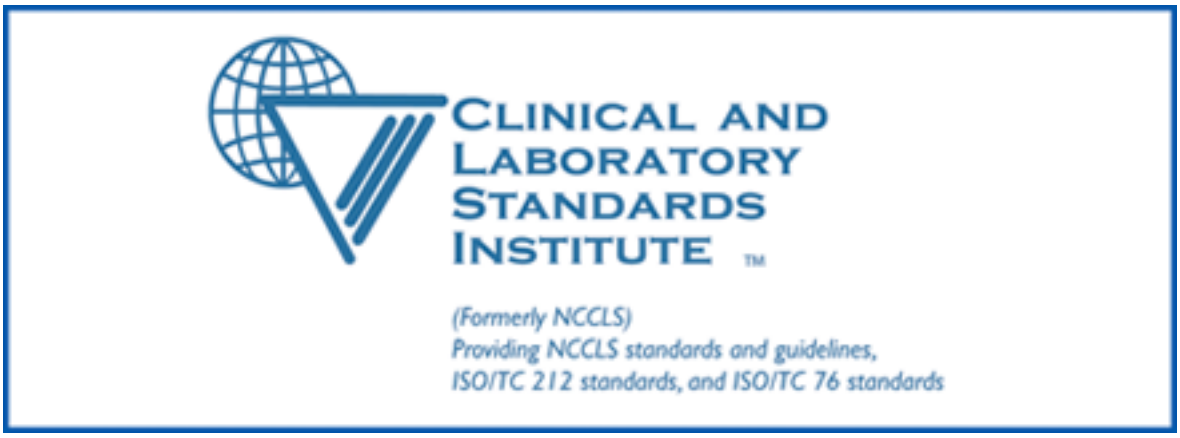
GP2-A4
Vol. 22 No. 5

Replaces GP2-A3
Vol. 16 No. 15

Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition



This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.

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

NCCLS

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

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

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

PUBLICATIONS

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

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

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

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

CONSENSUS PROCESS

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

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

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

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

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

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

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

COMMENTS

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

VOLUNTEER PARTICIPATION

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

Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition

Abstract

Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (NCCLS document GP2-A4) presents the important components of writing and managing procedures for the clinical laboratory. This guideline describes common and specific sections that should be included when developing laboratory procedures. Several examples of procedures for preanalytic, analytic, and postanalytic laboratory activities are provided in the form of appendixes; such appendixes are simply illustrative, and not prescriptive.

NCCLS. *Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition*. NCCLS document GP2-A4 (ISBN 1-56238-458-9). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2002.

GP2-A4
ISBN 1-56238-458-9
ISSN 0273-3099

Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition

Volume 22 Number 5

Lucia M. Berte, MA, MT(ASCP) SBB, DLM; CQA(ASQ)CQMgr
Beverly J. Charlton, CLC(AMT)
Barb Kirkley, MT(ASCP)
Jennifer Schiffgens, MBA, MT(ASCP)
Joyce I. Wilson, MS, MT(ASCP)
Sheila M. Woodcock, MLT, ART, MBA

Suggested Citation

(NCCLS. *Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition.* NCCLS document GP2-A4 [ISBN 1-56238-458-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.)

Proposed Guideline
May 1980

Tentative Guideline
June 1981

Approved Guideline
February 1984

Approved Guideline—Second Edition
July 1992

Approved Guideline—Third Edition
December 1996

Approved Guideline—Fourth Edition
April 2002

ISBN 1-56238-458-9
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**
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, MT(ASCP)	University of Maryland Medical System Baltimore, Maryland
Robert E. Moore, Ph.D., DABCC	Consulting & Research, Inc. Hartford, Connecticut
Jennifer Schiffgens, MBA, MT(ASCP)	Specialty Laboratories Santa Monica, California
Daniel W. Tholen, M.S.	Statistical Services Traverse City, Michigan
Marla Thomas	Litton Pathology Associates Blue Springs, Missouri

Advisors (Continued)

