

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition

This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis. In addition, a step-by-step outline for collecting, transporting, and storing specimens is included.

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



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.

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition

Abstract

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition (NCCLS document GP16-A2) is written for laboratory and nonlaboratory personnel responsible for the collection, transport, and analysis of urine specimens. The guideline addresses macroscopic evaluation, chemical analysis, and microscopic examination of urine. A step-by-step outline for collecting, transporting, and storing specimens is included. The necessary materials and equipment used in the process are considered.

NCCLS. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. NCCLS document GP16-A2 (ISBN 1-56238-448-1). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

THE NCCLS consensus process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of NCCLS documents. Current editions are listed in the *NCCLS Catalog*, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the *NCCLS Catalog*, contact the NCCLS Executive Offices. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org

GP16-A2
ISBN 1-56238-448-1
ISSN 0273-3099

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition

Volume 21 Number 19

Albert Rabinovitch, M.D., Ph.D.
Stephen J. Sarewitz, M.D.
Sheila M. Woodcock, MLT, ART, MBA
Douglas B. Allinger
Miguel Azar, M.D.
Donald A. Dynek, M.D.
Max Robinowitz, M.D.
Barbara A. Slade, M.D.



This publication is protected by copyright. No part of it may be reproduced, stored in a retrieval system, transmitted, or made available in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without prior written permission from NCCLS, except as stated below.

NCCLS hereby grants permission to reproduce limited portions of this publication for use in laboratory procedure manuals at a single site, for interlibrary loan, or for use in educational programs provided that multiple copies of such reproduction shall include the following notice, be distributed without charge, and, in no event, contain more than 20% of the document's text.

Reproduced with permission, from NCCLS publication GP16-A2—*Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition* (ISBN 1-56238-448-1). Copies of the current edition may be obtained from NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Permission to reproduce or otherwise use the text of this document to an extent that exceeds the exemptions granted here or under the Copyright Law must be obtained from NCCLS by written request. To request such permission, address inquiries to the Executive Director, NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA.

Copyright ©2001. The National Committee for Clinical Laboratory Standards.

Suggested Citation

(NCCLS. *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*. NCCLS document GP16-A2 [ISBN 1-56238-448-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.)

Proposed Guideline

July 1991

Tentative Guideline

December 1992

Approved Guideline

December 1995

Approved Guideline—Second Edition

November 2001

ISBN 1-56238-448-1

ISSN 0273-3099

Committee Membership

Area Committee on General Laboratory Practices

Stephen J. Sarewitz, M.D. Chairholder	Valley Medical Center Renton, Washington
Sheila M. Woodcock, MLT, ART, MBA Vice-Chairholder	QSE Consulting Nova Scotia, Canada
Douglas B. Allinger	Ortho-Clinical Diagnostics, Inc. Rochester, New York
Miguel Azar, M.D.	Dept. of Veterans Affairs Medical Center Minneapolis, Minnesota
Donald A. Dynek, M.D.	Pathology Medical Services, P.C. Lincoln, Nebraska
Albert Rabinovitch, M.D., Ph.D.	Specialty Laboratories Santa Monica, California
Max Robinowitz, M.D.	FDA Ctr. for Devices/Rad. Health Rockville, Maryland
Barbara A. Slade, M.D.	Centers for Disease Control and Prevention Atlanta, Georgia
Advisors	
Kaiser J. Aziz, Ph.D.	FDA Ctr. for Devices/Rad. Health Rockville, Maryland
James D. Barger, M.D.	College of American Pathologists Las Vegas, Nevada
Steven I. Gutman, M.D., MBA	FDA Ctr. for Devices/Rad. Health Rockville, Maryland
Gerald A. Hoeltge, M.D.	The Cleveland Clinic Foundation Cleveland, Ohio
Joan Johns, M.T.(ASCP)	University of Maryland Medical System Baltimore, Maryland
Robert E. Moore, Ph.D., DABCC	Consulting & Research, Inc. Hartford, Connecticut
Jennifer Schiffgens, M.B.A., M.T.(ASCP), CLS	Clinical Laboratory Improvement Consultants Chicago, Illinois
Daniel W. Tholen, M.S.	Statistical Services Traverse City, Michigan

Advisors (Continued)

Marla Thomas	Litton Pathology Associates Blue Springs, Missouri
Eleanor M. Travers, M.D.	Department of Veterans Medical Ctr. Baltimore, Maryland
Beth Ann Wise, M.T.(ASCP), M.S.Ed. <i>Staff Liaison</i>	NCCLS Wayne, Pennsylvania
Patrice E. Polgar <i>Editor</i>	NCCLS Wayne, Pennsylvania
Donna M. Wilhelm <i>Assistant Editor</i>	NCCLS Wayne, Pennsylvania

The Area Committee on General Laboratory Practices would like to recognize the valuable contributions of the members and advisors of the Subcommittee on Urinalysis that developed the first approved edition of this guideline.

Members

Helen M. Free, M.A., D.Sc., Chairholder
Frank Becker, M.T.(ASCP)
Meryl H. Haber, M.D.
Harvey W. Kaufman, M.D.
Jimmie R. Kyle
Barbara Lanphear, M.T.(ASCP)
Carole Mullins, M.T.(ASCP)
Susan Schweitzer, M.T.(ASCP), M.S.

Advisors

Marti K. Bailey, M.T.(ASCP)
John B. Dawson, M.A., F.R.C.P.
Frank DiSalvo
Thomas E. England, Ph.D.
Muriel Jobe, M.T.(ASCP), SH
J.P. Kilbourn, Ph.D.
Jerome S. Nosanchuk, M.D.
G. Berry Schumann, M.D.
Frances Sperl, M.T.
Nelson B. Watts, M.D., F.A.C.P.

Active Membership (as of 1 October 2001)

Sustaining Members

Abbott Laboratories
 American Association for
 Clinical Chemistry
 Bayer Corporation
 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 Society of
 Parasitologists, Inc.
 American Type Culture
 Collection, Inc.
 Asociacion de Laboratorios de Alta
 Complejidad
 Asociación Española Primera de
 Socorros (Uruguay)
 Asociacion Mexicana de
 Bioquímica Clínica 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
 CADIME-Camara De Instituciones
 De Diagnostico Medico

Canadian Society for Medical
 Laboratory Science—Société
 Canadienne de Science de
 Laboratoire Médical
 Canadian Society of Clinical
 Chemists
 Clinical Laboratory Management
 Association
 COLA
 College of American Pathologists
 College of Medical Laboratory
 Technologists of Ontario
 College of Physicians and
 Surgeons of Saskatchewan
 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
 Japan Society of Clinical Chemistry
 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
 Quality Management Program-
 Laboratory Service
 RCPA Quality Assurance Programs
 PTY Limited
 Sociedade Brasileira de Analises
 Clinicas
 Sociedade Brasileira de
 Patologia Clinica
 Sociedad Espanola de Bioquímica
 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 Association of Testing
 Authorities – Australia
 National Center of Infectious
 and Parasitic Diseases (Bulgaria)
 National Institute of Standards
 and Technology
 Ohio 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.
 Agilent Technologies, Inc.
 Ammirati Regulatory Consulting
 Anaerobe Systems
 Assessor
 AstraZeneca
 Aventis
 Avocet Medical, Inc.
 Axis-Shield PoC AS
 Bayer Corporation – Elkhart, IN

Bayer Corporation – Tarrytown, NY	Home Diagnostics, Inc.	Trek Diagnostic Systems, Inc.
Bayer Corporation – West Haven, CT	Immunicon Corporation	Vetoquinol S.A.
Bayer Medical Ltd.	I-STAT Corporation	Visible Genetics, Inc.
BD	International Technidyne Corporation	Vysis, Inc.
BD Biosciences – San Jose, CA	Kendall Sherwood-Davis & Geck	Wallac Oy
BD Consumer Products	LAB-Interlink, Inc.	Wyeth-Ayerst
BD Diagnostic Systems	Labtest Diagnostica S.A.	Xyletech Systems, Inc.
BD Italia S.P.A.	LifeScan, Inc. (a Johnson & Johnson Company)	YD Consultant
BD VACUTAINER Systems	Lilly Research Laboratories	YD Diagnostics (Seoul, Korea)
Beckman Coulter, Inc.	Medical Device Consultants, Inc.	
Beckman Coulter, Inc. Primary Care Diagnostics	Medtronic, Inc.	Trade Associations
Beckman Coulter K.K. (Japan)	Merck & Company, Inc.	AdvaMed
Bio-Development SRL	mvi Sciences (MA)	Association of Medical Diagnostic Manufacturers
Bio-Inova Life Sciences International	Nabi	Japan Association Clinical Reagents Ind. (Tokyo, Japan)
Bio-Inova Life Sciences North America	Neometrics is.	Medical Industry Association of Australia
BioMedia Laboratories Sdn Bhd	Nichols Institute Diagnostics (Div. of Quest Diagnostics, Inc.)	
bioMérieux, Inc.	Nissui Pharmaceutical Co., Ltd.	Associate Active Members
Biometrology Consultants	Nippon Becton Dickinson Co., Ltd.	20 th Medical Group (SC)
Bio-Rad Laboratories, Inc.	Norfolk Associates, Inc.	67 th CSH Wuerzburg, GE (NY)
Bio-Rad Laboratories, Inc. - France	Organon Teknika Corporation	Academisch Ziekenhuis-VUB (Belgium)
Biotest AG	Ortho-Clinical Diagnostics, Inc. (Raritan, NJ)	Acadiana Medical Laboratories, LTD (LA)
Bristol-Myers Squibb Company	Ortho-Clinical Diagnostics, Inc. (Rochester, NY)	Adena Regional Medical Center (OH)
Canadian External Quality Assessment Laboratory	Oxoid Inc.	Advocate Laboratories (IL)
Capital Management Consulting, Inc.	Pfizer Inc	The Aga Khan Hospital & Medical College, Karachi (Pakistan)
Checkpoint Development Inc.	Pharmacia Corporation	Akershus Central Hospital and AFA (Norway)
Clinical Design Group Inc.	Powers Consulting Services	Albany Medical Center Hospital (NY)
Clinical Laboratory Improvement Consultants	Premier Inc.	Albemarle Hospital (NC)
COBE Laboratories, Inc.	Procter & Gamble Pharmaceuticals, Inc.	Allegheny General Hospital (PA)
Community Medical Center (NJ)	The Product Development Group	Allegheny University of the Health Sciences (PA)
Control Lab (Brazil)	Quintiles, Inc.	Allina Laboratories (MN)
Copan Diagnostics Inc.	Radiometer America, Inc.	Alton Ochsner Medical Foundation (LA)
Cosmetic Ingredient Review	Radiometer Medical A/S	American Medical Laboratories (VA)
Cubist Pharmaceuticals	David G. Rhoads Associates, Inc.	Arkansas Department of Health
Cytometrics, Inc.	Roche Diagnostics GmbH	ARUP Laboratories (UT)
Dade Behring Inc. - Deerfield, IL	Roche Diagnostics, Inc.	ARUP at University Hospital (UT)
Dade Behring Inc. - Glasgow, DE	Roche Laboratories (Div. Hoffmann-La Roche Inc.)	Armed Forces Research Institute of Medical Science (APO, AP)
Dade Behring Inc. - Marburg, Germany	The R.W. Johnson Pharmaceutical Research Institute	Aurora Consolidated Laboratories (WI)
Dade Behring Inc. - Sacramento, CA	Sarstedt, Inc.	Azienda Ospedale Di Lecco (Italy)
Dade Behring Inc. - San Jose, CA	Carl Schaper	Bay Medical Center (MI)
DAKO A/S	Schering Corporation	Baystate Medical Center (MA)
Diagnostic Products Corporation	Schleicher & Schuell, Inc.	
Eiken Chemical Company, Ltd.	Second Opinion	
Enterprise Analysis Corporation	Showa Yakuhin Kako Company, Ltd.	
Fort Dodge Animal Health	Streck Laboratories, Inc.	
General Hospital Vienna (Austria)	SurroMed, Inc.	
Gen-Probe	Sysmex Corporation (Japan)	
GlaxoSmithKline	Sysmex Corporation (Long Grove, IL)	
Greiner Bio-One Inc.	The Toledo Hospital (OH)	
Health Systems Concepts, Inc.		
Helena Laboratories		

