C30-A2
Vol. 22 No. 17

Replaces C30-A
Vol. 14 No. 12

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition

This document contains guidelines for performance of point-of-care (POC) blood glucose testing that stress quality control, training, and administrative responsibility.

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

NCCLS

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

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition

Abstract

NCCLS document C30-A2— *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline— Second Edition* provides information for use by acute and chronic care facilities with laboratory support for structuring a point-of-care (POC) blood glucose testing service intended to ensure quality test results, as well as high-quality patient care. For facilities where laboratory support is not available, refer to NCCLS document AST4—*Blood Glucose Testing in Settings Without Laboratory Support.*

C30-A2 introduces policy-related issues with respect to administration of the program, persons who perform the tests, selection of methods, reporting of results, and the quality assurance aspects of point-of-care blood glucose testing. Also discussed are the uses of point-of-care blood glucose testing, authorization of operators, instrument verification, and procedural steps.

NCCLS. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition*. NCCLS document C30-A2 (ISBN 1-56238-471-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

C30-A2
ISBN 1-56238-471-6
ISSN 0273-3099

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition

Volume 22 Number 17

David B. Sacks, M.D., Chairholder
Patricia Bernhardt
Louis J. Dunka, Jr., Ph.D.
David E. Goldstein, M.D.
Glen L. Hortin, M.D.
Peter Mueller, Dr.rer.nat

Suggested Citation

(NCCLS. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition.* NCCLS document C30-A2 [ISBN 1-56238-471-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.)

Proposed Standard
August 1989

Tentative Standard
June 1991

Approved Standard
September 1994

Approved Guideline—Second Edition
August 2002

ISBN 1-56238-471-6
ISSN 0273-3099

Committee Membership

Area Committee on Clinical Chemistry and Toxicology

W. Gregory Miller, Ph.D. **Chairholder**	**Virginia Commonwealth University** **Richmond, Virginia**
Thomas L. Williams, M.D. **Vice-Chairholder**	**Methodist Hospital** **Omaha, Nebraska**
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.	LifeScan, Inc. Milpitas, California
Neil Greenberg, Ph. D.	Ortho-Clinical Diagnostics Rochester, New York
Patrick J. Parsons, Ph.D.	New York State Dept. of Health Albany, New York
Noel V. Stanton, M.S.	WI State Laboratory of Hygiene Madison, Wisconsin
Thomas L. Williams, M.D.	Nebraska Methodist Hospital Omaha, Nebraska

Advisors

Larry D. Bowers, Ph.D., DABCC	U.S. Anti-Doping Agency Colorado Springs, Colorado
George N. Bowers, Jr., M.D.	Hartford Hospital Hartford, Connecticut
Robert W. Burnett, Ph.D.	Hartford Hospital Farmington, Connecticut
Mary F. Burritt, Ph.D.	Mayo Clinic Rochester, Minnesota
Basil T. Doumas, Ph.D.	Medical College of Wisconsin Brookfield, Wisconsin
Kevin D. Fallon, Ph.D.	Instrumentation Laboratory Lexington, Massachusetts
Carl C. Garber, Ph.D.	Quest Diagnostics, Incorporated Teterboro, New Jersey

Advisors (Continued)

David E. Goldstein, M.D.	University of Missouri School of Medicine Columbia, Missouri
Gary A. Graham, Ph.D., DABCC	G2 Consulting Big Sandy, Texas
Harvey W. Kaufman, M.D.	Quest Diagnostics, Incorporated Teterboro, New Jersey
Richard R. Miller, Jr.	Dade Behring Inc. Newark, Delaware
Robert F. Moran, Ph.D., FCCM, FAIC	mvi Sciences Methuen, Massachusetts
David B. Sacks, M.D.	Brigham and Women's Hospital and Harvard Medical School Boston, Massachusetts
Bette Seamonds, Ph.D.	Mercy Health Laboratory Swarthmore, Pennsylvania
Professor Linda Thienpont	University of Ghent Ghent, Belgium
Hubert Vesper, Ph.D.	Centers for Disease Control and Prevention Atlanta, Georgia

Working Group on Glucose

David B. Sacks, M.D. **Chairholder**	**Brigham and Women's Hospital and Harvard Medical School** **Boston, Massachusetts**
Patricia Bernhardt	FDA Ctr. for Devices/Rad. Health Rockville, Maryland
Louis J. Dunka, Jr., Ph.D.	LifeScan, Inc. Milpitas, California
David E. Goldstein, M.D.	University of Missouri School of Medicine Columbia, Missouri
Glen L. Hortin, M.D.	National Institutes of Health Bethesda, Maryland
Peter Mueller, Dr.rer.nat	Roche Diagnostics GmbH Mannheim, Germany

Advisors

Carol A. Adiletto, M.S.	Inverness Medical Technology Waltham, Massachusetts
John Rex Astles, Ph.D.	Centers for Disease Control and Prevention Atlanta, Georgia
Roger R. Calam, Ph.D., DABCC	St. John Hospital and Medical Center Detroit, Michigan
Michael Flis	Roche Diagnostics Corporation Indianapolis, Indiana
Barry H. Ginsberg, M.D., Ph.D.	Becton Dickinson and Company Franklin Lakes, New Jersey
Olle Hagström	HemoCue AB Angelholm, Sweden
Joakim Hagvik	HemoCue AB Angelholm, Sweden
Ellis Jacobs, Ph.D., DABCC, FACB	The Mt. Sinai Hospital-NYU Medical Center New York, New York
Frederick L. Kiechle, M.D., Ph.D.	William Beaumont Hospital Royal Oak, Michigan
Richard J. Naples	Roche Diagnostics Corporation Indianapolis, Indiana
Ronald H. Ng, Ph.D.	Abbott Laboratories, MediSense Products Bedford, Massachusetts
Donald R. Parker, Ph.D.	Bayer Corporation Elkart, Indiana
Ann Tideman	Bayer Corporation Elkhart, Indiana
Bryan K. Vail, M.T.(ASCP)	VA Milwaukee Medical Center Milwaukee, Wisconsin
Jennifer K. McGeary, M.T.(ASCP), M.S.H.A. *Staff Liaison*	NCCLS Wayne, Pennsylvania
Patrice E. Polgar *Editor*	NCCLS Wayne, Pennsylvania
Donna M. Wilhelm *Assistant Editor*	NCCLS Wayne, Pennsylvania

Acknowledgement

The Area Committee on Clinical Chemistry and Toxicology would like to recognize the valuable contributions of the members and advisors of the Subcommittee on Ancillary Blood Glucose Testing that developed the first approved edition of this guideline.

Judith T. Barr, Sc.D., Chairholder
Jean Betschart, M.N., R.N., C.D.E.
Alfred Bracey, M.A.
Frederick L. Kiechle, M.D., Ph.D.
Marlene J. Koch, M.T., (ASCP)
Robert Metz, M.D., Ph.D.
Kathryn Mulcahy, R.N., M.S.N., C.D.E.
Nina Peled, Ph.D.
Steven J. Quinlan

Advisors

Daniel M. Baer, M.D.
Joan Kenny Bardsley
Sue Bogner, Ph.D.
Mary G. Day, M.T.(ASCP)
Jan Gagen
Mary Anne Gardineer
Barry H. Ginsberg, M.D., Ph.D.
June M. Gregonis
Linda Haas
Mary Tabb Johnston
Pauline Y. Lau, Ph.D.
Kenneth D. McClatchey, M.D., D.D.S.
Robert F. Moran, Ph.D., F.C.C.M., FAIC
Carol V. Nelson
Elizabeth G. Outlaw, M.T.
Aubrey S. Outschoorn, Ph.D.
Theodore J. Passon, Jr., Ph.D.
Christyne C. Price
Norman Pritchard
Robert Rej, Ph.D.
Dr. Richard E. Scott
Bette Seamonds, Ph.D.
Mary M. Stitak
Diana Trundle, Ph.D.
Dr. Stupdike

Active Membership
(as of 1 July 2002)

Sustaining Members

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

Professional Members

AISAR-Associazione Italiana per lo Studio degli
American Academy of Family Physicians
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 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.
British Society for Antimicrobial Chemotherapy
CADIME-Camara De Instituciones De Diagnostico Medico
Canadian Society for Medical Laboratory Science—Société Canadienne de Science de Laboratoire Médical
Clinical Laboratory Management Association
COLA
College of American Pathologists
College of Medical Laboratory Technologists of Ontario
College of Physicians and Surgeons of Saskatchewan
ESCMID
Fundación Bioquímica Argentina
International Association of Medical Laboratory Technologists
International Council for Standardization in Haematology
International Federation of Clinical Chemistry
Italian Society of Clinical Biochemistry and Clinical Molecular Biology
Japan Society of Clinical Chemistry
Japanese Committee for Clinical Laboratory Standards
Joint Commission on Accreditation of Healthcare Organizations
National Academy of Clinical Biochemistry
National Association of Testing Authorities – Australia
National Society for Histotechnology, Inc.
Ontario Medical Association Quality Management Program-Laboratory Service
RCPA Quality Assurance Programs PTY Limited
Sociedade Brasileira de Analises Clinicas
Sociedade Brasileira de Patologia Clinica
Sociedad Espanola de Bioquimica Clinica y Patologia Molecular
Turkish Society of Microbiology