Eleanor M. Travers, M.D.	Department of Veterans Affairs Medical Ctr. Annapolis, Maryland

Working Group on Technical Procedure Manuals

Lucia Berte, MA, MT(ASCP) SBB, DLM; CQA(ASQ)CQMgr	Quality Systems Consultant Denver, Colorado
Beverly J. Charlton, CLC(AMT)	University of Pittsburgh Medical Center Pittsburgh, Pennsylvania
Barb Kirkley, MT(ASCP)	Cleveland Clinic Foundation Cleveland, Ohio
Jennifer Schiffgens, MBA, MT(ASCP)	Specialty Laboratories Santa Monica, California
Joyce I. Wilson, MS, MT(ASCP)	University of Alabama at Birmingham Hospital Birmingham, Alabama
Sheila M. Woodcock, MLT, ART, MBA	QSE Consulting Nova Scotia, Canada
Beth Ann Wise, MT(ASCP), M.S.Ed. *Staff Liaison*	NCCLS Wayne, Pennsylvania
Patrice E. Polgar *Editor*	NCCLS Wayne, Pennsylvania
Donna M. Wilhelm *Assistant Editor*	NCCLS Wayne, Pennsylvania

Acknowledgements

The Area Committee on General Laboratory Practices would like to acknowledge the participation of the following persons in the review of *Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition*:

Joan Carlson, MLT, BSc. (MLS)	University of Alberta Hospital Lab.
Christine Flaherty, MHA, MT(ASCP)	Sutter Health
Mary Hopper, MA, MT(ASCP)	Mayo Clinic
Peggy Stupca, MS, CLSp(CG) and CL Sup	Mayo Clinic
Nita Sudderth, BS, MT(ASCP)	UroCor, Inc.

Active Membership
(as of 1 April 2002)

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.
Roche Diagnostics, Inc.

Professional Members

AISAR-Associazione Italiana per lo Studio degli
American Academy of Family Physicians
American Association for Clinical Chemistry
American Association for Respiratory Care
American Chemical Society
American Medical Technologists
American Public Health Association
American Society for Clinical Laboratory Science
American Society of Hematology
American Society for Microbiology
American Type Culture Collection, Inc.
Asociación Española Primera de Socorros (Uruguay)
Asociacion Mexicana de Bioquimica Clinica A.C.
Assn. of Public Health Laboratories
Assoc. Micro. Clinici Italiani-A.M.C.L.I.
British Society for Antimicrobial Chemotherapy
CADIME-Camara De Instituciones De Diagnostico Medico
Canadian Society for Medical Laboratory Science—Société Canadienne de Science de Laboratoire Médical
Clinical Laboratory Management Association
COLA
College of American Pathologists
College of Medical Laboratory Technologists of Ontario
College of Physicians and Surgeons of Saskatchewan
ESCMID
Fundación Bioquímica Argentina
International Association of Medical Laboratory Technologists
International Council for Standardization in Haematology
International Federation of Clinical Chemistry
Italian Society of Clinical Biochemistry and Clinical Molecular Biology
Japan Society of Clinical Chemistry
Japanese Committee for Clinical Laboratory Standards
Joint Commission on Accreditation of Healthcare Organizations
National Academy of Clinical Biochemistry
National Society for Histotechnology, Inc.
Ontario Medical Association Quality Management Program-Laboratory Service
RCPA Quality Assurance Programs PTY Limited
Sociedade Brasileira de Analises Clinicas
Sociedade Brasileira de Patologia Clinica
Sociedad Espanola de Bioquimica Clinica y Patologia Molecular
Turkish Society of Microbiology