Bbguas Duzen Laboratories (Turkey)
 Bo Ali Hospital (Iran)
 Bonnyville Health Center (Alberta, Canada)
 British Columbia Cancer Agency (Vancouver, BC, Canada)
 Broward General Medical Center (FL)
 Calgary Laboratory Services
 Carilion Consolidated Laboratory (VA)
 Carolinas Medical Center (NC)
 Cathay General Hospital (Taiwan)
 CB Healthcare Complex (Sydney, NS, Canada)
 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)
 Children's Hospital (LA)
 Children's Hospital (NE)
 Children's Hospital & Clinics (MN)
 Children's Hospital King's Daughters (VA)
 Children's Hospital Medical Center (Akron, OH)
 Children's Hospital of Philadelphia (PA)
 Clarian Health–Methodist Hospital (IN)
 Clendo Lab (Puerto Rico)
 CLSI Laboratories (PA)
 Commonwealth of Kentucky
 CompuNet Clinical Laboratories (OH)
 Covance Central Laboratory Services (IN)
 Danville Regional Medical Center (VA)
 DeKalb Medical Center (GA)
 Delaware Public Health Laboratory
 Department of Health & Community Services (New Brunswick, Canada)
 DesPeres Hospital (MO)
 Detroit Health Department (MI)
 Diagnostic Laboratory Services, Inc. (HI)
 Duke University Medical Center (NC)
 Durham Regional Hospital (NC)
 Dynacare Laboratories - Eastern Region (Ottawa, ON, Canada)
 Dynacare Memorial Hermann Laboratory Services (TX)
 E.A. Conway Medical Center (LA)
 Eastern Maine Medical Center
 East Side Clinical Laboratory (RI)
 Elyria Memorial Hospital (OH)
 Emory University Hospital (GA)
 Esoterix Center for Infectious Disease (TX)
 Fairfax Hospital (VA)
 Fairview-University 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)
 Franklin Square Hospital Center (MD)
 Fresenius Medical Care/Spectra East (NJ)
 Fresno Community Hospital and Medical Center
 Frye Regional Medical Center (NC)
 Gambro Healthcare Laboratory Services (FL)
 GDS Technology, Inc (IN)
 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)
 Health Sciences Centre (Winnipeg, MB, Canada)
 Heartland Health System (MO)
 Highlands Regional Medical Center (FL)
 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)
 Hospital Sousa Martins (Portugal)
 Hotel Dieu Hospital (Windsor, ON, Canada)
 Huddinge University Hospital (Sweden)
 Hurley Medical Center (MI)
 Indiana State Board of Health
 Indiana University
 Instituto Scientifico HS. Raffaele (Italy)
 International Health Management Associates, Inc. (IL)
 Jackson Memorial Hospital (FL)
 Jersey Shore Medical Center (NJ)
 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)
 Kenora-Rainy River Regional Laboratory Program (Ontario, Canada)
 Kern Medical Center (CA)
 Kimball Medical Center (NJ)
 King Fahad National Guard Hospital (Saudi Arabia)
 King Faisal Specialist Hospital (Saudi Arabia)
 King Khalid National Guard Hospital (Saudi Arabia)
 Kings County Hospital Center (NY)
 King's Daughters Medical Center (KY)
 Klinični Center (Slovenia)
 LabCorp (NC)
 Laboratories at Bonfils (CO)
 Laboratoire de Santé Publique du Quebec (Canada)
 Laboratório Fleury S/C Ltda. (Brazil)
 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)
 Lewis-Gale Medical Center (VA)
 Libero Instituto Univ. Campus BioMedico (Italy)
 Long Beach Memorial Medical Center (CA)
 Louisiana State University Medical Center
 Maccabi Medical Care and Health Fund (Israel)

Magee Womens Hospital (PA)
 Magnolia Regional Health Center (MS)
 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
 Mescalero Indian Hospital (NM)
 Methodist Hospitals of Memphis (TN)
 MetroHealth Medical Center (OH)
 Michigan Department of Community Health
 Monmouth Medical Center (NJ)
 Monte Tabor – Centro Italo - Brasileiro de Promocao (Brazil)
 Montreal Children’s Hospital (Canada)
 Montreal General Hospital (Canada)
 Morton Plant Mease Health Care (FL)
 MRL Pharmaceutical Services, Inc. (VA)
 MRL Reference Laboratory (CA)
 National Institutes of Health (MD)
 National University Hospital (Singapore)
 Naval Surface Warfare Center (IN)
 Nebraska Health System
 New Britain General Hospital (CT)
 New England Fertility Institute (CT)
 New England Medical Center Hospital (MA)
 New York Hospital Medical Center of Queens
 New York State Department of Health
 NorDx (ME)
 North Carolina State Laboratory of Public Health
 Northern Indiana Education Foundation
 North Kansas City Hospital (MO)
 North Mississippi Medical Center
 North Shore – Long Island Jewish Health System Laboratories (NY)
 Northridge Hospital Medical Center (CA)
 Northwestern Memorial Hospital (IL)
 Ohio Valley Medical Center (WV)
 O.L. Vrouwziekenhuis (Belgium)
 Ordre professionnel des technologistes 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)
 Pocono Hospital (PA)
 Polly Ryon Memorial Hospital (TX)
 Presbyterian Hospital of Dallas (TX)
 Prodia Clinical Laboratory (Indonesia)
 Providence Health System (OR)
 Providence Seattle Medical Center (WA)
 Queen Elizabeth Hospital (Prince Edward Island, Canada)
 Queensland Health Pathology Services (Australia)
 Quest Diagnostics Incorporated (CA)
 Quintiles Laboratories, Ltd. (GA)
 Reading Hospital and Medical Center (PA)
 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. Barnabas Medical Center (NJ)
 St. Boniface General Hospital (Winnipeg, Canada)
 St. Elizabeth Hospital (NJ)
 St-Eustache Hospital (Quebec, Canada)
 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’s Medical Center (CA)
 St. Luke’s Regional Medical Center (IA)
 St. Mark’s Hospital (UT)
 St. Mary Medical Center (IN)
 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 Cabrini Hospital (Montreal, PQ Canada)
 Santa Clara Valley Medical Center (CA)
 Seoul Nat’l University Hospital (Korea)
 Shanghai Center for the Clinical Laboratory (China)
 South Bend Medical Foundation (IN)
 Southern California Permanente Medical Group
 South Western Area Pathology Service (Australia)
 Southwest Texas Methodist Hospital
 Speciality Laboratories, Inc. (CA)
 Stanford Hospital and Clinics (CA)
 State of Washington Department of Health
 Stormont-Vail Regional Medical Center (KS)
 Sun Health-Boswell Hospital (AZ)
 Sunrise Hospital and Medical Center (NV)
 T.A. Sourasky Medical Center (Israel)
 Tampa General Hospital (FL)
 Temple University Hospital (PA)

Tenet Odessa Regional Hospital (TX)	University of Colorado Health Science Center	VA Outpatient Clinic (OH)
The Toledo Hospital (OH)	University of Chicago Hospitals (IL)	Vejele Hospital (Denmark)
Touro Infirmary (LA)	University of Florida	Viridae Clinical Sciences, Inc. (Vancouver, BC, Canada)
Trident Regional Medical Center (SC)	University of Illinois at Chicago	Washoe Medical Center Laboratory (NV)
Tripler Army Medical Center (HI)	University of the Ryukyus (Japan)	Watson Clinic (FL)
Truman Medical Center (MO)	University of Texas M.D. Anderson Cancer Center	Wilford Hall Medical Center (TX)
UCSF Medical Center (CA)	University of Virginia Medical Center	William Beaumont Hospital (MI)
UNC Hospitals (NC)	University of Washington	Williamsburg Community Hospital (VA)
University Hospital (Gent) (Belgium)	UPMC Bedford Memorial (PA)	Winn Army Community Hospital (GA)
University Hospitals of Cleveland (OH)	UZ-KUL Medical Center (Belgium)	Wishard Memorial Hospital (IN)
The University Hospitals (OK)	VA (Dayton) Medical Center (OH)	Yonsei University College of Medicine (Korea)
University of Alabama-Birmingham Hospital	VA (Denver) Medical Center (CO)	York Hospital (PA)
University of Alberta Hospitals (Canada)	VA (San Diego) Medical Center (CA)	Zale Lipshy University Hospital (TX)
	VA (Tuskegee) Medical Center (AL)	

OFFICERS

F. Alan Andersen, Ph.D.,
President
Cosmetic Ingredient Review

Donna M. Meyer, Ph.D.,
President Elect
CHRISTUS Health

Emil Voelkert, Ph.D.
Secretary
Roche Diagnostics GmbH

Gerald A. Hoeltge, M.D.
Treasurer
The Cleveland Clinic Foundation

William F. Koch, Ph.D.,
Immediate Past President
National Institute of Standards
and Technology

John V. Bergen, Ph.D.,
Executive Director

Susan Blonshine, RRT, RPFT,
FAARC
TechEd

Wayne Brinster
BD

Kurt H. Davis, FCSMLS, CAE
Canadian Society for Medical
Laboratory Science

Robert L. Habig, Ph.D.
Molecular Diagnostics, Inc.

Thomas L. Hearn, Ph.D.
Centers for Disease Control and
Prevention

Carolyn D. Jones, J.D., M.P.H.
AdvaMed

BOARD OF DIRECTORS

Tadashi Kawai, M.D., Ph.D.
International Clinical Pathology
Center

J. Stephen Kroger, M.D., FACP
COLA

Gary L. Myers, Ph.D.
Centers for Disease Control and
Prevention

Barbara G. Painter, Ph.D.
Bayer Corporation

Ann M. Willey, Ph.D., J.D.
New York State Department of
Health

Judith A. Yost, M.A., M.T.(ASCP)
Centers for Medicare & Medicaid
Services

Contents

Abstract	i
Committee Membership.....	v
Active Membership	vii
Foreword	xv
1 Introduction	1
1.1 Scope.....	1
1.2 Standard Precautions.....	2
1.3 Definitions	2
2 Materials and Equipment	2
2.1 Materials	2
2.2 Equipment.....	4
2.3 Quality Control (QC).....	6
3 Macroscopic/Physical Urinalysis	6
3.1 Specimen Identification	6
3.2 Specimen Acceptability	7
3.3 Color, Clarity, and Odor	7
3.4 Urine Concentration (Specific Gravity).....	7
4 Chemical Urinalysis	9
4.1 Precautions for Reagent Strip Use	9
4.2 Use of Reagent Strips.....	9
4.3 Confirmatory Tests	10
5 Microscopic Examination of Urine	10
5.1 Types of Microscopic Examinations.....	10
5.2 Microscopic Examination	11
5.3 Identification of Microscopic Entities.....	13
5.4 Quality Assurance of the Microscopic Examination	14
6 Automated Urinalysis.....	14
7 Quality Assurance	15
7.1 Introduction and Purpose	15
7.2 Recordkeeping	15
7.3 Procedure Manual	15
7.4 Materials and Equipment	16
7.5 Proficiency Testing (External Quality Assessment)	16
7.6 Continuing Education and Training.....	16
8 Collection and Transportation of Single-Collection Urine Specimens	17
8.1 Overview.....	17
8.2 Types of Urine Specimens	17
8.3 Instructing the Patient	18
8.4 Collecting the Specimen	18
8.5 Collecting Urine Specimens from Infants and Small Children.....	20

Contents (Continued)

8.6 Collection Containers..... 21

8.7 Transporting and Storing Specimens 22

8.8 Acceptability of Specimens and Quality Assurance 23

9 Collection and Preservation of 24-Hour Urine Specimens 23

9.1 Collecting 24-Hour Urine Specimens 24

9.2 Summary of 24-Hour Urine Preservatives..... 24

References 28

Additional References 30

Summary of Comments and Committee Responses 31

Summary of Delegate Comments and Responses 35

Related NCCLS Publications 36

Foreword

Important clinical information may be obtained from laboratory analysis of urine specimens. Much progress has been made since ancient times, when urine was poured on the ground and the attraction of insects to it indicated an abnormal specimen. Physical and chemical analysis of urine and microscopic examination of sediment, often performed today with sophisticated instrumentation, are as useful in physicians' office laboratories as they are in large clinical laboratories.