Government Members

Association of Public Health Laboratories
Armed Forces Institute of Pathology
BC Centre for Disease Control
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services/CLIA Program
Centers for Medicare & Medicaid Services
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 Center for Veterinary Medicine
FDA Division of Anti-Infective Drug Products
Iowa State Hygienic Laboratory
Massachusetts Department of Public Health Laboratories
National Center of Infectious and Parasitic Diseases (Bulgaria)
National Health Laboratory Service (South Africa)
National Institute of Standards and Technology
New York State Department of Health
Ohio Department of Health
Ontario Ministry of Health
Pennsylvania Dept. of Health
Saskatchewan Health-Provincial Laboratory
Scientific Institute of Public Health; Belgium Ministry of Social Affairs, Public Health and the Environment
Swedish Institute for Infectious Disease Control
Thailand Department of Medical Sciences

Industry Members

AB Biodisk
Abbott Laboratories
Abbott Laboratories, MediSense Products
Acrometrix Corporation
Ammirati Regulatory Consulting
Anaerobe Systems
Asséssor
AstraZeneca
AstraZeneca R & D Boston
Aventis
Axis-Shield POC AS
Bayer Corporation – Elkhart, IN
Bayer Corporation – Tarrytown, NY
Bayer Corporation – West Haven, CT
Bayer Medical Ltd.
BD

BD Biosciences – San Jose, CA
BD Consumer Products
BD Diagnostic Systems
BD Italia S.P.A.
BD VACUTAINER Systems
Beckman Coulter, Inc.
Beckman Coulter, Inc. Primary Care Diagnostics
Beckman Coulter K.K. (Japan)
Bio-Development SRL
Bio-Inova Life Sciences International
Bio-Inova Life Sciences North America
BioMedia Laboratories Sdn Bhd
BioMérieux (NC)
bioMérieux, Inc. (MO)
Biometrology Consultants
Bio-Rad Laboratories, Inc.
Bio-Rad Laboratories, Inc. - France
Biotest AG
Blaine Healthcare Associates, Inc.
Bristol-Myers Squibb Company
Canadian External Quality Assessment Laboratory
Capital Management Consulting, Inc.
Carl Schaper
Checkpoint Development Inc.
Chiron Corporation
ChromaVision Medical Systems, Inc.
Chronolab Ag
Clinical Design Group Inc.
Clinical Laboratory Improvement Consultants
Cognigen
Community Medical Center (NJ)
Control Lab (Brazil)
Copan Diagnostics Inc.
Cosmetic Ingredient Review
Cubist Pharmaceuticals
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
David G. Rhoads Associates, Inc.
Diagnostics Consultancy
Diagnostic Products Corporation
Eiken Chemical Company, Ltd.
Elan Pharmaceuticals
Electa Lab s.r.l.
Enterprise Analysis Corporation
Essential Therapeutics, Inc.
EXPERTech Associates, Inc.
F. Hoffman-La Roche AG
Fort Dodge Animal Health
General Hospital Vienna (Austria)
Gen-Probe
GlaxoSmithKline
Greiner Bio-One Inc.
Helena Laboratories
Home Diagnostics, Inc.
Immunicon Corporation
Instrumentation Laboratory
International Technidyne Corporation
IntraBiotics Pharmaceuticals, Inc.
I-STAT Corporation
Johnson and Johnson Pharmaceutical Research and Development, L.L.C.
Kendall Sherwood-Davis & Geck
LAB-Interlink, Inc.
Laboratory Specialists, Inc.
Labtest Diagnostica S.A.
LifeScan, Inc. (a Johnson & Johnson Company)
Lilly Research Laboratories
Macemon Consultants
Medical Device Consultants, Inc.
Merck & Company, Inc.
Minigrip/Zip-Pak
Molecular Diagnostics, Inc.
mvi Sciences (MA)
Nabi
Nichols Institute Diagnostics (Div. of Quest Diagnostics, Inc.)
NimbleGen Systems, Inc.
Nissui Pharmaceutical Co., Ltd.
Nippon Becton Dickinson Co., Ltd.
Norfolk Associates, Inc.
Novartis Pharmaceuticals Corporation
Ortho-Clinical Diagnostics, Inc. (Raritan, NJ)
Ortho-Clinical Diagnostics, Inc. (Rochester, NY)
Oxoid Inc.
Paratek Pharmaceuticals
Pfizer Inc
Pharmacia Corporation
Philips Medical Systems
Powers Consulting Services
Premier Inc.
Procter & Gamble Pharmaceuticals, Inc.
The Product Development Group
QSE Consulting
Quintiles, Inc.
Radiometer America, Inc.
Radiometer Medical A/S
Roche Diagnostics GmbH
Roche Diagnostics, Inc.
Roche Laboratories (Div. Hoffmann-La Roche Inc.)
Sarstedt, Inc.
SARL Laboratoire Carron (France)
Schering Corporation
Schleicher & Schuell, Inc.
Second Opinion
Showa Yakuhin Kako Company, Ltd.
Streck Laboratories, Inc.
SurroMed, Inc.
Synermed Diagnostic Corp.
Sysmex Corporation (Japan)
Sysmex Corporation (Long Grove, IL)
The Clinical Microbiology Institute
The Toledo Hospital (OH)
Theravance Inc.
Transasia Engineers
Trek Diagnostic Systems, Inc.
Versicor, Inc.
Vetoquinol S.A.
Visible Genetics, Inc.
Vysis, Inc.
Wallac Oy
Wyeth-Ayerst
Xyletech Systems, Inc.
YD Consultant
YD Diagnostics (Seoul, Korea)

Trade Associations

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

Associate Active Members

20th Medical Group (SC)
31st Medical Group/SGSL (APO, AE)
67th CSH Wuerzburg, GE (NY)
121st General Hospital (CA)
Academisch Ziekenhuis-VUB (Belgium)
Acadiana Medical Laboratories, LTD (LA)
Adena Regional Medical Center (OH)
Advocate Healthcare Lutheran General (IL)
Akershus Central Hospital and AFA (Norway)
Albemarle Hospital (NC)
Allegheny General Hospital (PA)
Allegheny University of the Health Sciences (PA)
Allina Health System (MN)

Alton Ochsner Medical Foundation (LA)
American Medical Laboratories (VA)
Antwerp University Hospital (Belgium)
Arkansas Department of Health
ARUP at University Hospital (UT)
Armed Forces Research Institute of Medical Science (APO, AP)
Associated Regional & University Pathologists (UT)
Aurora Consolidated Laboratories (WI)
Azienda Ospedale Di Lecco (Italy)
Bay Medical Center (MI)
Baystate Medical Center (MA)
Bbaguas Duzen Laboratories (Turkey)
Bermuda Hospitals Board
Bo Ali Hospital (Iran)
British Columbia Cancer Agency (Vancouver, BC, Canada)
Brooks Air Force Base (TX)
Broward General Medical Center (FL)
Calgary Laboratory Services
Carilion Consolidated Laboratory (VA)
Cathay General Hospital (Taiwan)
CB Healthcare Complex (Sydney, NS, Canada)
Central Peninsula General Hospital (AK)
Central Texas Veterans Health Care System
Centre Hospitalier Regional del la Citadelle (Belgium)
Centro Diagnostico Italiano (Milano, Italy)
Champlain Valley Physicians Hospital (NY)
Chang Gung Memorial Hospital (Taiwan)
Changi General Hospital (Singapore)
Children's Hospital (NE)
Children's Hospital & Clinics (MN)
Children's Hospital Medical Center (Akron, OH)
Children's Hospital of Philadelphia (PA)
Children's Medical Center of Dallas (TX)
Clarian Health–Methodist Hospital (IN)
Clendo Lab (Puerto Rico)
Clinical Laboratory Partners, LLC (CT)
CLSI Laboratories (PA)
Columbia Regional Hospital (MO)
Commonwealth of Kentucky
Community Hospital of Lancaster (PA)
CompuNet Clinical Laboratories (OH)
Cook County Hospital (IL)
Cook Children's Medical Center (TX)
Covance Central Laboratory Services (IN)
Danish Veterinary Laboratory (Denmark)
Danville Regional Medical Center (VA)
Delaware Public Health Laboratory
Department of Health & Community Services (New Brunswick, Canada)
DesPeres Hospital (MO)
DeTar Hospital (TX)
Detroit Health Department (MI)
Diagnosticos da América S/A (Brazil)
Dr. Everett Chalmers Hospital (New Brunswick, Canada)
Doctors Hospital (Bahamas)
Duke University Medical Center (NC)
E.A. Conway Medical Center (LA)
Eastern Maine Medical Center
East Side Clinical Laboratory (RI)
Eastern Health (Vic., Australia)
Elyria Memorial Hospital (OH)
Emory University Hospital (GA)
Esoterix Center for Infectious Disease (TX)
Fairview-University Medical Center (MN)
Federal Medical Center (MN)
Florida Hospital East Orlando
Foothills Hospital (Calgary, AB, Canada)
Fort St. John General Hospital (Fort St. John, BC, Canada)
Fox Chase Cancer Center (PA)
Fresenius Medical Care/Spectra East (NJ)
Fresno Community Hospital and Medical Center
Frye Regional Medical Center (NC)
Gambro Healthcare Laboratory Services (FL)
Gateway Medical Center (TN)
Geisinger Medical Center (PA)
Grady Memorial Hospital (GA)
Guthrie Clinic Laboratories (PA)
Hahnemann University Hospital (PA)
Harris Methodist Erath County (TX)
Harris Methodist Fort Worth (TX)
Hartford Hospital (CT)
Headwaters Health Authority (Alberta, Canada)
Health Network Lab (PA)
Health Partners Laboratories (VA)
Heartland Regional Medical Center (MO)
Highlands Regional Medical Center (FL)
Hoag Memorial Hospital Presbyterian (CA)
Holmes Regional Medical Center (FL)
Holzer Medical Center (OH)
Hopital du Sacre-Coeur de Montreal (Montreal, Quebec, Canada)
Hôpital Maisonneuve – Rosemont (Montreal, Canada)
Hospital for Sick Children (Toronto, ON, Canada)
Hospital Sousa Martins (Portugal)
Hotel Dieu Hospital (Windsor, ON, Canada)
Houston Medical Center (GA)
Huddinge University Hospital (Sweden)
Hurley Medical Center (MI)
Indiana State Board of Health
Indiana University
Institute of Medical and Veterinary Science (Australia)
International Health Management Associates, Inc. (IL)
Jackson Memorial Hospital (FL)
Jersey Shore Medical Center (NJ)
John C. Lincoln Hospital (AZ)
John F. Kennedy Medical Center (NJ)
John Peter Smith Hospital (TX)
Kadlec Medical Center (WA)
Kaiser Permanente Medical Care (CA)
Kaiser Permanente (MD)
Kantonsspital (Switzerland)
Keller Army Community Hospital (NY)
Kenora-Rainy River Regional Laboratory Program (Ontario, Canada)