Government Members

Association of Public Health Laboratories
Armed Forces Institute of Pathology
BC Centre for Disease Control
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services/CLIA Program
Centers for Medicare & Medicaid Services
Chinese Committee for Clinical Laboratory Standards
Commonwealth of Pennsylvania Bureau of Laboratories
Department of Veterans Affairs
Deutsches Institut für Normung (DIN)
FDA Center for Devices and Radiological Health
FDA Center for Veterinary Medicine
FDA Division of Anti-Infective Drug Products
Health Care Financing Administration/CLIA Program
Health Care Financing Administration
Iowa State Hygienic Laboratory
Massachusetts Department of Public Health Laboratories
National Association of Testing Authorities – Australia
National Center of Infectious and Parasitic Diseases (Bulgaria)
National Health Laboratory Service (South Africa)
National Institute of Standards and Technology
New York State Department of Health
Ohio Department of Health
Ontario Ministry of Health
Pennsylvania Dept. of Health
Saskatchewan Health-Provincial Laboratory
Scientific Institute of Public Health; Belgium Ministry of Social Affairs, Public Health and the Environment
Swedish Institute for Infectious Disease Control
Thailand Department of Medical Sciences

Industry Members

AB Biodisk
Abbott Laboratories
Abbott Laboratories, MediSense Products
Acrometrix Corporation
Advanced Medicine, Inc.
Agilent Technologies, Inc.
Ammirati Regulatory Consulting
Anaerobe Systems
Asséssor
AstraZeneca
Aventis
Axis-Shield POC AS
Bayer Corporation – Elkhart, IN

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

Trade Associations

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

Associate Active Members

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

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

Laboratory Corporation of America (NJ)
Laboratory Corporation of America (MO)
LAC and USC Healthcare Network (CA)
Lakeland Regional Medical Center (FL)
Lancaster General Hospital (PA)
Langley Air Force Base (VA)
LeBonheur Children's Medical Center (TN)
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)
Malcolm Grow USAF Medical Center (MD)
Manitoba Health (Winnipeg, Canada)
Martin Luther King/Drew Medical Center (CA)
Massachusetts General Hospital (Microbiology Laboratory)
MDS Metro Laboratory Services (Burnaby, BC, Canada)
Medical College of Virginia Hospital
Medicare/Medicaid Certification, State of North Carolina
Memorial Medical Center (IL)
Memorial Medical Center (LA) Jefferson Davis Hwy
Memorial Medical Center (LA) Napoleon Avenue
Mescalero Indian Hospital (NM)
Methodist Hospital (TX)
Methodist Hospitals of Memphis (TN)
MetroHealth Medical Center (OH)
Michigan Department of Community Health
Mississippi Baptist Medical Center
Monte Tabor – Centro Italo - Brazileiro de Promocao (Brazil)
Montreal Children's Hospital (Canada)
Montreal General Hospital (Canada)
MRL Pharmaceutical Services, Inc. (VA)
MRL Reference Laboratory (CA)
Nassau County Medical Center (NY)
National Institutes of Health (MD)
Naval Surface Warfare Center (IN)
Nebraska Health System
New Britain General Hospital (CT)
New England Fertility Institute (CT)
North Carolina State Laboratory of Public Health
Northern Indiana Education Foundation
North Kansas City Hospital (MO)
North Shore – Long Island Jewish Health System Laboratories (NY)
Northwestern Memorial Hospital (IL)
O.L. Vrouwziekenhuis (Belgium)
Ordre professionnel des technologists médicaux du Québec
Ospedali Riuniti (Italy)
The Ottawa Hospital (Ottawa, ON, Canada)
Our Lady of Lourdes Hospital (NJ)
Our Lady of the Resurrection Medical Center (IL)
Pathology and Cytology Laboratories, Inc. (KY)
The Permanente Medical Group (CA)
Piedmont Hospital (GA)
Pikeville Methodist Hospital (KY)
Pocono Hospital (PA)
Presbyterian Hospital of Dallas (TX)
Queen Elizabeth Hospital (Prince Edward Island, Canada)
Queensland Health Pathology Services (Australia)
Quest Diagnostics Incorporated (CA)
Quintiles Laboratories, Ltd. (GA)
Regions Hospital
Reid Hospital & Health Care Services (IN)
Research Medical Center (MO)
Rex Healthcare (NC)
Rhode Island Department of Health Laboratories
Riyadh Armed Forces Hospital (Saudi Arabia)
Royal Columbian Hospital (New Westminster, BC, Canada)
Sacred Heart Hospital (MD)
Saint Mary's Regional Medical Center (NV)
St. Alexius Medical Center (ND)
St. Anthony Hospital (CO)
St. Anthony's Hospital (FL)
St. Barnabas Medical Center (NJ)
St-Eustache Hospital (Quebec, Canada)
St. Francis Medical Ctr. (CA)
St. John Hospital and Medical Center (MI)
St. John Regional Hospital (St. John, NB, Canada)
St. Joseph Hospital (NE)
St. Joseph's Hospital – Marshfield Clinic (WI)
St. Joseph Mercy Hospital (MI)
St. Luke's Regional Medical Center (IA)
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 Clara Valley Medical Center (CA)
Seoul Nat'l University Hospital (Korea)
Shanghai Center for the Clinical Laboratory (China)
South Bend Medical Foundation (IN)
Southwest Texas Methodist Hospital (TX)
South Western Area Pathology Service (Australia)
Southern Maine Medical Center
Specialty Laboratories, Inc. (CA)
Stanford Hospital and Clinics (CA)
State of Washington Department of Health
Stony Brook University Hospital (NY)
Stormont-Vail Regional Medical Center (KS)
Sun Health-Boswell Hospital (AZ)
Sunrise Hospital and Medical Center (NV)
Swedish Medical Center – Providence Campus (WA)
Tampa General Hospital (FL)
Temple University Hospital (PA)
Tenet Odessa Regional Hospital (TX)
The Toledo Hospital (OH)
Touro Infirmary (LA)
Trident Regional Medical Center (SC)