Urinalysis is an integral part of clinical laboratory testing. Its usefulness is proven in diagnosis of disease (diseases of the kidney, urinary tract, and liver, as well as metabolic disorders such as diabetes), in monitoring the effectiveness of treatment of chronic problems, and in screening for asymptomatic conditions (which is also called "wellness monitoring"). The value of negative/normal results should not be underestimated.

Specimen collection, transportation, and storage are equally as important as urinalysis. Acceptable specimens improve the quality and reliability of urinalysis results. The committee believes that GP16-A2 is a practical guideline that is useful for all parties, laboratorians and nonlaboratorians alike, who are responsible for carrying out the procedure. This is related information that may benefit a variety of institutions using this document.

The committee believes that GP16-A2 will serve as a common reference point and facilitate communication between the site where the specimen is collected and the laboratory where the analysis is performed. By providing a clear picture of how specific actions can affect the test result or how one can give better instruction in specimen collection, the overall testing process will be improved.

Key Words

Brightfield microscopy, chemical preservatives, flow microscopy, formed elements, harmonic oscillation, microscopic results, multiconstituent controls, pathologic conditions, physicochemical results, reagent strips, refractometer, sediment, slide microscopy, urinalysis

Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition

1 Introduction

Urinalysis is the testing of urine with procedures commonly performed in an expeditious, reliable, accurate, safe, and cost-effective manner.

For the purposes of this guideline, the term “urinalysis” includes some or all of the following:

- macroscopic evaluation (e.g., color and clarity);
- physical measurements (e.g., volume and specific gravity);
- chemical reagent strip or tablet testing; and
- microscopic examination.

Each laboratory, in consultation with its clinicians, should determine which procedures to use and the extent of the examination. These determinations should be based on an evaluation of known and published studies, as well as the type of patient population (e.g., asymptomatic patient population screening yields few positive results, whereas in-hospital nephrology patients have a higher yield). The decision to perform microscopic examinations should be made by each individual laboratory based on its specific patient population.¹⁻⁹

Urinalysis is performed for a variety of reasons, including:

- to aid in the diagnosis of disease;
- to screen a population for asymptomatic, congenital, or hereditary diseases (i.e., to monitor wellness);
- to monitor the progress of disease;
- to monitor the effectiveness or complications of therapy; and
- to screen asymptomatic industrial workers for acquired diseases.

Information on testing for drugs of abuse can be found in NCCLS document T/DM8—*Urine Drug Testing in the Clinical Laboratory*.

1.1 Scope

This document is written for laboratory and nonlaboratory personnel responsible for the collection, transport, and analysis of urine specimens. The guideline addresses macroscopic evaluation, chemical analysis, and microscopic examination of urine. A step-by-step outline for collecting, transporting, and storing specimens is included. The necessary materials and equipment used in the process are considered.

The focus of this guideline relates to urine collection and performance of the traditional, routine chemical and microscopic urinalysis. Algorithmic approaches to evaluation of urine samples with respect to

potential screening by dipstick with subsequent performance (or nonperformance) of culture, is beyond the scope of this guideline.

1.2 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 thus are 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 recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*.

1.3 Definitions^a

Catheter, *n* – A hollow tube of rubber or plastic, passed through the urethra for the purpose of collecting urine directly from the urinary bladder.

Centrifugation tube, *n* – A glass or plastic tube in which urine is centrifuged for the purpose of preparing sediment for microscopic evaluation; **NOTE:** Supernatant may also be tested when formed elements interfere with some chemical assays.

Reagent strip, *n* – A plastic strip to which is affixed various reaction pads for the qualitative or semiquantitative assay of specific chemical constituents (e.g., glucose, protein) or physical parameters (e.g., pH, specific gravity); **NOTE:** Following exposure to urine, these reaction pads are interpreted visually or evaluated with a reagent strip reader instrument.

Sediment, *n* – The formed elements of urine that are concentrated by centrifugation or detectable with flow-through cytometers in a whole urine sample; **NOTE:** Elements include cells (leukocytes, renal tubular, etc.), casts (hyaline, waxy, etc.), crystals (triple phosphate, cystine, etc.), microorganisms (bacteria, yeast, etc.), and others.

2 Materials and Equipment

2.1 Materials

Containers, tubes, and slides should be labeled in a way that ensures proper patient identification. All materials used to perform a urinalysis should be particle-free.

2.1.1 Collection Devices

Description of proper containers for urine collection and transportation, as well as other related information, appears in Section 8.6.

^a Some of these definitions are found in NCCLS document NRSL8—*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.

2.1.2 Centrifugation Tubes

A proper tube for urine centrifugation has the following features:

- clear plastic or glass to permit macroscopic examination of urine and enough strength to avoid breakage during centrifugation;
- volume gradations to ensure a standardized volume of urine;
- closures to reduce hazards from spillage and centrifuge aerosols;
- a conical or constricted bottom to concentrate sediment if manual microscopy will be performed;
- freedom from interfering chemicals; and
- a label to ensure proper identification.

NOTE: *Reuse of centrifugation tubes is not recommended.*

2.1.3 Transfer Pipets

Disposable transfer pipets are recommended to reduce the biohazards associated with resuspending and transferring the sediment; their reuse is not recommended. Transfer pipets should be clean and particle-free.

2.1.4 Microscope Slides/Viewing Devices

Commercially available, disposable, standardized microscope slides or viewing devices with calibrated chambers are preferred. The use of plain glass microscope slides and cover slips is not encouraged, because they do not yield standardized, reproducible results.¹⁰ While plastic slides with integral chambers are preferred from a “sharps” safety perspective, they may not be amenable to polarization microscopy.

NOTE: *Reuse of slides is not recommended.*

2.1.5 Reagent Test Strips (Dipsticks)

Reagent strips consisting of a plastic support that have one or more chemical test sites are available in many configurations. These sites are also known as “dry reagent chemistry reaction sites.”

Despite the absence of noticeable deterioration of the reagent or test strip, regulatory requirements (e.g., in the U.S., federal regulations) may dictate that reagents not be used after their expiration date. Certain storage precautions can be required to maintain reactivity of the agents. To obtain good test results, it is necessary to do the following:

- (1) Store reagent strips in their original containers according to the manufacturer’s recommendations. Exposure to direct light and room humidity can affect the reagent strips and produce erroneous results.
- (2) Keep the containers tightly closed and stored at manufacturer-recommended temperatures.
- (3) Remove only a few reagent strips at a time, and immediately close the container tightly; unused strips should not be returned to the container.

(4) Avoid combining reagent strips from different containers.

(5) Avoid touching chemical test sites on the reagent strips.

NOTE: Reagent tablets are available for measurement of reducing substances, bilirubin, and ketone bodies (e.g., acetone, acetoacetic acid). They should be handled according to manufacturers' instructions.

2.1.6 Preservatives^{11,12} and Specimen Storage

In general, chemical preservatives should be avoided for urinalysis. Urinalysis should be performed within two hours of collection. If testing is delayed, refrigeration is adequate for some chemical components (exceptions are bilirubin and urobilinogen), but it can precipitate amorphous urates or phosphates, which obscure the microscopic field. If the urine is also to be cultured, it should be refrigerated during transit and held refrigerated until cultured. For multiple analyses, aliquots of the well-mixed urine may be treated differently, depending on use. There is no agreed-upon length of time for refrigeration as a preservative, because this depends on the individual urine constituents. (For more detailed information on use of preservatives for timed urine specimens, see Section 9.) For compounds that are photosensitive (e.g., bilirubin), it may be necessary to protect the specimen from light.

If commercially available “urine preservation” systems are used, they should first be evaluated by the laboratory. Such systems, while perhaps useful for some analytes, may have limitations for specific urine tests.

2.1.7 Urinalysis Requisition Form

Requisition forms and computerized entry systems should be designed to indicate the type of urine specimen to be collected, as well as the date and time that collection is required.

The design should include space for recording the following information:

- the actual date and time of specimen collection;
- specialized collection circumstances (e.g., catheter, clean catch, first-morning specimen);
- whether the specimen was refrigerated before transporting;
- the time the specimen was received in the laboratory and the time the analysis was performed; and
- the tests requested.

The form should also include an area for noting any specific situations that might influence the results of the analysis (e.g., preservatives for specimens that should be shipped; medications, such as aspirin, vitamins, or antibiotics; likely presence of menstrual blood; strenuous exercise before specimen collection; and any pertinent clinical information). Refer to Section 3.1 for additional patient information related to specimen identification.

2.2 Equipment

2.2.1 Microscopes

A modern, high-quality brightfield microscope with the following characteristics should be used in the urinalysis laboratory:

- a binocular head to allow the use of both eyes when viewing the slide;
- a built-in light source;
- a mechanical stage to allow the easy and smooth positioning of the slide;
- a basic set of objectives (e.g., 10x and 40x) and an ocular (e.g., 10x or 12.5x);
- the same objectives and field size of ocular if more than one microscope is used; and
- polarizing filters for examination of crystals and foreign bodies.

2.2.2 Reagent Strip Readers

Dry reagent chemistry results can be determined by visually matching the reacted reagent strip to a block-chart of various colors or intensities. However, instruments have been designed to objectively measure the intensity of these reactions and eliminate the variances from reaction-timing and color interpretation. These instruments are reflectance photometers and measure light reflected from a test pad surface.

Many of the quality assurance requirements have been integrated into the system by the manufacturer (e.g., timing, calibration, and error codes). When using these instruments, it is important to do the following:

- (1) Read and follow the directions in the operating manual.
- (2) Establish and follow a maintenance schedule.
- (3) Keep the instrument clean and make sure to wipe up all spills immediately, while following standard precautions. (See NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue.*) This will also help to avoid sample cross-contamination.

2.2.2.1 Calibration of Readers

The recommended protocol in the manufacturer's instrument manual should be followed.

2.2.2.2 Maintenance of Readers

Cleaning of the optics and mechanical parts ensures optimal operation. Consult the instrument manual of the readers and follow the manufacturer's recommended procedures.

2.2.3 Specific Gravity Devices

Refractometers evaluate the specific gravity of a solution by measuring the total dissolved solids in a liquid as indicated by the refractive index of the solution. (Refer to Section 3.4 for detailed information.)

2.2.4 Centrifuges

2.2.4.1 Characteristics

A centrifuge for urine sedimentation with the following characteristics should be used:

- self-locking lid when rotor is spinning; and

- ambient temperature (15 to 25 °C).

2.2.4.2 Calibration and Maintenance

Calibrate the centrifuge to provide a relative centrifugal force (RCF) of 400. Consult the manufacturer's instrument manual for the recommended protocol. Calibration should be performed at periodic intervals determined by the laboratory, depending on its use.

2.3 Quality Control (QC)

Adhere to all regulations applicable to the practice region, as well as manufacturers' instructions.