Kern Medical Center (CA)
Kimball Medical Center (NJ)
King Faisal Specialist Hospital (Saudi Arabia)
King Khalid National Guard Hospital (Saudi Arabia)
King's Daughter Medical Center (KY)
Klinični Center (Slovenia)
Laboratories at Bonfils (CO)
Laboratoire de Santé Publique du Quebec (Canada)
Laboratório Fleury S/C Ltda. (Brazil)
Laboratory Corporation of America (NJ)
Laboratory Corporation of America (MO)
LAC and USC Healthcare Network (CA)
Lakeland Regional Medical Center (FL)
Lancaster General Hospital (PA)
Langley Air Force Base (VA)
LeBonheur Children's Medical Center (TN)
L'Hotel-Dieu de Quebec (Canada)
Libero Instituto Univ. Campus BioMedico (Italy)
Louisiana State University Medical Center
Maccabi Medical Care and Health Fund (Israel)
Magee Womens Hospital (PA)
Malcolm Grow USAF Medical Center (MD)
Manitoba Health (Winnipeg, Canada)
Martin Luther King/Drew Medical Center (CA)
Massachusetts General Hospital (Microbiology Laboratory)
MDS Metro Laboratory Services (Burnaby, BC, Canada)
Medical College of Virginia Hospital
Medicare/Medicaid Certification, State of North Carolina
Memorial Medical Center (IL)
Memorial Medical Center (LA) Jefferson Davis Hwy
Memorial Medical Center (LA) Napoleon Avenue
Methodist Hospital (TX)
Methodist Hospitals of Memphis (TN)
MetroHealth Medical Center (OH)
Michigan Department of Community Health
Mississippi Baptist Medical Center
Monte Tabor – Centro Italo - Brazileiro de Promocao (Brazil)
Montreal Children's Hospital (Canada)
Montreal General Hospital (Canada)
MRL Pharmaceutical Services, Inc. (VA)
MRL Reference Laboratory (CA)
Nassau County Medical Center (NY)
National Institutes of Health (MD)
Naval Hospital – Corpus Christi (TX)
Naval Surface Warfare Center (IN)
Nebraska Health System
New Britain General Hospital (CT)
New England Fertility Institute (CT)
New Mexico VA Health Care System
North Carolina State Laboratory of Public Health
North Kansas City Hospital (MO)
North Shore – Long Island Jewish Health System Laboratories (NY)
Northwestern Memorial Hospital (IL)
O.L. Vrouwziekenhuis (Belgium)
Ordre professionnel des technologists médicaux du Québec
Ospedali Riuniti (Italy)
The Ottawa Hospital (Ottawa, ON, Canada)
Our Lady of Lourdes Hospital (NJ)
Our Lady of the Resurrection Medical Center (IL)
Pathology and Cytology Laboratories, Inc. (KY)
The Permanente Medical Group (CA)
Piedmont Hospital (GA)
Pikeville Methodist Hospital (KY)
Pocono Hospital (PA)
Presbyterian Hospital of Dallas (TX)
Queen Elizabeth Hospital (Prince Edward Island, Canada)
Queensland Health Pathology Services (Australia)
Quest Diagnostics Incorporated (CA)
Quintiles Laboratories, Ltd. (GA)
Regions Hospital
Reid Hospital & Health Care Services (IN)
Research Medical Center (MO)
Rex Healthcare (NC)
Rhode Island Department of Health Laboratories
Riyadh Armed Forces Hospital (Saudi Arabia)
Royal Columbian Hospital (New Westminster, BC, Canada)
Sacred Heart Hospital (MD)
Saint Mary's Regional Medical Center (NV)
St. Alexius Medical Center (ND)
St. Anthony Hospital (CO)
St. Anthony's Hospital (FL)
St. Barnabas Medical Center (NJ)
St-Eustache Hospital (Quebec, Canada)
St. Francis Medical Ctr. (CA)
St. John Hospital and Medical Center (MI)
St. John Regional Hospital (St. John, NB, Canada)
St. Joseph Hospital (NE)
St. Joseph's Hospital – Marshfield Clinic (WI)
St. Joseph Mercy Hospital (MI)
St. Jude Children's Research Hospital (TN)
St. Luke's Regional Medical Center (IA)
St. Mary of the Plains Hospital (TX)
St. Mary's Hospital & Medical Center (CO)
St. Paul's Hospital (Vancouver, BC, Montreal)
St. Vincent Medical Center (CA)
Ste. Justine Hospital (Montreal, PQ, Canada)
Salina Regional Health Center (KS)
San Francisco General Hospital (CA)
Santa Clara Valley Medical Center (CA)
Seoul Nat'l University Hospital (Korea)
Shanghai Center for the Clinical Laboratory (China)
South Bend Medical Foundation (IN)
Southwest Texas Methodist Hospital (TX)
South Western Area Pathology Service (Australia)
Southern Maine Medical Center

Specialty Laboratories, Inc. (CA)
Stanford Hospital and Clinics (CA)
State of Washington Department of Health
Stony Brook University Hospital (NY)
Stormont-Vail Regional Medical Center (KS)
Sun Health-Boswell Hospital (AZ)
Sunrise Hospital and Medical Center (NV)
Swedish Medical Center – Providence Campus (WA)
Tampa General Hospital (FL)
Temple University Hospital (PA)
Tenet Odessa Regional Hospital (TX)
The Toledo Hospital (OH)
Touro Infirmary (LA)
Trident Regional Medical Center (SC)
Tripler Army Medical Center (HI)
Truman Medical Center (MO)
UCSF Medical Center (CA)
UNC Hospitals (NC)
University College Hospital (Galway, Ireland)
University Hospital (Gent) (Belgium)
University Hospitals of Cleveland (OH)
The University Hospitals (OK)
University of Alabama-Birmingham Hospital
University of Alberta Hospitals (Canada)
University of Colorado Health Science Center
University of Chicago Hospitals (IL)
University of Illinois Medical Center
University of the Ryukyus (Japan)
University of Texas M.D. Anderson Cancer Center
University of Virginia Medical Center
University of Washington
UZ-KUL Medical Center (Belgium)
VA (Denver) Medical Center (CO)
Virginia Department of Health
VA (Kansas City) Medical Center (MO)
VA (Western NY) Healthcare System
VA (San Diego) Medical Center (CA)
VA (Tuskegee) Medical Center (AL)
VA Outpatient Clinic (OH)
Vejle Hospital (Denmark)
Washington Adventist Hospital (MD)
Washoe Medical Center Laboratory (NV)
West Jefferson Medical Center (LA)
West Shore Medical Center (MI)
Wilford Hall Medical Center (TX)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
Williamsburg Community Hospital (VA)
Winn Army Community Hospital (GA)
Winnipeg Regional Health Authority (Winnipeg, Canada)
Wishard Memorial Hospital (IN)
Yonsei University College of Medicine (Korea)
York Hospital (PA)

Contents

Contents (Continued)

Foreword

When rapid results are required for medical staff members to make therapeutic decisions, and the time required to obtain results from the clinical laboratory would compromise patient care, point-of-care (POC) blood glucose testing is appropriate. Note, however, that this type of testing supplements, rather than substitutes for, testing in the clinical laboratory.

Designing a POC blood glucose testing service requires the close and active collaboration of many departments within the user institution. The primary focus of responsibility for POC blood glucose testing may vary with the specific needs of each institution.