Tripler Army Medical Center (HI)
Truman Medical Center (MO)
UCSF Medical Center (CA)
UNC Hospitals (NC)
University Hospital (Gent) (Belgium)
University Hospitals of Cleveland (OH)
The University Hospitals (OK)
University of Alabama-Birmingham Hospital
University of Alberta Hospitals (Canada)
University of Colorado Health Science Center
University of Chicago Hospitals (IL)
University of Illinois Medical Center
University of the Ryukyus (Japan)
University of Texas M.D. Anderson Cancer Center
University of Virginia Medical Center
University of Washington
UZ-KUL Medical Center (Belgium)
VA (Denver) Medical Center (CO)
VA (Kansas City) Medical Center (MO)
VA (Western NY) Healthcare System
VA (San Diego) Medical Center (CA)
VA (Tuskegee) Medical Center (AL)
VA Outpatient Clinic (OH)
Vejle Hospital (Denmark)
Washington Adventist Hospital (MD)
Washoe Medical Center Laboratory (NV)
West Jefferson Medical Center (LA)
Wilford Hall Medical Center (TX)
William Beaumont Hospital (MI)
Williamsburg Community Hospital (VA)
Winn Army Community Hospital (GA)
Winnipeg Regional Health Authority (Winnipeg, Canada)
Wishard Memorial Hospital (IN)
Yonsei University College of Medicine (Korea)
York Hospital (PA)

Contents

Contents (Continued)

Foreword

Previous editions of NCCLS document GP2 have focused on essential elements to include in laboratory analytic test procedures.

This edition of GP2 has been expanded to provide:

- guidelines for writing procedures for the preanalytic, analytic, and postanalytic activities that represent the laboratory's path of workflow;
- guidelines for writing procedures specifically for multitest automated analyzers;
- an introduction to the management and control of laboratory procedure documents after they are approved for use; and
- the use of process flowcharts to depict the linkages between laboratory procedures.

The information and examples provided in this edition are also consistent with the guidance described in NCCLS document GP26—*A Quality System Model for Health Care.*

This edition of GP2 is applicable to any size laboratory, wherever it may be in the transition of its quality program from traditional quality control and quality assurance practices to the concepts of quality systems management.