2.3.1 Chemical Urinalysis

Positive and negative multiconstituent controls to validate the performance of *each* chemical test are recommended. Positive controls should be designed to yield weakly positive results, so that control material will be sensitive to early deterioration of the test system. Controls should be tested at a frequency defined by the laboratory, related to workload. For example, a laboratory consuming one container of dipsticks over a month may choose to perform weekly QC, while a laboratory using several containers of dipsticks per day may perform one set of QC specimens per container.

Generally, commercial controls are used for this application. Alternatively, individual previously tested urines can be divided into aliquots and analyzed on each shift as a precision check by comparison of retest results with the original results.

Values obtained for the control materials should fall within the limits established by the laboratory.

Participation in an external urinalysis quality assessment (proficiency) survey to evaluate the performance of the chemical urinalysis is recommended.

2.3.2 Microscopic Urinalysis

Commercial control products may not be available for all sediment elements. Replicate testing of fresh patient specimens can establish the reproducibility of microscopic analysis, both within a laboratory and between laboratories. For any detected element, the result should agree within \pm one reporting range.

If there is disagreement about the presence or quantity of a microscopic element, the examination should be repeated. If necessary, an experienced supervisor or qualified laboratory director should resolve any discrepancy. Each laboratory should establish criteria for reviewing abnormal sediment results.

It is also recommended that reference texts, atlases, charts, and posters be available.¹³⁻²⁰ A repository of photomicrographs from peer/referee proficiency testing programs (e.g., College of American Pathologists) is a useful resource.

3 Macroscopic/Physical Urinalysis

3.1 Specimen Identification

Information supplied on the urinalysis requisition/reporting form should include the following: patient name; age or date of birth; sex; patient location (inpatient or outpatient); identification number; type of specimen (e.g., catheter, midstream, clean catch, or other); requesting physician; initials of the person filling out the requisition form; diagnosis or major symptoms; potential interfering prescription and

nonprescription medications, including dietary supplements (e.g., vitamin C); date and time of collection; and time received in the laboratory. (See Section 8.6.6 for further patient information.)

3.2 Specimen Acceptability

Because the accuracy of a urinalysis is dependent on the quality of the specimen submitted, care should be taken to submit a properly collected and transported urine specimen. (See Section 8.)

Although random specimens may be used for chemical analysis using test strips, the preferred urine specimen, particularly for microscopy, is a well-mixed, first-morning (concentrated eight hours), uncentrifuged, 15 to 25 °C specimen; it should be tested within two hours after collection. This first-morning urine will be the most concentrated, which maximizes recovery of sediment elements.

The urine specimen should arrive promptly in the laboratory and be analyzed as soon after arrival as possible. **Generally, it is accepted that after standing two hours at room temperature, the chemical composition of urine changes, and formed elements begin to deteriorate.** Urine constituents, such as bilirubin and urobilinogen, are unstable. Bacteria can destroy glucose, and pH changes can occur if the urine is allowed to stand. Casts, erythrocytes, and leukocytes are especially susceptible to lysis in urine specimens with a low specific gravity (<1.010) and in urine specimens with an alkaline pH (>7.0).

If a delay of more than two hours after collection cannot be avoided, the specimen should be refrigerated (2 to 8 °C). The specimen should be at room temperature before proceeding with the analysis. Delays and associated temperature history should be documented if urine specimens are not tested promptly.

Unlabeled or improperly labeled specimens are not acceptable, and they should be discarded after the physician is notified.

A minimally sufficient quantity of urine to permit both macroscopic and microscopic evaluation is usually considered to be 12 mL (50 mL is preferred). Urine specimens from infants may necessitate the use of smaller volumes.

The urine specimen should be collected in a clean, leakproof, disposable container. The specimen should be free of fecal contamination and contain no bathroom tissue or other foreign materials. If these criteria are not met, the ordering physician or designee should be notified of the specimen's unacceptability; another specimen may be requested.

3.3 Color, Clarity, and Odor

Largely of historical interest, there are few occasions when the color, clarity, and odor of urine are of clinical significance. In consultation with clinicians, each laboratory should determine whether or not these parameters should be part of the routine urinalysis. However, any unusual color, clarity, or odor should be noted on the report form. Ammoniacal odors are most commonly due to bacterial degradation of urea, and they can indicate an old specimen or urinary tract infection. Laboratories should establish standard methods and terminology to reduce ambiguity and subjectivity when reporting the color, clarity, and odor of urine specimens.

3.4 Urine Concentration (Specific Gravity)

Urine specific gravity (SG) and osmolality are the two most commonly used measurements of urine concentration. Clinically, urine osmolality is the most useful and precise assessment of urine concentration, while SG is more easily performed, particularly in point-of-care testing. SG of urine is the ratio of the weight of the specimen to the weight of an equal volume of distilled water at the same temperature. The ratio is expressed using a numeric value; for human urine, normal values are in the

range of 1.003 to 1.035. The commonly used laboratory methods for specific gravity are indirect measurements that utilize a mathematical or empirical relationship to estimate SG values. In some laboratories, osmometry is performed instead of specific gravity measurements.

Refractometers are often used for measuring specific gravity. This method is based on the fact that light is refracted in proportion to the amount of total solids dissolved in a liquid. For use in urinalysis, the refractometer should have a scale that is calibrated for urine.

Refractometer use is popular, because it is temperature-compensated for use between 60 °F (15 °C) and 100 °F (38 °C) and it requires a relatively small volume of urine. Elevated results can be seen when urine contains x-ray contrast media, plasma expanders, and large amounts of glucose or protein. A correction for large amounts of glucose or protein should be made to refractometer results, because they are both high-molecular-weight substances that have no relationship to renal concentrating ability but will increase specimen density. Protein will elevate refractometry SG determinations by 0.003 for each gram per deciliter and glucose by 0.004 for each gram per deciliter.²¹ For specimens containing x-ray contrast media or plasma expanders, osmolality or the reagent test strip can be utilized, because they are not affected by those high-molecular-weight substances.

Harmonic oscillation may also be used to determine specific gravity. Shifts in harmonic oscillation are measured, and relative density is calculated. This measurement is based on the property-of-state relationship between the velocity of sound and density. Such devices offer the advantage of automation and excellent correlation with refractometry, yet require no clarification of cloudy specimens. Dissolved substances that are typically found in urine correlate closely with gravimetric measurement.

Colorimetric reagent test strips are available for the estimation of specific gravity. These tests measure ion concentration and rely on the relationship that as SG increases so does the ionic concentration. These strips measure urine specific gravity in increments of 0.005 from 1.000 through 1.030. Alkaline urines can affect the indicator system and, for visually read reagent strips, 0.005 should be added to the SG result for urine with alkaline pH. Strips read instrumentally are automatically adjusted for pH by the instrument. Such devices offer the advantage of automation and excellent correlation with gravimetric measurement, without the need to correct for glucose or protein or to clarify cloudy/turbid specimens. Manufacturers' directions must be followed.

The oldest technique to measure urine specific gravity is hydrometry. The hydrometer uses liquid displacement to estimate SG. A hydrometer calibrated for urine is called a "urinometer." This device has several disadvantages, including the need for a relatively large volume of urine (10 to 15 mL) and its glass construction, with attendant risk of sharps injury. Use of the urinometer requires that it float in a container that is wide enough so that the device does not touch the walls. Temperature affects the urinometer reading and therefore requires correction of the apparent value; reading the urine meniscus can be difficult; and urinometers can be inaccurate and require calibration after purchase. Therefore, the urinometer should not be the method of choice for determining urine SG.

All of these methods can be influenced, not only by the number of molecules present, but also by their size and/or ionic charge. Large molecules contribute more to the reading of specific gravity than small sodium and chloride ions. Therefore, because urea is of less value than sodium or chloride in the evaluation of renal concentration ability, in some instances it can be necessary to determine the osmolality of urine specimens.

3.4.1 Quality Assurance

A quality assurance program for SG testing should include daily use of control materials. Follow the manufacturer's quality assurance recommendations. Document and keep performance checks in accordance with applicable government regulations and regional scientific/clinical recommendations. As

with the physical parameters of color, clarity, and odor, the laboratory should determine when and if SG is a clinically useful part of the urinalysis report.

4 Chemical Urinalysis

The chemical analysis of urine is performed using one of many different urine “dipsticks” available from several manufacturers. These “dipsticks” or reagent strips consist of a plastic strip that contains one or more chemically impregnated reaction pads. A color reaction develops upon contact of the urine with the reagent pads. Reagent strips are a simple and fast way to semiquantitatively test urine. The following types of reagent strips are commonly available:

- ketone bodies (e.g., acetoacetic acid and/or acetone);
- albumin;
- glucose;
- leukocyte esterase;
- blood/hemoglobin;
- nitrite;
- bilirubin;
- pH;
- urobilinogen; and
- specific gravity.

4.1 Precautions for Reagent Strip Use

Refer to Section 2.1.5 for special instructions.

4.2 Use of Reagent Strips

Train personnel in the use of particular reagent strips. Strips from different manufacturers, and different lots from the same manufacturer may not be interchangeable. Thoroughly review the manufacturer’s instructions found in the package insert before testing. Procedures can vary among different products. Check the manufacturer’s instructions with each new lot number for any changes in procedure.

The amount of time required for the color reaction to develop on the reagent pad varies with each test. The manufacturer’s timing instructions should be followed. A timing device with a second hand is required for visual reading. Automated strip readers are set to read the reaction pad at a given time according to the manufacturer’s instructions.

It is important to know the sensitivity and specificity of each test on the reagent strip being used. This information is usually found in the package insert, and the testing laboratory may wish to conduct its own verification studies.

Visual reading of the reagent strip is subject to some degree of variability due to different color interpretations by individual persons. The reagent strip should be held close to the color chart in adequate lighting. Personnel should be tested for difficulty with color discrimination (i.e., “color blindness”) to ensure that color changes are properly interpreted.²²

Substances can be present in the urine that can interfere with the chemical reaction and cause false-negative or false-positive results. Consult the manufacturer's package insert for these interfering substances and any other limitations. If urine test strip results differ from expected values, investigate the problem according to the manufacturer's procedures or the laboratory procedure manual.

4.3 Confirmatory Tests

Confirmatory chemical urinalysis tests detect the same substance with the same or greater sensitivity and/or specificity, or they use a different reaction or methodology to detect that substance. Repeating a reagent strip reaction or analysis is not a confirmatory test. Commonly used confirmatory chemical urinalysis tests include the sulfosalicylic acid (SSA) test for albuminuria and the tablet test for bilirubin.

Beyond chemical analyses, manual and automated wet microscopic urinalysis systems represent confirmatory tests for blood, leukocyte esterase, and nitrite detected by reagent strips. Microbiologic studies are confirmatory tests for urinary tract infections where the reagent strip shows a positive result for leukocyte esterase and nitrite, and wet microscopic urinalysis reveals bacteriuria and leukocytes. Frequently, conventional urine cytology and cytodiagnostic urinalysis can be used as a confirmatory test for wet microscopic urinalysis, indicating abnormalities such as inflammatory, infectious, and neoplastic conditions. Image cytometry and deoxyribonucleic acid (DNA) analysis using the Feulgen stain may have value as a confirmatory stain for urothelial neoplasia, as may newer molecular techniques for nucleic acids.

5 Microscopic Examination of Urine

Numerous articles address the need for a urine sediment microscopic examination. With the addition of the leukocyte esterase and nitrite tests to reagent strips, the cost-effectiveness of the microscopic examination on urine specimens with normal physicochemical results has been questioned.¹⁻¹⁰ *The decision to perform microscopic examinations should be made by each individual laboratory based on its specific patient population.* Ordinarily, microscopic examination is performed in the following instances:

- when requested by the physician;
- when determined by laboratory protocol (e.g., with immunosuppressed, urology-nephrology, diabetic, or pregnant patients); and
- when any abnormal physicochemical result is obtained.