Guidelines for all aspects of a POC blood glucose testing service are presented in this document. The committee believes that a facility must consider all of the recommendations within this document when developing a POC blood glucose testing service. Individual users must demonstrate their ability to operate instruments and perform quality assurance (QA) procedures. Strict adherence to procedures as recommended by the manufacturers must be observed.

Readers of this document are cautioned to monitor changes in laboratory regulations so that POC blood glucose testing procedures can be modified to comply with new requirements.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and are thus more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

Key Words

Authorization, blood glucose, diabetes, operator, point-of-care (POC) testing, training, verification

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1- *A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

QSEs

Documents & Records	Information Management
Organization	Occurrence Management
Personnel	Assessment
Equipment	Process Improvement
Purchasing & Inventory	Service & Satisfaction
Process Control	Facilities & Safety

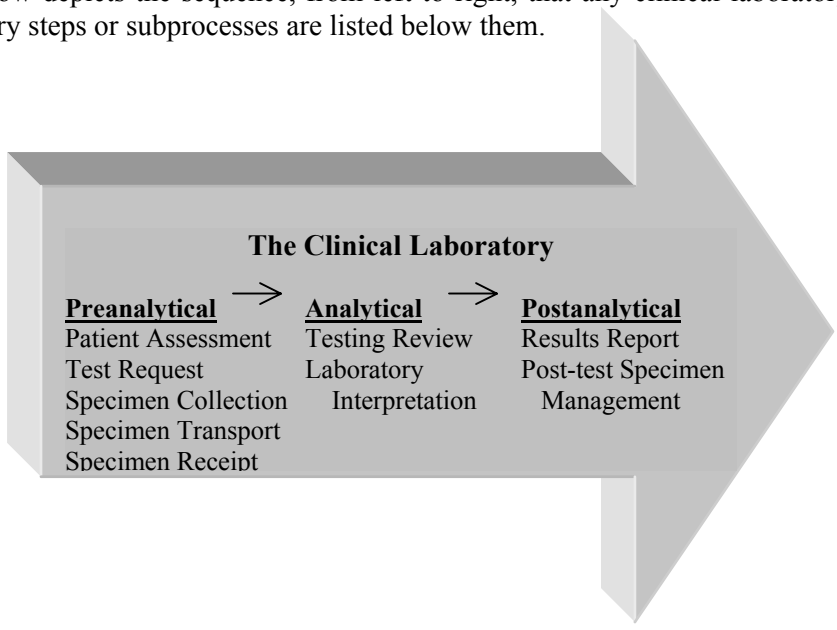
C30-A2 Addresses the Following Quality System Essentials (QSEs)

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
X		X			X						

Adapted from NCCLS document HS1— *A Quality System Model for Health Care*

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow that consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information. The arrow depicts the sequence, from left to right, that any clinical laboratory follows. In addition, the necessary steps or subprocesses are listed below them.



Adapted from NCCLS document HS1—*A Quality System Model for Health Care*

Most of NCCLS's documents relate to the clinical laboratory, so the most common path of workflow will be that depicted above. The path of workflow for other healthcare activities, e.g., respiratory services, imaging services, etc., or for other types of organizations, e.g., medical device manufacturers, will differ from that of the clinical laboratory. All such paths of workflow describe the sequence of activities necessary to produce the organization's or an entity's specific product or services. For those documents that relate to other paths of workflow, the icon will reflect different process steps.

C30-A2 Addresses the Following Steps Within the Clinical Laboratory Path of Workflow

Preanalytical					**Analytical**		**Postanalytical**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpre-tation	Results Report	Post-test Specimen Management
X		X			X		X	

Adapted from NCCLS document HS1—*A Quality System Model for Health Care*

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition

1 Introduction

Point-of-care (POC) blood glucose testing, as performed by trained personnel in acute and chronic care facilities, provides rapid blood glucose results that are used by medical staff members to make therapeutic decisions. In providing this service, the institution assumes a commitment to maintain high-quality POC blood glucose testing and effective methods for communicating the results to appropriate patient-care providers.

There is a need for specific guidelines and policies for POC blood glucose testing due to the unique characteristics of this activity. POC blood glucose testing often requires the coordination and cooperation of multiple departments, training of operators with limited laboratory training, and use of specimens and technologies that differ from those used by laboratories.

1.1 Scope

This guideline provides instructions and recommendations concerning the administration of POC blood glucose monitoring programs at acute and chronic care facilities where laboratory support is available. POC blood glucose monitoring systems provide rapid results required by medical staff members to make therapeutic decisions. For facilities where laboratory support is not available, refer to NCCLS document AST4—*Blood Glucose Testing in Settings Without Laboratory Support.*

This document applies to quantitative *in vitro* POC whole blood glucose monitoring systems intended for use by healthcare professionals for management of patients with diabetes mellitus and other conditions with perturbations in glucose homeostasis. These test systems may be indicated for use with arterial, venous, or capillary whole blood samples obtained from adults, children, or neonates. This guideline does not pertain to glucose measurement for the purpose of screening for diabetes or diagnosing diabetes mellitus or other disorders of glucose metabolism.

Laboratory clinical chemistry analyzers or dedicated systems used to perform routine and stat glucose testing on plasma, serum, whole blood, urine, and cerebrospinal fluid are not included in the scope of this guideline.

2 Definitions[a]

Authorization, *n* - Recognition of a person who has satisfied the qualification requirements to perform POC blood glucose testing within an institution.

Competency, *n* - Following successful completion of a training program, the assessment of a person's ability to perform POC blood glucose testing.

Director, *n* - The person designated as having primary responsibility for the POC blood glucose testing service.

Instrument verification, *n* - A documented procedure for ensuring that POC blood glucose testing instruments are performing according to the manufacturer's established criteria.

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

Logbook, *n* - A document containing information in physical or electronic form.

Operator, *n* - A person who is authorized to perform POC blood glucose testing.

Plasma equivalent, *n* – A glucose result obtained from a whole blood glucose monitoring system that is calibrated to yield a result equivalent to the result obtained on plasma which has been separated from the cellular components and measured on a laboratory analyzer; **NOTE:** At nominal (43%) hematocrit, this value will be approximately 11% higher than the whole blood concentration.[1]

Point-of-care (POC) testing (bedside, near-patient testing), *n* -Testing performed outside a central laboratory environment, generally nearer to, or at the site of, the patient.

Quality assurance (QA), *n* - All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

Quality control (QC; external or interlaboratory), *n* – 1) The operational techniques and activities that are used to fulfill requirements for quality; 2) In healthcare testing, the set of procedures designed to monitor the test method and the results to assure test system performance; **NOTE:** QC includes testing control materials, charting the results and analyzing them to identify sources of error, and evaluating and documenting any remedial action taken as a result of this analysis.

Whole blood equivalent, *n* – A glucose result obtained from a whole blood glucose monitoring system which is calibrated to yield a result equivalent to the result obtained on whole blood measured on a laboratory analyzer.

3 Policy

POC blood glucose testing in acute and chronic care facilities can be performed when the criteria in the following sections are met:

3.1 Administration

At each facility, the focus of primary responsibility for management of the service shall be identified. When establishing a POC blood glucose testing service, all applicable regulations/requirements and institutional accreditation standards shall be met.

3.2 Persons Who Perform the Tests

3.2.1 Within an Institution

All personnel deemed eligible by the institution to perform POC blood glucose testing must demonstrate competency by successfully completing a formal training program (see Section 9.1.1), resulting in an institutional authorization to perform POC glucose testing for a specified period of time.

3.2.2 Patients

Patients in the hospital or chronic care facility who wish to perform their own POC blood glucose testing for the purposes of therapy may be permitted to do so only with the explicit written authorization of the attending physician responsible for the patient's treatment. In so doing, the patient shall remain consistent with the policies of the institution, which has permitted this departure from standard procedures. Official hospital records shall be kept on all patients' blood glucose test results; those results are entered into the record as obtained from tests performed by the patient.

3.3 Methods

The selection of a method for POC blood glucose testing is based on a review of the performance characteristics of the POC blood glucose testing system and institutional needs. For example, if the system is to be used for a particular specimen type, such as neonatal capillary blood, the manufacturer's claims should be checked to ensure that the specimen type is recommended for use and the stated performance characteristics are suitable for use in the institution.

While most POC blood glucose testing systems use whole blood specimens for sampling and performing the tests, manufacturers may calibrate these systems to report either plasma equivalent or whole blood equivalent test results. It is recommended that the POC system chosen be calibrated to match the method in use in the clinical laboratory of the institution. That is, institutions reporting plasma glucose results from instruments in the clinical laboratory should select POC systems that report plasma equivalent results, and institutions reporting whole blood glucose results from instruments in the clinical laboratory should select POC systems that report whole blood equivalent results.

Note that the International Federation of Clinical Chemistry (IFCC) recommends harmonization to the concentration of glucose in plasma.[2]

The performance of the POC method should be demonstrated by comparison with the institution's laboratory blood glucose testing method. Several NCCLS documents provide detailed protocols for method performance evaluations (EP9— *Method Comparison and Bias Estimation Using Patient Samples,* EP10— *Preliminary Evaluation of Quantitative Clinical Laboratory Methods,* and EP15— *User Demonstration of Performance for Precision and Accuracy*).