Key Words

Document management, electronic procedures, laboratory procedure, procedure manual, technical procedures

Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition

1 Introduction

The laboratory should provide carefully documented instructions—in the form of procedures—for all activities that support the performance of analytic testing. These instructions provide essential information for both new and experienced employees on how to perform all their job tasks—including nontesting tasks such as collecting blood specimens and using the laboratory's computer system.

Written procedures should encompass an entire task from start to finish. Therefore, it makes sense to write separate instructions for tasks that are performed at different times by different people.

GP2-A4 is intended to be used by the following persons:

- administrative and technical personnel who write laboratory procedures;
- manufacturers; and
- educators.

2 Scope

This publication describes how to:

- identify laboratory procedures using the laboratory's operational path of workflow; and
- write procedures for preanalytic, analytic, and postanalytic laboratory activities.

In addition, this edition of GP2 provides useful information about preparing, approving, maintaining, changing, and reviewing laboratory documents.

3 Definitions[a]

Document, *n* – Any recorded item of a factual or informative nature, either paper or electronic.

Form, *n* – A paper or electronic document on which the results from the performance of a procedure or other information are captured.

Policy, *n* – A written statement of overall intentions and directions defined by those in the organization and endorsed by management.

Procedure, *n* – A specified way to perform an activity; **NOTE:** For a quality system, a procedure is a set of instructions that describe the stepwise actions to be taken to complete activities identified in processes.

Process, *n* – Set of interrelated or interacting activities that transform inputs into outputs; **NOTE:** It may be documented as flowcharts or tables that describe the path of operational workflow in the laboratory.

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

4 Path of Workflow

Laboratory work is a sequence of key processes in which the laboratory uses resources, such as people, machines, methods, and materials to transform orders for laboratory tests into results and reports for patient management. Key processes for the laboratory are referred to as the "path of workflow," which is shown in Figure 1.

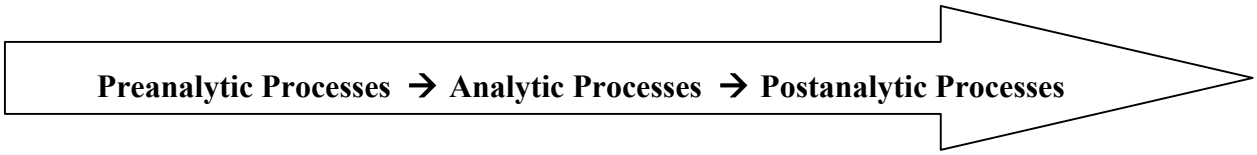


Figure 1. Laboratory Path of Workflow. Adapted from NCCLS document GP26—*A Quality System Model for Health Care.*

4.1 Preanalytic Processes

Preanalytic key processes in the path of workflow for the anatomic and clinical laboratory specialties include all activities from the time the laboratory tests are ordered through the time that the specimens are processed and delivered to the laboratory testing location or transported to reference laboratories. For anatomic pathologists and cytotechnologists, preanalytic activities extend from the time the tissue is removed or collected to the point where the slides are prepared and ready for diagnostic assessment and interpretation. The preanalytic portion of the laboratory's path of workflow is shown in Figure 2.

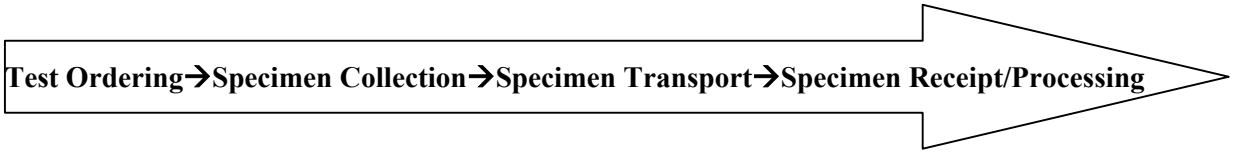


Figure 2. Laboratory Preanalytic Key Processes. Adapted from NCCLS document GP26—*A Quality System Model for Health Care.*

4.2 Analytic Processes

Analytic key processes for the clinical laboratory specialties include the activities of performing the test, verifying the validity of the test results, interpreting the findings, and recording the findings. In the anatomic pathology specialties, analytic key processes include the diagnostic assessment of the slides, peer review, and recording the findings.