5.1 Types of Microscopic Examinations

The majority of urine sediment examinations are done using wet mounts and brightfield microscopy. Staining can be extremely helpful in the identification of cells and casts. Common supravital stains appropriate for wet mounts include a Sternheimer Malbin (crystal violet and safranin O) and 0.5% toluidine blue. Refer to the manufacturers' instructions or appropriate reference for specific staining procedures.

A modern, high-quality microscope adjusted to Koehler illumination should be used for examining the urine sediment (see Section 2.2.1). The use of phase optics enhances the identification of microscopic sediment elements. For abnormal sediments, polarization microscopy is strongly recommended for the

identification of lipids and crystals. Differential interference contrast (Nomarski) microscopy may be useful for selected applications.

An alternative to the manual microscopic method is examination of the urine sediment with an automated or semiautomated instrument. This type of system provides for viewing the specimen with no manual sample preparation, and it helps in the classification of analytes. These systems inherently provide increased reproducibility compared with manual microscopy by different individuals. Further discussion is beyond the scope of this document.

5.2 Microscopic Examination

The following information applies to centrifuged urine.

Consistency in all aspects of the microscopic examination is essential to the production of meaningful results. A properly documented and maintained procedure manual helps ensure that all personnel within the laboratory perform the microscopic examination in the same manner. Each person should evaluate the sediment using the same procedure, look for the presence of the same sediment entities, and use the same criteria for identification.¹³⁻²⁰

Laboratories may wish to consider use of standardized commercial systems, which make it possible to report abnormal sediment elements per unit of volume instead of per high- or low-power microscopic field for comparison between laboratories.

Specific factors that should be standardized within the laboratory, and the values associated with each, are listed below. Commercial system technologies can provide equivalent results. These technologies may use smaller volumes and have different standard times and speeds. The manufacturers' recommendations should be followed for specific systems.

The information that follows is based on traditional methodologies.

5.2.1 Volume of Urine Examined

The volume of urine used for examination should be standardized within the laboratory (e.g., 10, 12, and 15 mL are commonly used volumes). If a smaller volume is used (e.g., pediatrics, neonates), make a notation on the final report.

5.2.2 Time of Centrifugation

To ensure equal sedimentation of all specimens, the recommended time of centrifugation is five minutes.

5.2.3 Speed of Centrifugation

The recommended relative centrifugal force (RCF) is approximately 400. To calculate RCF from rotations per minute (RPM) for a specific centrifuge, use the following formula:

$$\text{RCF} = 1.118 \cdot 10^{-5} \cdot r \cdot N^2$$

where:

RCF = relative centrifugal "force";

r = the radius in cm (from the center of the spindle to the bottom of the tube); and

N = rotations per minute.

5.2.4 Concentration Factor of the Sediment

The sediment of all urine specimens should be resuspended in a standardized volume for consistency between patient specimens, as well as serial samples from the same patient. There are standardized commercial systems that use special tubes or pipets to retain a specific volume of urine sediment.

5.2.5 Volume of Sediment Examined

There are standardized commercial systems that provide a slide with chambers of a given volume that will hold a specific amount of concentrated sediment.

5.2.6 Slides and Cover slips

If glass microscope slides and cover slips are used, the following manual procedure is recommended for examining and calculating the urine sediment:

- (1) Measure the volume of well-mixed urine to be centrifuged.
- (2) Standardize centrifugation (time and speed).
- (3) Measure the volume of urine left in the tube in which the sediment will be resuspended.
- (4) Measure the amount of sediment placed on the slide.
- (5) Use a standard cover slip.
- (6) Record the high-power magnification of the microscope.
- (7) Record the diameter of the high-power field.
- (8) Calculate and report the elements per milliliter of urine.

For example, using 15 mL of urine:

- Diameter of the high-power field = 0.35 mm
- Area of the high-power field = 0.096 mm²
- Area under the cover slip = 484 mm²
- $\frac{484}{0.096} = 5040$ $\frac{\text{High - Power Fields}}{\text{Under Cover Slip}}$
- Measure 0.020 mL of sediment onto the slide \approx 1.2 mL urine
- 5040 high-power fields \approx 1.2 mL urine \approx 4000 high-power fields/mL

Therefore:

$$(\text{Count/High-Power Field}) \cdot 4000 = \text{Count/mL.}$$

5.2.7 Reporting Format

Every person at a given institution who performs a microscopic examination should use the same terminology, reporting format, and reference intervals. Decisions about which formed elements should be reported and quantified should be made by the individual laboratory, based on the patient population and professional skill level of the persons performing the testing.

5.3 Identification of Microscopic Entities

A review of available information, including physicochemical results, is essential before reporting the microscopic examination. The data contained in these reports should substantiate the microscopic results and vice-versa. Any discrepancies should be resolved before the final report is sent to the clinician.

5.3.1 Identifiable Sediment Entities (Formed Elements)

Sediment entities that should be identifiable using a urine microscopic examination include the following:

- Epithelial cells: Transitional (urothelial)
 Squamous
 Renal tubular
- Blood cells: Red blood cells (RBC)
 White blood cells (WBC)
- Casts: Hyaline
 Granular
 Waxy
 Cellular
 RBC
 WBC
 Bacterial
 Broad
 Fatty
- Microorganisms: Bacteria
 Yeast
 Parasites
 Viral inclusions
- Crystals: Amorphous
 Calcium oxalate
 Uric acid
 Triple phosphate
- Miscellaneous: Sperm
 Mucus
 Contaminants

Advanced microscopy skills may be required for the identification of other elements.

5.3.2 Stains

Supravital staining is not sufficient for the identification or confirmation of all urine sediment entities. Laboratories performing a complete wet microscopic urinalysis should be able to identify/confirm the following entities using one or more of the special stains listed:

- Fat: Oil red O stain
Sudan III stain
- Oval fat bodies: Same as above
- Bacteria: Gram stain
Papanicolaou stain
- Eosinophils: Hansel stain
Wright stain
Giemsa stain
Wright-Giemsa stain
Papanicolaou stain
- Hemosiderin: Prussian blue

Usually, the use of special stains requires an additional preparation. A concentrated smear, imprint, or cytocentrifuged slide is helpful in identifying the aforementioned entities.

The Papanicolaou stain is the stain of choice for characterizing renal tubular epithelial cells; abnormal urothelial, glandular, and squamous cells; and hematopoietic conditions. Hansel stain is suggested to detect eosinophiluria and possible allergic nephritis.

5.4 Quality Assurance of the Microscopic Examination

5.4.1 Procedural Quality Control (QC)

All personnel should follow the same documented procedure using the same equipment. Microscopic QC controls should be run each day the test is performed. Controls containing RBCs and WBCs are commercially available. Duplicate urine testing can be used as a precision check for the identification of casts, renal cells, and other formed elements.

5.4.2 Reporting Quality Control

All personnel should use the same terminology and report results in a standard format. Unexpected control results should be identified, and appropriate corrective action should be taken and documented.

6 Automated Urinalysis

Automated urinalysis systems are designed to provide maximum convenience to the user, enhance productivity, and eliminate sample preparation.

Semiautomated urinalysis instruments are available that perform the microscopic examination, reagent strip chemistry, and specific gravity measurement. Such instruments can quantify and standardize urine sediment analysis. A laminar flow, slideless microscope hydrodynamically focuses stained urine for viewing with a video system and a high-speed image processor system. The system automatically classifies formed elements for confirmation by a qualified operator, which provides increased

reproducibility and ease of use. A key advantage is the larger number of sediment elements actually enumerated, as compared with manual microscopy, similar to the benefit of automated blood WBC differential instruments.

Other instruments are available that centrifuge the specimen into tubes designed for direct viewing using a microscope. Systems are available that simplify sample preparation or reduce the volume required. Although these instruments use different methodologies, all of them screen specimens and help reduce the use of slides, centrifuge tubes, and manipulative handling of the urine specimen.

Semiautomated and fully automated reagent strip readers are also available for use in the performance of reagent strip chemistry and specific gravity determinations. Refer to Section 2.2.2 for more information.

7 Quality Assurance

7.1 Introduction and Purpose

A quality assurance program involves the continued monitoring of every aspect of a procedure to ensure the highest possible standard of care for the well being of the patient. Quality assurance programs should establish coordination and communication between all involved parties; this includes the patient, the laboratory, and the clinician. The testing of “controls,” or quality control, is but one aspect of quality assurance. Other areas include implementation and oversight of policies/procedures for specimen collection and handling; recordkeeping; technical competence; standardization; continuing education; and a scheduled, documented review process.

7.2 Recordkeeping

Recordkeeping is a vital part of quality assurance in the laboratory. Records should be available for all shifts, and they should cover controls and instrument checks. Documented procedures for the detection and correction of errors, out-of-control results, and review of test results are necessary. Patient results should be reported with accompanying reference intervals.

Records of patient results should be kept in accordance with regulatory and accrediting agencies.

A record or log (book or computer) should be available at the workbench, and it should include:

- the lot number of reagent strips and expiration date;
- all patient and control results;
- date and time of specimen collection and arrival at the laboratory; and
- identification of the person who performed the test(s).

7.3 Procedure Manual

A complete urinalysis procedure manual, including directions for performing the test, should be available at the workbench. It should include the following information:

- specimen acceptability and rejection criteria (e.g., age of specimen, use of preservatives, and minimum quantity);
- information about controls;

- reference intervals;
- alert (panic) values and communication protocol;
- confirmatory testing;
- specimen collection and transport (see Section 8); and
- recording results/recordkeeping.

NOTE: Current package inserts should be available at the workbench. Refer to NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals* for the recommended format of procedures.

7.4 Materials and Equipment

7.4.1 Storage

Proper storage and careful monitoring/recording of the use of reagents and their expiration dates will reduce the likelihood of using deteriorated or expired products or reagents. Monitoring reagent stocks is an essential, important quality assurance activity.

7.4.2 Instrumentation

All instrument readers should have the following items:

- a procedure manual at the workbench (portions may originate from manufacturer-provided manuals);
- a documented maintenance and function verification schedule;
- service and repair records; and
- the manufacturer's instruction manual available at the workbench.

7.5 Proficiency Testing (External Quality Assessment)

External proficiency testing/quality assessment programs that are sponsored by manufacturers, professional and medical organizations (e.g., in the U.S., College of American Pathologists), and some public health laboratories are available as a check on accuracy. Unknown specimens are distributed several times a year for evaluation by the individual laboratory. Results are recorded, and a summary is sent to the participating laboratories to compare performance with other laboratories.

In-house and commercial controls for microscopic examination will serve as a precision check only. Transparencies included in some proficiency surveys assess the ability of technologists to correctly identify microscopic elements, but they do not assess the reproducibility of urine sedimentation or slide preparation, and locating formed elements.

7.6 Continuing Education and Training

The laboratory should organize regularly held conferences and seminars to ensure the cooperation and updating of the skills of medical personnel involved in specimen collection and transportation. All changes in procedure or reference intervals that affect specimen collection, transportation, and result interpretation should be announced to all personnel, including clinicians.

Workshops, seminars, and self-study programs are examples of continuing education activities that should be sponsored and supported. Technical personnel should have their skills updated on an ongoing basis. Current reference texts, atlases, charts, and posters are types of materials that should be readily available.

To ensure the quality of urinalysis testing, independent of the site of performance, the qualifications of testing personnel should match the complexity of the testing performed. Test reliability can be demonstrated, regardless of employee qualifications and complexity of testing, through proficiency testing and blind sample studies.

Only properly trained personnel should perform a complete urine microscopic examination. Lacking such expertise, a laboratory may be limited to reagent strip testing to provide semiquantitative information about hematuria, pyuria, and bacteriuria, as examples.

8 Collection and Transportation of Single-Collection Urine Specimens

Procedural guidelines for the collection and transportation of urine specimens to the clinical laboratory are important, because diagnostic and therapeutic decisions may be based on the results of the urinalysis. Variables such as collection method, container, transportation, and storage are significant, because they affect the outcome of the analysis.