Section 6 of this document outlines how to demonstrate the performance of POC glucose monitoring systems in comparison with the laboratory testing method.

3.4 Results

Specific policies and procedures shall be developed for recording, documenting, validating, and reporting results. These policies and procedures should include an appropriate reporting procedure for instances when the glucose value is in a specified critical high or low range.

3.5 Quality Assurance (QA)

To ensure reliable performance at all testing sites, a QA program is mandatory.

4 Appropriate Uses of POC Blood Glucose Testing

POC blood glucose testing is a valuable tool for the management of blood glucose concentrations in patients with diabetes and other conditions listed in Section 4.1. Blood glucose concentrations in such patients, especially those with type 1 diabetes mellitus, often fluctuate and frequent adjustments in the patient's insulin dosage may be necessary. It is often impractical in these circumstances to obtain laboratory blood glucose measurements as frequently or as rapidly as is required.

4.1 Applications

Examples of applications of POC blood glucose testing include the following:

- The management of therapy to regulate blood glucose concentrations in patients with diabetes.

- The rapid detection of extreme blood glucose concentrations in patients whose symptoms and/or signs suggest hypoglycemia or severe hyperglycemia.

- The intraoperative and perioperative management of blood glucose concentrations in surgical patients.

- The monitoring (in the immediate postpartum period) of mothers with diabetes, as well as their infants, and the monitoring of other high-risk neonates.

- The rapid identification of extreme blood glucose concentrations in patients who present with a coma of unknown origin, especially in the emergency department.

- The monitoring of patients who receive parenteral hyperalimentation or medication likely to affect their blood glucose concentrations.

- Patient education for diabetes management.

4.2 Limitations

It is important to recognize that, in certain circumstances, there are inherent limitations to each POC blood glucose testing system. For a variety of reasons, most POC blood glucose instruments are less accurate than laboratory instruments. With certain systems, significant errors in POC blood glucose testing results may occur when samples from patients with a very low or very high packed cell volume (PCV; hematocrit) are tested.

In tests done on hypoglycemic patients, the error may be clinically significant. In all cases, users of POC blood glucose testing instrumentation shall be aware of all limitations described by the manufacturer. In areas where the POC method has known limitations or questionable results, for example, results below a certain glucose concentration, the institution shall establish a policy for confirmation of POC results using a laboratory glucose analyzer.

For information on physiological and pathophysiological factors that may affect glucose concentrations in blood specimens, refer to Section 8.2.3.

4.3 Areas of Use

Each institution shall define the areas where POC blood glucose testing instrumentation is to be used (e.g., the nursery, critical care units, medical-surgical units, the postanesthetic recovery room, or in dialysis areas). All areas of use shall be staffed with personnel who are authorized by the institution to perform POC blood glucose testing.

5 Administration

5.1 Designation of Responsibility

Primary responsibility for management of this service shall reside with a director(s) of the POC blood glucose testing service. The director(s) shall be knowledgeable in all aspects of the program (e.g., clinical implications, instrumentation, troubleshooting, administration of the POC blood glucose testing service, QA, blood collection, analysis, and documentation). The director(s) may delegate the responsibility to perform these duties to a limited number of persons whose scope of responsibility is defined.

POC blood glucose testing services in acute and chronic care facilities require a director who is responsible for the following duties:

- Selecting appropriate methodology and instrumentation to perform POC blood glucose testing.
- Designing, implementing, and monitoring the POC blood glucose testing service.
- Developing QA and QC procedures and methods.
- Implementing training programs and authorization for personnel who perform testing.
- Preparing and reviewing a detailed policy/procedure manual.
- Implementing a regular maintenance schedule for equipment.
- Monitoring applicable regulatory requirements and implementing appropriate procedures.

5.2 Coordination of Services

Training, QA, and service/maintenance are specific areas that may require the service director to coordinate with other departments.

Where appropriate, a standing committee may be formed to advise the POC blood glucose testing service on relevant policies and procedures (e.g., training, authorization of personnel, and QA). The committee should include representatives from the medical staff (or healthcare providers) including but not limited to representatives from the areas of the laboratory, nursing, physicians, infection control, QA, institutional administration, and diabetes education.

6 Performance Demonstration of POC Blood Glucose Monitoring System

6.1 Initial Performance Demonstration

Performance criteria (e.g., precision, accuracy, and linearity within assay range) for the selected glucose monitoring system are specified by the manufacturer and should be demonstrated by the institution in the hypoglycemic, euglycemic and hyperglycemic ranges. Documentation of this procedure should be retained for the life of the monitoring system.

Patient specimens, commercially available materials designed to support POC blood glucose testing may be used in the initial assessment of precision, accuracy, linearity, and reportable range, using protocols approved by the evaluating laboratory. Consult NCCLS documents EP9— *Method Comparison and Bias Estimation Using Patient Samples,* EP10— *Preliminary Evaluation of Quantitative Clinical Laboratory Methods,* and EP15— *User Demonstration of Performance for Precision and Accuracy.*

6.2 Demonstration of Performance of Additional Glucose Monitors

When demonstration of performance of the first monitor is complete, subsequent monitors of the same type shall be evaluated. This can be accomplished by an abbreviated procedure, e.g., comparison to an initial monitor using a limited number of controls or patient specimens.

6.3 Comparing Results between the POC Blood Glucose Monitoring System and a Laboratory Instrument

6.3.1 Factors to Consider before Evaluating a POC Glucose Monitoring System

Review the package insert and operating manual of the POC blood glucose monitoring system for information regarding whether plasma equivalent or whole blood equivalent results are reported, the recommended specimen type(s) and specimen handling procedures. This information will influence how the evaluation is planned. Attention to the following considerations is important:

- Proper procedures for collecting blood specimens. See NCCLS documents H3— *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture,* H4— *Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture,* and H11— *Procedures for the Collection of Arterial Blood Specimens.*

- Precautionary measures to avoid interferences in POC glucose monitoring:

  — Avoid sugary contaminants on the patient's fingers by cleansing the site prior to skin puncture.
  — Make sure that the skin is clean and dry before puncture.
  — If alcohol is used for cleansing, make sure the skin is dry before puncture to avoid mixing alcohol with the blood specimen, because this may cause hemolysis or interfere with some POC glucose devices.
  — Avoid edematous areas.
  — DO NOT collect venous specimens from an arm proximal to an active intravenous therapy site
  — If blood is collected from an arterial line, flush the line adequately before blood collection (See Section 8.2.2)

- Glucose metabolism. Glucose metabolism by blood cells usually decreases the glucose concentration of whole blood specimens by approximately 5 to 7% per hour at room temperature.[1,3,4] The rate of glycolysis is increased in specimens with high white blood cell counts (e.g., in patients with leukemia).[5] Collections of specimens into tubes containing fluoride decreases, but does not completely prevent, glycolysis in the specimen.[5,6] Removal of cells from whole blood specimens stabilizes glucose. There is little change in glucose over time in serum or plasma that has been removed from cellular elements, but care shall be taken to avoid changes due to evaporation. Fluoride interferes with some methods; consult manufacturer's directives regarding suitable inhibition of glycolysis.

- Blood oxygenation. Depending on the chemistry of the monitoring system, high or low pO_2 may affect the response of some systems.

- Specimen types (capillary, venous, arterial, line draws)[7,8]

  — Certain specimens are not recommended for use with some monitoring systems.
  — Glucose concentrations may differ among different specimen types collected at the same time from the same individual. For example, capillary glucose concentrations may be up to 20 - 30 mg/dL (1.1 to 1.7 mmol/L) higher than venous concentrations in an individual who has recently ingested food and/or liquids/beverages/drinks.[9,10]

- Effects of hematocrit. Most glucose monitoring systems provide accurate measurements only within a defined hematocrit range, and they are not suitable for serum or plasma samples.[11,12] Results can be affected by the different water contents and viscosities of specimens with high and low hematocrits. Newborn infants represent a special population that often has high hematocrits that may affect glucose measurement. Refer to manufacturer's information regarding the acceptable hematocrit range and expected effects of hematocrit for a specific monitoring system.

- Factors that rapidly change blood glucose concentrations.

  — Within 2 hours after carbohydrate intake or insulin administration.

- Potential interferences with glucose measurement. A number of drugs such as mannitol, acetaminophen, ascorbic acid (vitamin C), and dopamine have been observed to affect glucose results by POC glucose meters.[3,13] Refer to manufacturer's information regarding potential interferences for a specific meter.

Prior to the start of the study, the operators should become familiar with the operation and maintenance of the POC glucose monitoring system. This can be achieved by training from the manufacturer's representative, or at a minimum by reviewing the instructions and practicing with blood specimens and control solutions on the glucose monitoring system.

6.3.2 Experimental Approach

An experimental approach should be employed which assures satisfactory concordance of POC and comparison instrument results, as defined by the director(s) of the POC blood glucose testing service. The experimental approach should be documented.

The following approach is suggested.

6.3.2.1 Blood Samples

Use of certain specimen types and handling procedures should follow the labeling instructions and recommendations made by the manufacturer of the glucose monitoring system.

6.3.2.1.1 Using Fresh Blood Samples with Unaltered Glucose Concentrations

- Collect sufficient volume of the appropriate specimen so that testing with both the POC glucose monitor and the laboratory instrument can be performed on portions of the same specimen.
- Over the course of the evaluation, collect at least 40 specimens that span the entire measurement range of the glucose monitoring system.