Traditionally, laboratories have been functionally and often physically divided into the specific clinical disciplines of chemistry, hematology, microbiology, and transfusion service for specialized testing methods and instruments. More recently, many laboratories have segregated along manual and automated testing methods. Each laboratory or clinical discipline—however it is organized—should identify its automated and manual testing processes.

Analytic key processes for the laboratory's path of workflow are shown in Figure 3.

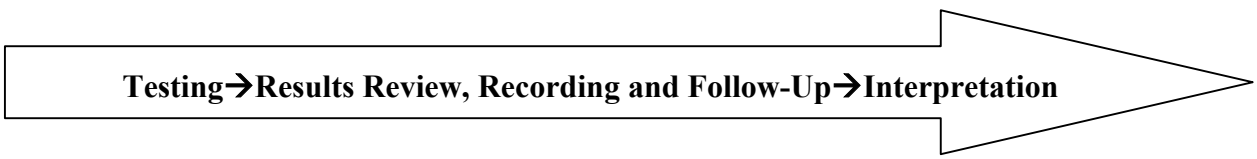


Figure 3. Laboratory Analytic Key Processes. Adapted from NCCLS document GP26—*A Quality System Model for Health Care.*

4.3 Postanalytic Processes

Postanalytic key processes in the path of workflow include activities related to reporting results and archiving results and specimen material. Postanalytic processes are shown in Figure 4.

Figure 4. Laboratory Postanalytic Key Processes. Adapted from NCCLS document GP26—*A Quality System Model for Health Care.*

5 Laboratory Procedure Contents – Common Elements

The laboratory should have procedures that describe preanalytic, analytic, and postanalytic activities in the laboratory operational workflow. The procedure document describes the series of steps to be followed by one individual to complete a specific task. Written procedures should specifically explain how to perform each activity in the laboratory's preanalytic, analytic, and postanalytic work processes.

A set of common elements should be included in each type of procedure. At a minimum, laboratory procedures should include:

- Title;
- Purpose or principle;
- Procedure instructions;
- References;
- Author; and
- Approval signatures.

Appendix A provides a tabular view of what should be included in a procedure document. Additional elements that are specific to analytic vs. nonanalytic procedures are also shown in Appendix A and defined in respective sections in this guideline. Appendixes B through F are examples of laboratory procedures. For additional information on the distinction between processes and procedures, see Appendix J.

5.1 Title

All procedures should have a title that clearly states the intent of the document. The title should be concise and descriptive, for example:

- "Blood Specimen Collection Process";
- "Performing Glucose Testing on Instrument X";
- "Waterbath Temperature Monitoring Procedure"; and
- "Preparing Gram Stain Working Solutions."

5.2 Purpose or Principle

The document should open with a section that simply states its purpose. For example, the "Purpose" section of a procedure could be stated as, "This procedure provides instructions for collecting fingerstick specimens for glucose analysis." The words, "This procedure provides instructions for …" can be standardized in the template for all procedure documents. Information regarding the theory, clinical implications of the test or test methodology, or historical background may also be included at the beginning of the document, thereby providing an educational, clinical, and scientific framework for the reader and user.

5.3 Procedure Instructions

The primary focus of a procedure is to provide instructions for "how to do" a particular task in a stepwise fashion—for example, the steps involved in verifying patient identification at the time of blood specimen collection.

5.4 References

Procedures should include the references that were used as the source of the information, when applicable. The references may originate from any of the following:

- manufacturer's product literature;
- text books;
- published standards and guidelines;
- laboratory policy manuals;
- laboratory information technology manuals;
- unpublished information obtained from experts in the field; and
- applicable regulations.

References should be listed in a standard medical format.

5.5 Author

The author(s) of the document should be noted. The laboratory has the option of including author information directly on the document, or on another document that can be referenced to the specific document. If the laboratory chooses to use a separate document to record the author, a mechanism should be in place that enables the referencing of the author back to the appropriate specific document.