8.1 Overview

Examples of general procedures for collecting urine specimens from the patient, transporting them to the laboratory, and storing them are discussed with an orientation primarily toward laboratory and clinical personnel who are responsible for these procedures. For commercially available collection systems, follow the manufacturers' recommendations. Container suitability and urinalysis requisition form information are also considered. This section is of interest to manufacturers of reagents and containers in terms of the end use of their products.

8.2 Types of Urine Specimens

8.2.1 Patient Collection

The following types of urine specimens can be collected by cooperative patients after instruction and without direct supervision:

- random;
- first morning or eight-hour; and
- timed specimen, including 24-hour.

8.2.2 Supervised Collection

Collecting the following types of specimens may require supervision by, or the participation of, trained personnel from the clinical laboratory staff:

- midstream “clean catch” specimen (see definition below);
- specimen for microbiological culture; and
- medicolegal cases.

8.2.3 Assisted Collection

Collecting the following types of specimens requires the active participation of trained personnel:

- catheter specimens;
- suprapubic aspiration specimens; and
- collections from infants.

8.3 Instructing the Patient

8.3.1 Specimen Description

Urine specimens, except those obtained by catheterization or suprapubic aspiration, are collected by having the patient voluntarily urinate and, insofar as possible, avoid contamination by vaginal secretion, smegma, pubic hair, powders, oils, lotions, and other extraneous materials. Specimens should not be recovered from diapers.

8.3.2 Patient Instruction

Many urine specimens can be collected by the cooperative patient after simple instruction from the clinical laboratory personnel responsible for the procedure.

The following steps should be taken:

- (1) When instructing patients, emphasize hand washing and general cleanliness.
- (2) Give patients a properly labeled specimen container and ask them to verify their name on the label.
- (3) Give oral instructions, and give a written instruction sheet or card with illustrations to the patient or display it in the area of urine collection for more information. Give patients collection instructions in their native language.
- (4) Instruct patients to secure the lid of the specimen container to prevent leakage.

8.4 Collecting the Specimen

8.4.1 Random Specimen

The random specimen may be collected at any time, but the actual time of collection (voiding) should be recorded on the specimen container. Several hours of urinary continence before collection can be necessary to provide a specimen suitable for analysis.

8.4.2 First Morning or Eight-Hour Specimen

The first morning or eight-hour specimen is normally collected immediately on the patient's arising from a night's sleep. This is also known as an "overnight" or "early morning" specimen. Other eight-hour periods may also be used to accommodate insomniacs and night-shift workers, as well as certain pediatric situations. Specimens to verify orthostatic proteinuria are collected after an eight-hour period of lying down. The bladder is emptied immediately before lying down, and the specimen is collected on arising so that the urine collected is that which accumulated while the patient was in the recumbent position. Any urine voided during the night should be collected and pooled with the first morning, voided specimen.

8.4.3 Timed Specimen

The timed specimen is collected at a specified time in the 24-hour period (e.g., at 10 a.m. or at a specified time in relation to another activity, such as two hours after eating a meal or immediately after prostatic massage).

8.4.4 24-Hour Urine Specimen

If it is necessary to measure the total amount of solutes excreted in a 24-hour period, a strictly timed 24-hour specimen is required, because many solutes exhibit diurnal variations. The lowest concentrations of catecholamines, 17-hydroxysteroids, and electrolytes occur in the early morning, whereas highest concentrations occur at noon or shortly thereafter. (For more information on 24-hour specimen collection, see Section 9.)

8.4.5 “Clean Catch” Specimen

8.4.5.1 Male

- (1) Before beginning the procedure, the patient should wash his hands with soap or a cleansing towelette.
- (2) Instruct the uncircumcised patient to withdraw the foreskin to expose the urethral meatus.
- (3) With a **sterile** cleansing towelette or the equivalent, cleanse the glans, beginning at the urethra and working away from it.
- (4) Have the patient begin urination, passing the first portion into the bedpan or toilet. Collect the midportion in the appropriate urine specimen container without contaminating the container (“clean catch”). Any excess urine can pass into the bedpan or toilet.
- (5) Offer assistance if the patient is unable to carry out the recommended procedure. Sterile gloves should be worn by the assistant.

8.4.5.2 Female

- (1) Before beginning the procedure, the patient should wash her hands with soap or a cleansing towelette.
- (2) Instruct the patient to squat over the bedpan or toilet.
- (3) With a sterile cleansing towelette or the equivalent, cleanse the urethral meatus and surrounding area.
- (4) Have the patient begin urination, passing the first portion into the bedpan or toilet. The midportion should be collected in the appropriate container without contaminating the container (“clean catch”). Any excess urine can pass into the bedpan or toilet.
- (5) Offer assistance if the patient is unable to carry out the recommended procedure. Sterile gloves should be worn by the assistant.

8.4.6 Catheter Specimen

A catheter specimen is one collected after inserting a catheter into the bladder through the urethra, using sterile technique. Urine may be collected as a single specimen from the catheter outflow.

8.4.7 Suprapubic Specimen

A suprapubic specimen is one collected by aspirating urine from the distended bladder through the abdominal wall, using sterile technique.

8.4.8 Microbiological Cultures

Any of the specimens presented in Sections 8.4.5 through 8.4.7 may be used for microbiological culture if special precautions are taken (see Sections 8.6.4 and 8.7.3).

8.5 Collecting Urine Specimens from Infants and Small Children

Use pediatric and newborn urine specimen collection bags with hypoallergenic skin adhesives for children who are too young to collect a urine specimen.

8.5.1 Random Specimen Procedure

To collect random specimens from children, clinical personnel should do the following:

- (1) Separate the child's legs.
- (2) Be sure pubic and perineal areas are clean, dry, and free of mucus. Do not apply powders, oils, or lotions to the skin.
- (3) Using a pediatric urine collection device, remove the protective paper, exposing the hypoallergenic skin adhesive attached to the bag.
 - For girls, stretch the perineum to remove skin folds. Press the adhesive firmly to the skin all around the external genitals. Be sure to start at the bridge of the skin, separate the rectum from the vagina, and work forward, avoiding contamination from the rectal area.
 - For boys, fit the bag over the penis and press the flaps firmly to the perineum.
 - Make sure the entire adhesive coating is firmly attached to the skin with no puckering of the adhesive.
 - For older children, follow the adult procedure described in Section 8.4.5.
- (4) Check the container periodically (e.g., every 15 minutes).
- (5) Retrieve the collected specimen from the patient and label it.
- (6) Without further contamination, pour or decant the specimen into a collection cup. Label the cup and transport it.

Some laboratories may prefer to collect specimens from very young babies with cotton-wool balls, rather than affixing adhesive tape to very delicate body areas. In such cases, it is critical that the sediment microscopist be aware of the potential for exogenous structures.

8.5.2 Procedure for Collecting a Specimen for Microbiological Culture

To collect a microbiological culture specimen from children, clinical personnel should do the following:

- (1) Before beginning the procedure, clinical personnel should wash their hands with soap or cleansing towelettes.
- (2) Separate the child's legs.
- (3) Cleanse the pubic and perineal areas with soap and water, and dry them so that these areas are clean, dry, and free of residual soap. Do not apply powders, oils, or lotions to the skin.
- (4) Remove the protective paper, exposing the hypoallergenic skin adhesive attached to the bag.
 - For girls, stretch the perineum to remove skin folds. Press the adhesive firmly to the skin all around the external genitals. Be sure to start at the bridge of the skin, separate the rectum from the vagina, and work forward, carefully avoiding contamination from the rectal area.
 - For boys, fit the bag over the penis and press the flaps firmly to the perineum.
 - Make sure the entire adhesive coating is firmly attached to the skin with no puckering of the adhesive.
- (5) Check the container periodically (e.g., every 15 minutes).
- (6) Retrieve the collected specimen and label it.
- (7) Without further contamination, pour or decant the specimen into a collection cup and secure the plastic lid. Label the cup and transport it.

8.6 Collection Containers

8.6.1 Composition

The primary collection container and transport container, if applicable, should be clean, leakproof, particle-free, and preferably made of a clear, disposable material that is inert with regard to urinary constituents. The container and closure should be free of interfering substances, e.g., detergents. Most laboratories prefer to use sterile containers for all urine collection.

8.6.2 Reuse

Do not reuse specimen containers.

8.6.3 Capacity

The primary collection container should have a capacity of at least 50 mL with a round opening at least 4.0 cm in diameter. The container should have a wide base to avoid accidental spillage. Smaller, specialized containers are used for specimens collected from young children.

8.6.4 Transport and Storage

The container used during transportation should have a secure closure to prevent leakage of the contents during transportation. The closure should be easily applied and removed. The laboratory should ensure the integrity of the specimen identification and condition from the time of specimen submission to analysis. For example, if the specimen is refrigerated, the laboratory should ensure that the refrigerator is properly maintained and that delays in specimen delivery do not compromise specimen integrity.

8.6.5 Sterile Container

When a urine specimen is submitted for microbiological studies, the sterile containers must have secure closures. The specimen should be submitted for microbiological studies before urinalysis, unless sterile technique is used to make aliquots from a portion of the specimen for urinalysis. Sterile containers are also suggested if more than two hours elapse between specimen collection and analysis.

8.6.6 Label

The container should be designed to accept a label that will adhere during refrigeration or freezing. The label should include sufficient space for the patient's full name; unique identification number; date and time of specimen collection; and the name of the preservative in the container, if applicable. Some laboratories might need a label to include other information or a barcode. To ensure proper specimen identification, place labels on the container, not on the closure.

8.6.7 Preservatives

For specimens not analyzed within two hours of collection, preserve the urine specimen using a specifically designed chemical preservative or a media transport device. Chemical preservatives are recommended if there is a delay in analysis (greater than two hours from collection); the specimen is being tested for an otherwise unstable analyte; or the specimen is being stabilized for microbiological studies.

8.7 Transporting and Storing Specimens

8.7.1 Transport

If the specimen is transported, the container should have a secure closure to prevent leakage of the contents. If appropriate, use a secondary container to ensure containment of possible spills. Rapidly transport urine specimens to the laboratory for prompt examination. Laboratories should ensure the integrity of specimens during transportation (e.g., pneumatic tube systems).

8.7.2 Refrigeration

If the specimen cannot be transported and analyzed immediately, it should be refrigerated (2 to 8 °C) after collection. (See Section 2.1.6 for more information.)

8.7.3 Microbiological Examination

If a microbiological examination is requested and the specimen cannot be transported immediately to the laboratory, take the following steps:

- (1) Specimens may be refrigerated at 2 to 8 °C for up to 24 hours and still yield valid culture information.
- (2) An aliquot of urine may be transferred into a transport tube containing a bacteriostatic preservative, several of which are commonly available; consult with the laboratory to perform testing. Preserved specimens do not require refrigeration.

Alternatively, where there is a very long transport time, an agar film (attached to a plastic support) may be dipped into the urine and placed into an appropriate closed container. Both agar and urine are sent to the testing laboratory, where subculturing may be performed from the agar sampling.

8.8 Acceptability of Specimens and Quality Assurance

8.8.1 Inspection

To ensure suitability for an analysis, the urine specimen should be inspected upon its receipt in the laboratory. Consider the following points when ensuring the suitability of the specimen:

- agreement of information on the requisition form and container label;
- acceptability of the elapsed time between collecting the specimen and its receipt in the laboratory;
- refrigeration or the presence of a suitable preservative if transport was delayed and microbiological studies were requested;
- suitability of the container and its condition (e.g., closure in place);
- adequate volume and absence of contaminating materials; and
- presence or absence of chemical preservative consistent with intended specimen use.

8.8.2 Acceptability

Laboratories performing microscopic urinalysis may wish to develop criteria for identifying suboptimal specimens, based on the presence of common microscopic contaminants indicative of genital/anal contamination (e.g., numerous mature squamous cells, “clue cells,” vegetable fibers), in which case the presence of bacteria may not indicate urinary tract infection.