6.3.2.1.2 Using Altered Blood Samples

- Use this approach only if it is consistent with the labeling instructions and recommendations by the manufacturer of the glucose monitoring system.
- Follow a glucose supplementing (spiking) procedure provided by the manufacturer of the glucose monitoring system.
- Hypoglycemic samples may be prepared by allowing the anticoagulated blood to undergo glycolysis to reach a low glucose concentration. A procedure recommended by the manufacturer should be followed.
- In general, prepare at least 40 specimens that span the measurement range of the glucose monitoring system, e.g., target glucose concentrations of 25, 50, 80, 150, 250, 400 and 600 mg/dL (1.4, 2.8, 4.4, 8.3, 13.9, 22.2 and 33.3 mmol/L).
- Use this approach only for obtaining sufficient samples with glucose <2.8 mmol/L (<50 mg/dL) or >22.2 mmol/L (>400 mg/dL)

6.3.2.2 Laboratory Instrument

The comparison method should be in stable operation according to manufacturer's and regulatory directives. If desired, a glucose standard reference material or a control material, which is traceable to a standard reference material, can be used to confirm the performance of the laboratory instrument. An example of such a material is Standard Reference Material SRM/RM 965 Glucose in Frozen Human Serum from the National Institute for Science and Technology (http://srmcatalog.nist.gov). The user should verify that the selected reference or control material is commutable with human serum for the laboratory method and thus will provide a valid check on method accuracy traceability. The manufacturer should be contacted for information on suitable commutable reference materials.

QC results of the laboratory instrument during the study should be reviewed for any significant changes.

6.3.2.3 Testing Blood Samples

Each sample should be tested in duplicate by the glucose monitoring system and by the laboratory instrument. Within five minutes of analysis on the POC glucose monitoring system, the blood sample should be tested by the laboratory's whole blood analyzer or centrifuged to separate plasma or serum from the cellular elements. Refer to manufacturer's recommendations for appropriate anticoagulants. The separated plasma or serum should be tested by the laboratory's analyzer within 60 minutes. If small-volume specimens are used in conjunction with the laboratory analyzer, care should be taken to minimize the time of exposure to air, to avoid specimen evaporation and falsely increased glucose concentrations.

6.3.2.4 Comparing the Test Results

For each sample tested, individual results from the POC glucose monitoring system are compared to the mean value from the laboratory analyzer. Duplicate laboratory results should match within 4% or 4 mg/dL (0.22 mmol/L), whichever is greater. If there was a deviation in the protocol (e.g., use or handling of a blood sample contraindicated by the protocol), the affected results should not be included in the comparison.

Ideally, 95% of the individual results from the POC glucose monitoring system should agree within ±15 mg/dL (±0.83 mmol/L) of the laboratory analyzer values at glucose concentrations below 75 mg/dL (4.2 mmol/L) and within ±20% of the laboratory analyzer values at glucose concentrations at or above 75 mg/dL (4.2 mmol/L).[14] However, these performance criteria are influenced by:

- the number of samples analyzed;
- the distribution of samples in the different regions of the measurement range;
- bias of the laboratory analyzer used in the study.

These factors should be considered when reviewing performance of the glucose monitoring system.

7 Quality Assurance Program

It is the responsibility of the POC director to establish a QA program that meets all local, regional, and national regulations/requirements and institutional accreditation standards.

7.1 Quality Assurance Log

A permanent record where QC results and other QA information (e.g., maintenance service record) are maintained shall be kept for each instrument. QC documentation should include the date and time of testing, the instrument recalibration or calibration verification (if indicated by manufacturer's directions), the strip lot number, control lot numbers, the instrument number, the operator's identification, and control results. The QA record should be reviewed by an appropriate individual at a frequency specified by the institution, and that review should be documented accordingly. QC records should be kept for a period of time that is consistent with accreditation, local, and institutional requirements.

In the absence of control ranges being stored in the software of the instrument, the acceptable limits for results obtained from testing control material shall be posted so that users can determine if results are "in control" or "out of control." All results shall be recorded. Any corrective action taken to restore an "out-of-control" situation should be carefully recorded in the log.

7.2 QC

Most POC blood glucose monitors are unit use devices, where the disposable element can be used for only one test. For this type of device, a QC test performed with one disposable element has limited predictive power for the quality of a test performed on a patient sample with another disposable element. For this reason, QC should be performed when a new lot of disposables is received and when atypical results are observed. Please refer to the most current version of NCCLS document EP18—*Quality Management for Unit-Use Testing* for recommendations on frequency of QC Testing. Other reasons for performing QC, such as assessing operator competency and compliance with regulatory requirements, may require more frequent performance of QC.

7.2.1 QC Material

QC material in the form of control solutions may be obtained from the manufacturer, a third party provider, or may be prepared by the laboratory. QC material from a source other than the manufacturer of the glucose monitoring system should be used only if it is consistent with the labeling instructions and recommendations of the manufacturer of the glucose monitoring system. These materials will have an established mean value and allowable limits. The program director should establish the allowable limits by using the manufacturer's recommendations or other criteria established by the institution. Other criteria are based on clinically useful limits or the ranges established by the institution's laboratory, based on replicate assays and calculation of means and standard deviations. It is recommended to run a minimum of two control materials at low and high concentrations appropriate for the patients being tested. The choice of concentrations may be different for different clinical settings. (See the most current version of NCCLS document C24—*Statistical Quality Control for Quantitative Measurements: Principles and Definitions*.)

7.2.2 Frequency of Instrument QC

Instrument QC checks should be performed on a regular basis, and at a minimum, be compliant with manufacturer's recommendations and regulatory requirements. Guidelines should be established to direct the operator to take appropriate action when a QC test result is out of range. If linearity checks are required by governmental or accrediting agencies, refer to the manufacturer's instructions.

7.2.3 Frequency of Operator QC

Because POC blood glucose testing is a technique-dependent procedure, each operator should perform a minimum of one QC test per month. More frequent QC testing is recommended.

7.2.4 Additional QC Checks

Additional QC checks should be performed each time a reagent lot is changed and when batteries are replaced, in order to investigate questionable results, possible instrument damage, or reagent deterioration.

7.3 Maintenance and Service

The manufacturer's recommendations for a regular maintenance schedule should be followed. This plan should be formulated in advance. The instrument-specific QC logbook should have documentation that states when and by whom these procedures are performed.

7.4 Proficiency Testing

It is recommended that the institution participate in a proficiency-testing program that meets accreditation, national, and local requirements.

8 Procedure

8.1 Procedure Manual

Each testing site should have immediate access to a procedure manual that contains the principle of operation, descriptions of reagents/equipment, calibration or calibration verification, QC, a stepwise procedure, the procedure for reporting results, procedure limitations, references, any supplemental material, and documentation that the manual is reviewed and updated on a routine basis. (See the most current version of NCCLS document GP2— *Clinical Laboratory Technical Procedure Manuals*).

8.2 Specimen Collection

8.2.1 Patient Condition

Check the patient for conditions that might affect the interpretation of test results (see Section 8.2.3).

8.2.2 Sample Collection

Whole blood samples should be collected by skin puncture from the heel (infants only), the finger, or from a flushed heparinized line. Arterial blood, other venous blood samples or capillary samples collected from other sites should not be used unless indicated in the manufacturer's instructions or verified by the institution (in conjunction with the laboratory). Operators should observe standard precautions. Specimen collection guidelines appear in NCCLS documents H4— *Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture*, H11—*Procedures for the Collection of Arterial Blood Specimens,* and LA4—*Blood Collection on Filter Paper for Neonatal Screening Programs*. When obtaining specimens from indwelling lines or catheters, refer to NCCLS document H3— *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture*. Volume and placement of the sample should conform to requirements specified by the manufacturer of the test reagent system.

The following are general precautions for the collection of the commonly used types of specimens for POC glucose monitoring:

- Finger Puncture (adults and older children)

  — The recommended puncture site is the palm-side surface of the end of the finger (not the side or the tip of the finger), across the fingerprints and not parallel to them. The middle and ring fingers are preferred. For diagrams, see NCCLS document H4— *Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture*.

  — DO NOT puncture the fingers of newborns. DO NOT use previously punctured, infected or edematous sites.

  — Clean the puncture site using an alcohol swab (70% aqueous isopropanol) and ALLOW THE ALCOHOL TO DRY for proper disinfecting action and to avoid mixing the blood with alcohol, which interferes with some POC tests.

  — It is a good practice to wipe away the first drop of blood with a dry gauze pad.

  - — Obtain a free-flowing drop of blood of adequate volume for the POC glucose test. Blood flow can be enhanced by holding the puncture site downward and gently applying intermittent pressure to the surrounding tissue above the site. Strong repetitive pressure should be avoided.

  - — When using the finger, diabetes specialists recommend using the side of the finger for a puncture site.[15]

- Special Considerations for Heel Puncture (neonates / infants, only)

  - — Warming the site is strongly recommended.

  - — Choose a site on the inside or outside surface of the heel (For illustrations, see the most current version of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture*).

  - — DO NOT use the curvature of the heel, central area of an infant's heel, or the arch of the foot.