5.6 Approval Signatures

There should be evidence that the procedure has been approved by the appropriate individual(s). (Note: Document approval by an appropriate individual is a requirement of regulatory and accrediting agencies in some countries.) The laboratory has the option of including signature approval information directly on the document, or on another document that can be referenced to the specific document. If the laboratory chooses to use a separate document to record signature approvals, a mechanism should be in place that

enables the referencing of the approval signature back to the specific document. Guidance for this approach to approval signatures is provided in Section 9.2.

6 Procedure Documents – Specific for the Path of Workflow

6.1 Preanalytic Procedures

Preanalytic procedures provide the instructions for all activities of laboratory workflow that take place before sample analysis. The laboratory should have separate written procedures for preanalytic activities, because they may be performed by nonlaboratory as well as laboratory persons at different times in the preanalytic work flow.

Preanalytic procedures include those for:

- test ordering—instructions for entering laboratory test orders into a computer system or completing paper requisitions including verification of clinical orders;
- specimen collection—instructions for identifying patients, collecting blood and nonblood specimens, and labeling collected specimens;
- specimen transport—instructions for transporting specimens to the laboratory, such as through the pneumatic tube system; and
- specimen processing—instructions for receiving and accessioning specimens in the laboratory, any storage or processing before delivery at the testing section, and any preparations for preparing specimens to be transported to other laboratories for testing (e.g., reference laboratories).

In addition to the elements common to all documents described in Section 5, preanalytic procedures should contain the following types of information; however, this information should be included only where it is needed to perform that procedure.

- Patient preparation—in procedures for specimen collection;
- Specimen collection—in procedures for collection techniques for blood and nonblood specimens;
- Required equipment and forms—in all preanalytic procedures where equipment and forms are used;
- Safety—general or specific instructions as described below;
- Specimen handling requirements—instructions for handling collected specimens during transport to the laboratory receiving area;
- Specimen storage requirements—instructions for where and how to store specimens before testing; and
- Problems or pitfalls.

6.1.1 Patient Preparation

Where applicable, preanalytic specimen collection procedures should include information about patient preparation such as instructions for:

- dietary requirements (e.g., fasting and special diets);
- timed testing (e.g., glucose tolerance, therapeutic drug monitoring); and
- aseptic techniques (e.g., when drawing blood cultures).

6.1.2 Specimen Collection

Where applicable, preanalytic specimen collection procedures should include information about specimen collection techniques that are:

- age-specific;
- sex-specific (e.g., clean-catch urine); and
- collection site-specific (e.g., the presence of intravenous lines, and alternatives to the antecubital collection site [such as capillary puncture, arterial puncture, line draw, etc.]).

6.1.3 Required Equipment and Forms

Where applicable, preanalytic procedures should include information about the required equipment to be used and forms needed for the procedure. For example:

- Test requisitions and labels;
- Specimen collection devices and materials (e.g., blood collection tubes, media, swabs);
- Specimen containers; and
- Instruments (tourniquets, hemostats, scissors, etc.).

6.1.4 Safety

Preanalytic procedures should include safety instructions for the collection and handling of biohazardous specimens. The instructions should be written for the intended readership—for example, those who handle the specimen such as nursing, transport, or laboratory personnel. If no special precautions are required, preanalytic procedures may refer the user to the safety policy manual for general safety requirements.

A "Special Safety Precautions" section should be included in preanalytic procedures when additional safety requirements—beyond the basic handling of biologic and other hazardous materials—are necessary (see NCCLS documents M29—*Protection of Laboratory Workers from Occupationally Acquired Infections* and GP17—*Clinical Laboratory Safety*.)

6.1.5 Specimen Handling Requirements

Where applicable, preanalytic procedures should include information about specimen handling requirements. This information includes:

- special transport requirements (e.g., on ice, within a certain time, in appropriate containers, etc.);
- safety precautions that are to be taken with potentially infectious specimens; and

- special transport requirements for dangerous/hazardous materials.