If the specimen does not meet the criteria for acceptability, contact the attending physician or designee for a decision on further action. Do not discard the “unacceptable” specimen until clinical personnel have been consulted and a mutually agreeable decision has been reached.

8.8.3 Documentation

Establish a quality assurance program that ensures that the following information is documented:

- specimen collection consistently results in the correct specimen type, adequate specimen volume for the requested analysis, the use of suitable containers, and proper labeling;
- specimen transportation to the laboratory is timely and in accord with recommended procedures; and
- specimen processing ensures prompt inspection after arrival in the laboratory and correct storage procedures (e.g., protection from heat and light, refrigeration).

9 Collection and Preservation of 24-Hour Urine Specimens

If it is necessary to measure the total amount of solutes excreted in a 24-hour period, a strictly timed 24-hour specimen is required, because many solutes exhibit diurnal variations. The lowest concentrations of catecholamines, 17-hydroxysteroids, and electrolytes occur in the early morning, whereas the highest concentrations occur at noon or shortly thereafter.

9.1 Collecting 24-Hour Urine Specimens

9.1.1 Container

Collect the specimen in one or more disposable, wide-mouthed, clean, plastic container(s) (with a plastic lid) large enough to hold about 3 L. Keep the collection container in the refrigerator or on ice during the 24-hour period. Provide amber-colored containers for light-sensitive analytes.

For nonambulatory catheterized patients, store the bag on ice; if the patient is ambulatory, empty the bag periodically and refrigerate the contents.

9.1.2 Label

The label on the collection bottle should include the patient's identification; test required; preservative used; and the dates and the times of the start and finish of the collection period. If spillage of the preservative could harm the patient, add a suitable warning to the label and explain this to the patient verbally. Basic elements of material safety data sheet (or equivalent) information should be provided to the patient.

9.1.3 Preservative

For patient and healthcare worker safety, a goal should be to avoid preservatives when possible. If a special preservative is required, add it to the collection bottle before the urine collection begins. See the table following Section 9.2 for appropriate preservatives. When more than one preservative type is analytically acceptable, efforts should be made to select the least hazardous additive.

9.1.4 Collection

The 24-hour collection should begin by having the patient empty his or her bladder or catheter bag at a fixed time and discard the specimen. Note the date and time that the collection started. If the preservative is a biohazard, the patient should be advised to collect the urine in a separate clean container and then carefully transfer the urine to the collection container for the laboratory.

9.1.5 Instruction

Instruct the nurse or patient to collect *all* voided urine during the 24-hour collection period and add it to the collection container. Written instructions must be written in simple form, and in a language comprehensible to the patient.

9.1.6 Completion

The collection should end exactly 24 hours after it began by having the patient empty his or her bladder, or catheter bag, and adding this specimen to the collection container.

9.2 Summary of 24-Hour Urine Preservatives

The following table for preservatives of 24-hour urine specimens is based on the individual recommendations of the largest reference clinical laboratories and major textbooks. General and specific differences and discrepancies are noted between these sources, the clinical significance of which is unknown. Laboratorians are urged to follow the recommendations of the clinical laboratory performing the analyses. Clinical laboratories performing these tests are urged to study the optimal and acceptable means of preservation and transportation.

When more than one test is required, the specimen requirements can conflict. One approach is to collect multiple 24-hour specimens. Another approach is to mix each urine specimen collected, subdivide each urine specimen into equal volumes, and pour each subdivision into the appropriate large urine container. The large specimen containers would require only one-half (for a two-way split) or one-third (for a three-way split) of the preservative otherwise recommended. The total volume would be the total volume collected over the 24-hour period. A third approach is use containers that split the urine specimen into two sides with the proper preservative added to each side.

Occasionally, patients have a 24-hour urine volume that exceeds the volume of a single container. In this case, two 24-hour urine containers should be used. The urine from the two containers should be well mixed before analysis. This is most often performed by pouring urine back and forth from one container to the other. The amount of preservative in the second container may be reduced to account for the low volume that is typically collected in the second container.

Table. Preferred 24-Hour Urine Preservatives

NOTES: a) As these requirements may change from time to time, submitting laboratories should check for current requirements from reference laboratories before collecting samples; **b)** Samples for collagen cross-links may need protection from light. Trace metal samples require only refrigeration. Some laboratories adjust the pH of collections for porphyrins to neutrality, with sodium bicarbonate, and protect the samples from light. For β -hcG, some laboratories specify addition of thimerosal before freezing. Again, collection sites should contact their laboratories for current specific requirements.

Analyte	Refrigerate (2 to 8 °C)	Freeze (-24 to -16 °C)	6 N HCl*	Boric Acid*	Acetic Acid*	Other
Albumin (microalbumin)	1,2,3,5	2		6		
Alcohol, ethyl	2	2				
Aldosterone	4	7	1,2,5a,7	3,5,6,7		
Amino acid	5a	3a,4	1,5	7		3t
Aminolevulinic acid		5a	1,5,6,7		7	3s,5s
Amylase	6					4rt
Beta-2-microglobulin	2	2				2h
Calcium	2	2	1,3,4,5,6,7			
Catecholamines, fractionated	2	3,5a	1,3,4,5,7		6,7	
Chloride	1,2,4,5,6	2		6		
Citrate		3a	4	1,2,5,7		3t
Cortisol	1,4,7	5	2	6,7	3,7	
C-peptide		5				
Creatine	1,5	3,4	1u	1u,6		
Creatinine	1,2,5	2,4,5a	5a	5a,6		
Cystine		2,3a,7	1,4,5,7			3t
Dehydroepiandrosterone				4		
Electrolytes Sodium Potassium	1,2,4,5,6	2	1u	1u,5a		
Estriol	6					
Estrogens, total				6,7	7	
Follicle stimulating hormone	6			3		
Glucose				4,5,6		
Histamine		1,4	3,5			
Homovanillic acid			1,2,3,6		6	
17-hydroxycorticosteroids				1,2,4	5	
Hydroxyproline		3a	1,2,4	5		3t
5-hydroxyindolacetic acid	4		2,3,4a	1,4a,5		
Immunoelectrophoresis	3,4	2				

Table. Preferred 24-Hour Urine Preservatives (Continued)

Analyte	Refrigerate (2 to 8 °C)	Freeze (-24 to -16 °C)	6 N HCl*	Boric Acid*	Acetic Acid*	Other
17-ketogenic steroids			4a	1,2,4,6	3,5,6	
17-ketosteroids			4a	1,2,4,6	3	
Lead†	3,4		1		5,6	
Lipase						
Magnesium	1,6		3,6			
Metanephrines			1,2,4,6		5,6	
Methoxyhydroxyphenol-glycerol (MHPG)	1,3		1u	1u		
N-methylimidazoleacetic acid					3	
Nitrogen	3,6		1,6			
Oxalate	6		1,2,3,6			
Para-aminobenzoic acid						
Phosphate (phosphorus)	1,4	2	4a,5			
Phosphoethanolamine						
Porphyrins	2	2				1sc, 2s, 3sc, 4s, 5sc,6s
Protein, total	1,2,3,4,5			5		
Pyridinium collagen cross-links			2	2		
Tetrahydro compound S					5	
Urea nitrogen	1,4					
Uric acid	2,4,6	3a	1u	1u,5		1rtu, 6b
Urobilinogen						3sc
Vanillylmandelic acid		2	1,4,6	6	3,5	
Xanthine and hypoxanthine		3				

* = Recommended concentration and pH varies.

† = Lead-free.

Key:

- 1 = Quest Diagnostics
- 2 = Specialty Laboratories
- 3 = Mayo Medical Laboratories
- 4 = LabCorp
- 5 = Henry JB, ed. *Clinical Diagnosis and Management by Laboratory Methods*. 19th ed. Philadelphia: WB Saunders; 1996.
- 6 = Burtis CA, Ashwood ER, eds. *Textbook of Clinical Chemistry*. 2nd ed. Philadelphia: WB Saunders; 1994.

- a = Acceptable
- u = Unacceptable
- t = Toluene
- s = Protect from sunlight
- rt = Room temperature
- b = Sodium bicarbonate
- c = Sodium bicarbonate and ethylenediaminetetraacetic acid (EDTA)
- h = 1M NaOH to adjust pH to 6-9

References

- ¹ Morrison MC, Lum G. Dipstick testing of urine - can it replace urine microscopy? *Am J Clin Pathol.* 1986;85:590-594.
- ² Hamoudi AC, et al. Can the cost savings of eliminating urine microscopy in biochemically negative urines be extended to the pediatric population? *Am J Clin Pathol.* 1986;86:658-660.
- ³ Cramer AD, et al. Macroscopic screening urinalysis. *Lab Med.* 1989(Sep):623-627.
- ⁴ Pels RJ, et al. Dipstick urinalysis screening of asymptomatic adults for urinary tract disorders. II. Bacteriuria. *JAMA.* 1989;262:1220-1224.
- ⁵ Wenz B, Lampasso JA. Eliminating unnecessary urine microscopy. Results and performance characteristics of an algorithm based on chemical reagent strip testing. *Am J Clin Pathol.* 1989;92:78-81.
- ⁶ Schumann GB, Friedman SK. Comparing slide systems for microscopic urinalysis. *Lab Med.* 1996;27:270-277.
- ⁷ Hooper DW. Detecting GD and preeclampsia: effectiveness of routine urine screening for glucose and protein. *J Reprod Med.* 1996;41:885-888.
- ⁸ Jou WW, Powers RD. Utility of dipstick analysis as a guide to management of adults with suspected infection or hematuria. *South Med J.* 1998;91:266-269.
- ⁹ van Nostrand JD, et al. Poor predictive ability of urinalysis and microscopic examination to detect urinary tract infection. *Am J Clin Pathol.* 2000;113:709-713.
- ¹⁰ Ferris JA. Comparison and standardization of the urine microscopic examination. *Lab Med.* 1983;14:659-662.
- ¹¹ Lauer BA, et al. Effect of chemical preservation of urine on routine urinalysis and non-culture tests for bacteriuria. *Med Lab Sci.* 1983;40:27-32.
- ¹² Weinstein MP. Clinical evaluation of a urine transport kit with lyophilized preservative for culture, urinalysis, and sediment microscopy. *Diagn Microbiol Infect Dis.* 1985;30:501-508.
- ¹³ Haber MH. Urinary sediment: a textbook atlas. Chicago, IL: American Society of Clinical Pathologists Press; 1981.
- ¹⁴ Bradley M. Urine crystals - identification and significance. *Lab Med.* 1982;13:348-353.
- ¹⁵ Zaharopoulos P, Wong JY. Matrix crystals in urine sediments. *Lab Med.* 1988;19:429-431.
- ¹⁶ Brunzel NA. Fundamentals of urine and body fluid analysis. Philadelphia, PA: WB Saunders; 1994.
- ¹⁷ King C. Comparison of methods for detecting indinavir crystals in urine. *Am J Clin Pathol.* 1998;110:540.
- ¹⁸ Hortin GL, et al. Detection of indinavir crystals in urine. Dependence on method of analysis. *Arch Pathol Lab Med.* 2000;124:246-250.
- ¹⁹ Ringsrud KM. Cells in the urine sediment. *Lab Med.* 2001;32:153-155.

- ²⁰ Ringsrud KM. Casts in the urine sediment. *Lab Med.* 2001;32:191-193.
- ²¹ Smith C, et al. Effect of X-ray contrast media on results for relative density of urine. *Clin Chem.* 1983;29:730-731.
- ²² Fetter MC. Colorimetric tests read by color-blind people. *Am J Med Technol.* 1963;6:349-355.

Additional References

Burtis CA, Ashwood ER, eds. *Textbook of Clinical Chemistry*. 2nd ed. Philadelphia: WB Saunders; 1994.