  - — Use a device which punctures no deeper than 2.0 mm to avoid puncturing underlying bone.

- Indwelling Lines or Catheters

  - — A line or catheter is a piece of tubing inserted into a patient's vein or artery for administering fluids and medications, monitoring pressures, or obtaining blood samples for diagnostic tests.

  - — Persons who will obtain blood from indwelling cardiovascular (arterial, central venous) or umbilical lines should be properly trained.

  - — Lines are flushed with a solution to reduce the risk of thrombosis. This solution must be cleared from the line before blood specimens are drawn for POC testing. Discarding an amount of blood at least two times the dead-space volume of the line is necessary before collecting blood for a POC or laboratory test.

  - — Do not collect samples from an indwelling line that has a solution containing glucose.

8.2.3 Physiological and Pathophysiological Factors That May Affect Glucose Concentrations in Blood Specimens

The glucose concentration in different blood specimens (e.g., arterial, venous, and capillary blood) can differ significantly due to physiological variables. These differences are not predictable and can be influenced by factors such as metabolic status, fasting or postprandial states, exercise, etc.

When fasting, venous blood glucose concentration is comparable to that of capillary blood. For several hours after ingestion of carbohydrates, glucose concentrations may be substantially lower in venous blood than in capillary blood.

Conditions that reduce peripheral blood circulation may strongly influence capillary blood glucose results. These conditions include severe dehydration, severe hypotension, shock, and hyperglycemic-hyperosmolar state (with or without ketosis).[16,17]

Regardless of the source of blood collection, the glucose concentration in plasma is higher than that in erythrocytes because the water content of plasma exceeds that in erythrocytes. Consequently, plasma glucose concentration is higher than whole blood glucose concentration; the difference varies with the hematocrit of the specimen. At a hematocrit of 43%, the glucose concentration in the plasma is ~11%

higher than that in whole blood.[1] Glucose monitoring systems can be calibrated by the manufacturers to report plasma-equivalent results, which are, on average, 10 to 12% higher than whole blood results.

8.2.4 Special Precautions

When performing POC blood glucose testing, precautions shall be taken to avoid transmitting blood-borne diseases between patients. Lancets and the platforms of spring-loaded lancets shall be discarded after each use, according to manufacturer's instructions. Instruments contaminated by blood shall be disinfected. Procedures should adhere to those that appear in the most current version NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

8.3 Instrument Calibration

Calibration or coding of the instrument to the strip should be performed according to the manufacturer's instructions. These procedures shall be documented in the QC record.

8.4 Test Procedure

8.4.1 Preliminary Steps

Before beginning the test, the operator should complete the following preliminary steps:

(1) Determine that QC testing has been performed and documented; and if not, perform and document QC according to established policies (see Section 7.1).

(2) Check the reagent container to determine the date on which it was opened (when appropriate), the expiration date of the reagent, and check that the reagent has been properly stored (e.g., lid is on container, correct storage temperature).

(3) Verify that the test strip appears to be undamaged; if it is, discard strip.

8.4.2 Test for Blood Glucose

Perform the test for blood glucose according to the manufacturer's directions.

8.5 Results

Record results in the medical record in a manner that clearly distinguishes between those performed at the POC site and those performed in the laboratory, as well as between patient- and staff-generated results. The date and time of testing, and the operator identification should be a part of the result entry.

8.5.1 Critical Values

Critical high- and low-concentration limits should be established by each institution based on patient-care considerations; action policies should be established for values that fall outside these concentrations.

8.5.2 Results Outside Measuring Range

Policies for handling results that fall outside the measurement range of the instrument should be included in the procedure.

9 Institutional Authorization Process

Authorization to perform POC blood glucose testing within the institution should be limited to those persons who have completed a qualification process that includes a training program and demonstration of proficiency. A list of personnel currently authorized to perform POC blood glucose testing should be readily available.

9.1 Training Program

9.1.1 Training

The guidelines listed below are intended to ensure that the training program contains an adequate body of information and follows a standardized format. The training program should be reviewed yearly and updated where appropriate.

A training session(s), preferably including audiovisual material, should contain the following components (with institution-specific modifications where appropriate):

- Instruction on the intended uses of POC blood glucose testing within the institution and the limitations of the test system selected.

- Instruction on critical high and low values, with appropriate follow-up actions.

- Explanation of potential influences on test results, including:

  — Limitations inherent to the method (see Section 4.2);
  — Drugs, metabolites and endogenous substances that may interfere with the glucose monitoring system;
  — Applying insufficient blood for a test;
  — Applying a second drop of blood to the monitoring system before or after the test has started;
  — Samples with high or low hematocrit values;
  — Factors related to sample types and collection procedures described in Section 6.3.1;
  — Physiological factors described in Section 8.2.3.

- Explanation of the differences observed in glucose concentrations between whole blood and serum or plasma.

- Explanation of the policy for the timing of tests, with provisions for emergency testing and flexibility for special medical orders.

- Instruction on, or demonstration of procedures for obtaining adequate blood samples from the finger, the heel (infants), and flushed heparinized lines.

- Instruction on the operation of the specific POC blood glucose testing instrument used at the institution. (Full use of educational material supplied by the manufacturer is encouraged.)

- Instruction on how to document test results in accordance with the institution's recording procedures.

- Infection control instruction that conforms to institutional policies on standard precautions for potential contact with blood and the disposal of blood-contaminated material.

- Procedures for QC of instruments, reagents, and operator proficiency, with actions to be taken in the event of error.

- Procedures for instrument operation, maintenance, and troubleshooting.

- Instruction on the sources of potential error specific to the system or the procedure.

9.1.2 Verification

A written examination should be administered to verify the trainee's knowledge of the educational material outlined in the previous section.

9.2 Demonstration of Operator Competency for POC Blood Glucose Testing

9.2.1 Practice

After completing the training program (see Section 9.1), the trainee should practice collecting and testing samples.

9.2.2 Assessment of Competency

The competency of trainees shall be assessed. Trainees shall demonstrate competency in performing the procedure; evidence of this competency shall be documented. The evaluator should refer to the instrument-specific skill checklist supplied by the manufacturer and modify it as appropriate for the institution. The instructor should assess the competency of the trainee by observing the trainee's performance of all steps of a blood glucose test, including sample collection.

9.2.3 Quality Control Testing Procedure Proficiency

The trainee shall demonstrate the following to the instructor: mastery of QC testing procedures and the documentation of QC results as outlined by the instrument-specific skill checklist.

9.3 Continuing Authorization

Continuing authorization should depend on a satisfactory QC record and demonstration of technical competency as mentioned in Section 9.2.2. Operator authorization should be reviewed periodically for all personnel at an interval determined by the organization. (The recommendation is at least once per year)

If a new testing system is implemented, all the operators should be reauthorized on the new system.

9.4 Withdrawal of POC Blood Glucose Testing Authorization

POC blood glucose testing authorization should be withdrawn by removing operators from the list of authorized personnel if they fail to follow QA or documentation guidelines, or if they perform inaccurate blood glucose tests. Institutions should develop policies and protocols to determine if and how authorization should be reinstated.

References

[1] Sacks DB. Carbohydrates. In: Burtis CA, Ashwood ER, eds. Tietz *Textbook of Clinical Chemistry*, 3rd ed. W.B. Saunders Co. Philadelphia, PA, 1999, pp. 750-808.

[2] Burnett RW, D'Orazio P, Fogh-Andersen N, et al. Scientific Division, Working Group on Selective Electrodes. IFCC recommendation on reporting results for blood glucose. *Clin Chem Acta.* 2001; 307(1-2):205-209.

[3] Kost GJ, Nguyen TH, Tang Z Whole-blood glucose and lactate. Trilayer biosensors, drug interference, metabolism, and practice guidelines. *Arch Pathol Lab Med.* 2000; 124:8,1128-1134.

[4] Ervin K, Azizi K, Chu C, Davis C. The rate of glycolysis in whole blood samples at room temperature (22°C). *Clin Chem.* 1995; (6)44:742.

[5] Field JB, Williams HE. Artifactual hypoglycemia associated with leukemia. *N Engl J Med.* 1961;265:946-948.

[6] Chan AYW, Swaminathan R, Cockram CS. Effectiveness of sodium fluoride as a preservative of glucose in blood. *Clin Chem.* 1989;35:315-317.

[7] Larsson-Conn U. Differences between capillary and venous blood glucose during oral glucose tolerance tests. *Scan J Clin Lab Invest*. 1976;36:805-808.

[8] Kupke IR, Kather B, Zeugner S. On the composition of capillary and venous blood serum. *Clin Chim Acta.* 1981;112:177-185.

[9] Melnic J, Potter JL. Variance in capillary and venous glucose levels during a glucose tolerance test. *Am J Med Tech.* 1982; (6): 543-545.

[10] Kuwa K, Nakayama T, Hoshino T, Tominga M. Relationships of glucose concentrations in capillary whole blood, venous whole blood and venous plasma. *Clin Chim Acta.* 2001;307:187-192.

[11] Tang Z, Lee JH, Louie RF, Kost GJ. Effects of different hematocrit levels on glucose measurements with handheld meters for point-of-care testing. *Arch Pathol Lab Med*. 2000;124:1135-1140.

