbore tubing, with emphasis on avoiding evaporation and contamination. Sweat chloride determination is described using coulometric titration. Nonselective screening methods, such as conductivity and osmolality, are mentioned. While chloride determinations provide greater discrimination in CF, sweat sodium determination by flame photometry is measured in some European countries, and a procedure is included in Appendix F. Quality control issues are discussed, along with analytical and biological sources of error. This document is primarily directed towards laboratory and clinical personnel responsible for collecting, analyzing, reporting, and evaluating sweat chloride test results.

3 Definitions [a]

Calibrator, *n* - **1)** A material or device of known, or assigned quantitative characteristics (e.g., concentration, activity, intensity, reactivity, responsiveness) used to adjust the output of a measurement procedure or to compare the response obtained with the response of a test specimen and/or sample. **NOTES:** a) The quantities of the analytes of interest in the calibration material are known within limits ascertained during its preparation and may be used to establish the relationship of an analytical method's response to the characteristic measured for all methods or restricted to some; b) Calibration materials with different amounts of analytes may be used to establish a calibration or response "curve" over a range of interest.

Control, *n* – A device, solution, or lyophilized preparation intended for use in the quality control process. **NOTES:** a) The expected reaction or concentration of analytes of interest are known within limits ascertained during preparation and confirmed in use; b) Control materials are generally not used for calibration in the same process in which they are used as controls.

Iontophoresis, *n* - The migration of small ions in an electrical field; **NOTE:** In the sweat test, pilocarpine is iontophoresed into the skin to stimulate sweating.

[a] Some of these NCCLS definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents*. For more detailed source information, please refer to the most current edition of that document.