College of American Pathologists, Commission on Laboratory Accreditation. *Urinalysis and Clinical Microscopy Checklist*. Northfield, IL: College of American Pathologists; 2001.

Graff LA. *Handbook of Urinalysis*. Philadelphia: JB Lippincott; 1983.

Haber MH, Corwin HL. Urinalysis. *Clin Lab Med*. 1988;8:415-616.

Henry JB. *Clinical Diagnosis and Management by Laboratory Methods*, 19th ed. Philadelphia: WB Saunders; 1996.

Howanitz JH, Howanitz PJ, eds. *Laboratory Medicine: Test Selection and Interpretation*. New York: Churchill Livingstone; 1991.

McClatchey KD. *Clinical Laboratory Medicine*. Baltimore: Williams & Wilkins; 1994.

Noe DA, Rock RC, eds. *Laboratory Medicine: The Selection and Interpretation of Clinical Laboratory Studies*. Baltimore: Williams & Wilkins; 1994.

Strasinger SK. *Urinalysis and Body Fluids*. 2nd ed. Philadelphia: FA Davis; 1989.

NCCLS consensus procedures include an appeals process that is described in detail in Section 9.0 of the Administrative Procedures. For further information contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Committee Responses

GP16-A: *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline*

General

1. GP16 is not extensive enough: it contains no microbiological analytical methods and has somewhat neglected current developments in the field, especially in cellular morphology and specific protein analysis. It also lacks recommendations for efficient strategies. My view is that a guideline should be delineated on the basis of analyses done from the same urine specimen in the clinical situation needing urinalysis (suspicion of urinary tract infection or screening for renal disease), not according to disciplines.
 - **The focus of this guideline relates to urine collection and performance of the traditional routine chemical and microscopic urinalysis. Algorithmic approaches to evaluation of urine samples with respect to potential screening by dipstick with subsequent performance or nonperformance of culture is beyond the scope of this guideline.**
2. Inclusion of pregnancy testing information would be beneficial.
 - **The focus of this guideline relates to urine collection and performance of the traditional routine chemical and microscopic urinalysis. This immunologically detected analyte is beyond the scope of this guideline.**

Section 2.3.1

3. The standard says that two levels must be run each day. A good case can be made that these dipsticks are very stable and that it is a waste of resources to test these each day. Certainly they need to be tested upon opening and, depending upon how quick they are used, probably weekly would be sufficient. It is rare for a dipstick control to be out, and when it is, it usually is because of a bad lot or damage in transit rather than degradation on site. A requirement to run two controls a day to be in compliance with NCCLS standards could drive some providers out of the market to the detriment of patient care.
 - **The committee agrees with the comment. The previous recommendation for two levels of control has been replaced with “Controls should be tested at a frequency defined by the laboratory, related to workload. For example, a laboratory consuming one container of dipsticks over a month may choose to perform weekly QC, while a laboratory using several containers of dipsticks per day may perform one set of QC specimens per container.”**

Section 3.4

4. The third paragraph, last sentence (For specimens containing... substances) is not coherent.
 - **The committee reviewed the sentence and believes its intent is clear.**

5. In the fifth paragraph, revise the fifth and sixth sentences to: “Such devices offer the advantage of automation and excellent correlation with gravimetric measurement, without the need to correct for glucose or protein content or to clarify cloudy specimens.”

- **The proposed revision was incorporated.**

Section 5

6. We oppose the opinion expressed in the first paragraph. It borders malpractice (if it isn't so) not to perform microscopy.

- **The committee believes that use of the term “malpractice” is inappropriate, inasmuch as this guideline does not dictate practice. Rather, it simply references the literature discussing omission of microscopies, and offers more than one practice option.**

Section 5.3

7. If people follow this guideline they will not have any time to get the work done. For example, the “unit of vol” approved for microscopy has never found its way into routine clinical practice. It is just not all that clinically useful.

- **Rather than stating, “It is recommended that laboratories use standardized...”, the wording has been revised to read, “Laboratories may wish to consider use of standardized commercial systems...”.**

8. During literature searches, no references were found to document the traditionally used times and speeds of centrifugation. That is, no data whatsoever were found to support the necessity or even the adequacy of the conditions which are not “recommended” in the document. Our experimental work showed that urine sediments could be prepared at much higher speeds and in much shorter times. This was consistent with work done by other manufacturers, as well as with our work with the high-speed centrifuging of blood.

- **These values have been used for decades, and are not mandatory. Consistency within and across laboratories is the clinically important issue.**

9. The following matter is equally important: the document refers to “standardized commercial systems.” However, there is effectively only one “standardized commercial system(s)” readily available to the clinical laboratory that meets the specific requirements in the document (e.g., Section 5.3.4 “... special tubes or pipets to retain a specific volume...”; Section 5.3.5 “...slide with chambers...”). Indeed, an unfair competitive advantage has been granted as well, over other “standardized commercial systems.” It is essential that Section 5.3 be rewritten to accommodate these other, tested methodologies and equipment.

- **The wording is changed from “recommended” to “may wish to consider.”**

Section 5.3.6 (now Section 5.2.6)

10. I am not aware of this procedure being used anywhere in the US. It may be occurring in some research laboratory, but it certainly doesn't add value because of the clinical decision limits used for this test.

The recommended procedure for examining and calculating the urine sediment is time consuming and not cost-effective for clinical laboratories, including POLs. Reporting of microscopic elements in

units “per HPF” or “per LPF” has significance to the physician sufficient to provide the diagnosis and treatment information relative to the results. More quantitative information would be sought through further testing when required. The quantitation in units/mL is not required for reliable results. Efforts to quantitate a test [analyte] beyond its clinical significance only increases the cost of the relevant information acquired.

- **The quantitative approach outlined in Section 5.2.6 is not mandatory, but simply an attempt to provide more rigorous information comparable to automated microscopy systems. Many laboratories simply place a “drop” of sediment on a slide and semiquantitatively express the concentrations of morphologic elements “per high-power field (HPF)” or “per low-power field (LPF).” This approach, while less precise, is clinically adequate in most situations.**

Section 8

11. There is no mention acknowledging the regulations governing transport of diagnostic or infectious materials. The International Air Transport Association (IATA) recently revised their guidelines (Dangerous Goods Regulations, 36th Edition) which specifically affected the transport of infectious specimens. Briefly, the regulations indicate that for specimens known to contain an infectious entity and the entity can be identified, specialized documentation (Shipping Declaration) and U.N. packaging is required. There are different recommendations on packaging when specimens are undergoing diagnostic testing and there is no knowledge of an infectious entity. I recommend the committee consider incorporation of the appropriate transport regulations into this section.

- **Laboratories must observe all applicable local regulations for transport of materials with potential biological and chemical hazards.**

Section 8.3.2

12. It is generally not good practice to label a specimen container **before** the specimen has been procured. A greater chance of patient/specimen misidentifications exists. Also, depending on the accuracy of the collection, the label may be destroyed during collection.

- **The committee disagrees. Labeling after collection is more likely to produce unlabeled specimens, a more common event experienced by receiving laboratories.**

Sections 8.4.5.1 and 8.4.5.2

13. “Man” and “Woman” should be changed to “Male” and “Female.” Many children are capable of collecting specimens themselves, yet do not qualify as “men” or “women.”

- **The committee agrees, and the designations are changed.**

Section 8.6.6

14. This section should read “place labels on the container, not on the closure or the lid.” This will prevent specimen misidentifications if more than one urine container is open at a time.

- **We consider “lid” to be synonymous with “closure,” and no change is needed.**

Section 8.8.1

15. I suggest to add a section on microscopic specimen acceptability to Section 8.8.1 (or elsewhere if more appropriate), such as: “Laboratories which perform microscopic urinalysis may wish to develop

criteria for identifying suboptimal specimens based upon presence of common microscopic contaminants (e.g., the presence of large numbers of squamous epithelial cells, or exogenous fibers or “clue cells” would indicate a suboptimal specimen in which other microscopic results such as the presence of bacteria may be suspect).”

- **A new paragraph has been added to Section 8.8.2 along the suggested lines.**

Section 9.1.3

16. Addition of preservative to the urine collection container before collection is not necessary in most instances. General practice allows collection to be made in an unpreserved container, and then preservative added by clinical personnel postcollection. This reduces the possible harm to patients and family members while the container is in their possession.

- **For routine urinalyses involving small volumes (e.g., 12 mL; see Section 3.2), preservatives are not employed. Section 9 deals exclusively with 24-hour collections, where preservatives may be employed. For such preservatives to be effective, they must be in the container before specimen collection.**

Summary of Delegate Comments and Responses

GP16-A2: *Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition*

Section 2.1.6

1. Section 2.1.6 should be updated to include commonly used and well-validated UA and UC collection tubes. For example, B-D gray top urine culture transport is an FDA-approved device for transporting urine at room temperature. Samples are stable for up to 72 hours for most common pathogens and contaminants.
- **Text has been added to indicate that commercially available systems should first be evaluated by the laboratory. Such systems, while perhaps useful for some analytes, may have limitations for specific urine tests.**

Section 2.2.2(3)

2. Cleaning also minimizes possible cross-contamination.
- **A sentence has been added to address the commenter's concern.**

Sections 3.2, 4.1, and 5.1

3. Much of the same information is repeated in Sections 3.2, 4.1, and 5.1, but each section is called something different or inconsistent.
- **Sections 4.1 and 5.1 have been deleted, and their contents moved to Section 3.2, with elimination of redundant text.**

Table

4. The concentration of preservatives is preferably mentioned.
- **This table is intended to be illustrative only. The specific concentrations or amounts of additives may vary according to the testing laboratory, and laboratories not listed may have different recommendations. Also, these recommendations may change from time to time, as indicated in the Notes at the beginning of the table.**

Summary of Comments

5. The response to Comment 16 is partially true. For common urinary calculus components, addition of preservative later allows a single collection to be used for multiple analytes (Cf. Ng, et al. *Clin Chem.* 1984;30:467).
- **Preanalytic issues for specialized tests such as urine calculi analysis are beyond the scope of this document.**

Related NCCLS Publications*

- C28-A2** **How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition (2000).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.
- GP2-A3** **Clinical Laboratory Technical Procedure Manuals—Third Edition; Approved Guideline (1996).** This document provides guidance for the patient-testing community by addressing the design, preparation, maintenance, and use of paper or electronic technical procedure manuals.
- M29-A** **Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline (1997).** A consolidation of M29-T2 and I17-P, 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 instruments and materials; and recommendations for the management of blood-borne exposure.
- GP16-T-V1** **Urinalysis – The Inside Story: Collection.** This videotape demonstrates proper urine collection procedures including handling, labeling, and transporting the specimens. It describes and illustrates random, clean catch, and timed urine specimens; self, supervised, and assisted specimen collection; proper collection containers and specimen labeling; proper specimen storage; use of preservatives; and specimen transport. The GP16-A guideline accompanies the videotape, along with laminated summary sheets.
- GP16-T-V2** **Urinalysis – The Inside Story: Evaluation.** This video provides an overview of equipment, proper techniques, and quality that must be maintained to ensure accurate results of routine urinalysis. It also explains proper working conditions, criteria for a suitable urine specimen, and guidelines for completing forms; physical examination of a sample; chemical characteristics, use of reagent strips, and confirmatory tests; microscopic evaluation including performance criteria, sample preparation, and examination of sediment entities; and quality assurance procedures such as recordkeeping, equipment maintenance, continuing education, and proficiency testing. The GP16-A guideline accompanies the videotape, along with laminated summary sheets.
- 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).
- T/DM8-A** **Urine Drug Testing in the Clinical Laboratory; Approved Guideline (1999).** This guideline addresses the development of procedures for urine analysis to determine the presence of certain controlled substances. Specimen collection and processing, methods of analysis, quality assurance, and reporting of results are also described.

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

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 1-56238-448-1