[12] Gatti RA. Hematocrit values of capillary blood in newborn infants. *J Pediatr.* 1967;70:117.

[13] Tang Z, Du X, Louie RF, Kost GJ. Effects of drugs on glucose measurements with handheld glucose meters and a portable glucose analyzer. *Am J Clin Pathol.* 2000;113:75-86.

[14] International Organization for Standardization (ISO). In vitro diagnostic systems—Requirements for in vitro blood glucose monitoring systems for self-testing in managing diabetes mellitus. ISO/DIS 15197.2. Geneva:2001.

[15] American Diabetes Association. American Diabetes Association Complete Guide to Diabetes. Alexandria, VA: ADA; 1996;409.

[16] Atkin SH, Dasmahapatra A, Jaker MS, Chorost MI, and Reddy S: Fingerstick glucose determination in shock. *Annals of Internal Medicine.*1991;114:1020-1024.

[17] Sylvain HF, Pokorny ME, English SM, et al. Accuracy of fingerstick glucose values in shock patients. *Am J Crit Care.*1995;4:44-48.

NCCLS consensus procedures include an appeals process that is described in detail in Section 9 of the Administrative Procedures. For further information contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Working Group Responses

C30-A: *Ancillary (Bedside) Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline*

Foreword

1. This document waffles on who should be responsible for designing and monitoring a point-of-care blood glucose testing program. It is difficult to envision such a program without the clinical laboratory being the focal point. The statements in the first paragraph of "Foreword" and in Section 3.1 also support the laboratory's role in these programs. However, these statements seem patronizing in comparison to the second paragraph of the Foreword.

- **The Foreword has been revised and the issue of responsibility is addressed in the Introduction and Section 3.1.**

Section 1

2. Add the following bullet: "Monitor and implement changes in Federal (State etc.) laboratory regulations."

- **The bullet has been added; however, Section 1 was revised, and the bulleted list was moved to Section 5.1.**

Section 3.3

3. A reference is needed for this statement, which is surely method- and sample-dependent. What measurement, which instrument, and which method is the first bullet based on? A reference is needed here.

- **This section has been extensively rewritten. Additional information has also been added in Section 6. Pertinent references have been added.**

Section 4

4. Add to the end of the first sentence: "and other conditions as listed in Section 4.2."

- **The revision has been incorporated as suggested.**

Section 4.1

5. The second paragraph is already stated in the Foreword.

- **The sentence has been deleted.**

Section 9.1.1 (Previously Section 6.1.1)

6. Modify the first sentence as follows: "The guidelines listed below are intended to ensure that the training program contains an adequate body of information and follows a standardized format. The training program should be reviewed yearly and updated where appropriate."

- **The revision has been incorporated as suggested.**

7. Modify the twelfth bullet as follows: "… instrument calibration, or calibration verification, maintenance, …"

- **The bullet has been rewritten.**

Section 9.2.2 (Previously Section 6.2.2)

8. Consider the need to recommend a more rigid program.

- **All of Section 9.2 has been revised.**

Section 7.1 (Previously Section 8.1)

9. Add the following to the second sentence: "… recalibration or calibration verification (if indicated …"

- **The section has been rewritten to address the commenter's comment.**

Section 7.2.1 (Previously Section 8.2.1)

10. Since this is specifically for glucose, I would like to see more specific ranges stated for QC to cover, for example, at the clinical decision points for hypoglycemia or hyperglycemia.

- **The section has been revised to include a minimum recommendation.**

11. The quality control material should test certain key ranges of the response: low, normal, high, etc.

- **See the response to Comment 10.**

Section 7.2.3 (Previously Section 8.2.3)

12. This section states that because point-of-care blood glucose testing is a technique-dependent procedure, each operator should perform a minimum of one QC test per week. More frequent QC testing is recommended. We suggest that you reconsider this standard to possibly a quarterly frequency in addition to the required yearly competency check.

- **The minimum recommendation has been changed to one QC test per month.**

Section 8.4.1 (Previously Section 9.4.1)

13. (2): How do you check if the reagent has been properly stored?

- **This statement has been revised.**

Summary of Delegate Comments and Working Group Responses

C30-A2: *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition*

Section 4

1. The reader is directed to Section 4.2 on Limitations and should probably instead be directed to Section 4.1 on Applications.

- **The text has been modified as recommended.**

Section 6.3.2.1.2

2. The following bullet should be added: "Use this approach only for obtaining sufficient samples with glucose<2.8 mmol/L (<50 mg/dL) or >22.2 mmol/L (>400 mg/dL)."

- **A bullet has been added as recommended.**

3. The third bullet should be revised to read: " Hypoglycemic samples may be prepared by allowing the anticoagulated blood to undergo glycolysis to reach a low concentration. A procedure recommended by the manufacturer should be followed."

- **The text has been revised as recommended.**

Section 7.2

4. Section 7.2 needs to be reworded. I take major exception to some statements made in Section 7.2. "For this type of (unit use) device, a single QC test performed with one disposable element has limited predictive power for the quality of a test performed on a patient sample with another disposable element." If this statement is true, it means that the slide-to-slide variation is so great that the results of one sampling cannot be related to another sampling. The statement about doing QC "when any significant changes to the system are detected," needs clarification. How would anyone know when a significant change occurs if analyzing QC has such limited predictive power? What would "atypical" results be? I suppose we should expect loss of them due to the highly variable nature of the slide implied in the above statement. I believe that periodic testing of unit use test devices with QC material establishes that the test units have not been subject to environmental conditions that have affected the test results. This is especially important in point-of-care situations where storage conditions may vary.

- **Section 7.2 has been modified to respond to the commenter's concerns. The remainder of the text is consistent with current guidelines for QC of unit use devices.**

Section 7.2.3

5. Section 7.2.3 states each operator should perform a minimum of one QC test per month. We suggest basing the frequency of running QC on how often operator performs technique.

- **The original recommendation for QC testing has been maintained since monthly frequency is considered an appropriate interval to maintain operator competency.**

Section 8.2.2

6. Add the following sub-bullet: " Diabetes specialists usually recommend using the side of for a puncture site (American Diabetes Association to Diabetes. American Diabetes Association, Alexandria, Page 109).

- **In response to the comment, the text has been modified to read: "When using the finger, diabetes specialists recommend using the side of the finger for a puncture site," and includes the following reference: *American Diabetes Association Complete Guide to Diabetes.* Alexandria, VA: American Diabetes Association. 1996:409.**

Section 8.3

7. Some systems (such as the Accuchek) have, for lack of a better phrase, an electronic chip, with a code, that is designated for particular test strips. It is recommended to add in Section 8.4.1, Preliminary Steps, a statement that if the operator is using one of these systems, the operator should verify that the inserted chip is appropriate for the vial of test strip that will be used for the test. (The code is written on the test strip vial and on the chip, so it is easy to verify.)

- **This point is adequately addressed in the first sentence of Section 8.3.**

Section 9.1.1

8. "See Section 4.1 for limitations to the method" should be changed to "See Section 4.2."

- **The text has been modified as recommended.**

References

9. Reference #14 is a repeat of reference #3.

- **This editorial correction has been made.**

Related NCCLS Publications*

AST4-A **Blood Glucose Testing in Settings Without Laboratory Support; Approved Guideline (1999).** This document provides recommendations for personnel performing blood glucose testing at sites outside the traditional clinical laboratory. The guideline addresses test performance, quality control, personnel training, and administrative responsibility.

EP9-A **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (1995)**. This document addresses procedures for determining the bias between two clinical methods or devices, and for the design of a method comparison experiment using split patient samples and data analysis.

EP10-A **Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline (1998)**. This guideline addresses experimental design and data analysis for preliminary evaluation of the performance of an analytical method or device.

EP18-P **Quality Management for Unit-Use Testing; Proposed Guideline (1999).** This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding and management of sources of error and help to ensure correct results. It is targeted for those involved in the supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of test results.

GP2-A4 **Clinical Laboratory Technical Procedure Manual; Approved Guideline—Fourth Edition (2002)**. This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.

H3-A4 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard— Fourth Edition (1998)**. This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It also includes recommendations on order of draw.

H4-A4 **Procedures for the Collection of Diagnostic Blood Specimens By Skin Puncture; Approved Standard—Fourth Edition (1999).** This document provides a technique for the collection of diagnostic blood specimens by skin puncture, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic blood specimens obtained by skin puncture are also included.

H11-A3 **Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Third Edition (1999).** This standard describes principles for collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen.

LA4-A3 **Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard—Third Edition (1997).** This document provides techniques for specimen collection; specifications for specimen matrix and shipment; and requirements for the specimen collection kit.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

Related NCCLS Publications (Continued)

M29-A2 **Protection of Laboratory Workers from Occupationally Acquired Infectious – Second Edition; Approved Guideline (2001)**. This document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

NRSCL8-A **Terminology and Definitions for Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical laboratory (NRSCL).

NOTES

NOTES

NOTES

NOTES

NOTES

NOTES

NOTES

NCCLS ▼ 940 West Valley Road ▼ Suite 1400 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100
FAX 610.688.0700 ▼ E-MAIL: exoffice@nccls.org ▼ WEBSITE: www.nccls.org ▼ ISBN 1-56238-471-6