6.1.6 Specimen Storage Requirements

Where applicable, preanalytic procedures should include requirements for specimen storage before testing. This information should include:

- locations where specimens are stored before testing;
- acceptable storage temperatures; and
- stability of the specimen over time, where timelines might affect testing.

6.1.7 Problems or Pitfalls

Preanalytic procedure documents should include information about problems or pitfalls that may occur in the performance of the procedure. Where applicable, users should be referred to other procedures. Examples of this kind of information include what to do when:

- received specimens are unacceptable;
- the computer is "down;" and
- patients present for testing without a proper order.

6.1.8 Preanalytic Computer Activities

Procedures that provide instructions for using the laboratory's information system for preanalytic activities should be designed around the respective prompts in a computer program's sequences.

6.2 Analytic Procedures

Analytic procedures cover the activities from the time the specimen reaches the testing area to the time results are reviewed and preliminary interpretations are made.

Analytic procedures for manual tests differ from procedures for automated testing. Manual testing procedures are usually method-specific. Gram stain, direct antiglobulin test, and erythrocyte sedimentation rate are traditional examples of manual method-based analytic procedures. Automated testing procedures are represented by the menu of multiple test methods that can be performed on a single instrument or analyzer (such as for coagulation or chemistry). In addition, test results provided by both manual and automated methods can be qualitative, semiquantitative, or quantitative. The attributes of manual vs. automated testing, and qualitative vs. quantitative results, influence the sections that should be included in each type of procedure. The differences between procedures for manual and automated testing are described in the sections that follow.

6.2.1 Elements of Manual Analytic Method-Based Procedures

In addition to the elements that are common to all documents, analytic procedure documents should include the following sections, wherever applicable:

- Specimen Information;
- Test Method Instructions;

- Reagents and/or Media;
- Supplies;
- Special Safety Precautions;
- Equipment Calibration and Maintenance;
- Quality Control;
- Calculations (for quantitative procedures only);
- Expected Values;
- Interpretation of Results; and
- Method Limitations.

6.2.1.1 Specimen Information

The analytic procedure should include the following information regarding the specimen required for the test:

- specimen type;
- specimen source;
- amount of specimen required, including minimum requirements;
- acceptable collection containers and sterility requirements;
- specimen stability and storage requirements; and
- criteria for unacceptable specimens and follow-up action.

6.2.1.2 Test Method Instructions

The test method should be reflected in the title of the procedure document. For example:

- "Antibody Screen by Gel Technique;"
- "Microscopic Urinalysis by Phase Microscopy;"
- "Gram Stain Procedure;" and
- "Fingerstick Glucose Testing on the XYZ Instrument."

This section should present the stepwise instructions for performing the test by the method described in the package insert or operator's manual. If procedure instructions taken from manufacturer's literature are altered or deleted, this may change the test method performance and, therefore, appropriate validation procedures must be performed.

See Appendixes B through F for examples of procedure instructions.

6.2.1.3 Reagents and Media

The procedure should include a list of the reagents or media used in performing the procedure.

An analytic test procedure should provide instructions for preparing reagents only when the reagents are to be prepared each time the procedure is performed. Instructions for stock and working solutions of reagents and stains that are prepared at times other than performance of the actual procedure should be written into separate procedures. For example, the "Reagents" section in a procedure that provides instructions for performing a Gram stain should only list the reagents used to stain smear specimens. There should be separate procedures for preparing, labeling, and storing the different stock and working solutions. This reduces the length of a procedure and puts reagent "recipes" in a separate place where they can be easily referenced.

Because reagent receipt does not take place at the time of performing analytic testing, a separate written procedure is needed for receiving, inspecting, and appropriately testing laboratory reagents and test kits.

Procedures for reagent and media preparation should include the following:

- list of required reagents and/or media;
- reagent name or chemical formula;
- acceptable reagent grade;
- special safety requirements (e.g., general category or class of hazard; special handling instructions);
- step-by-step instructions for reagent or media preparation;
- degree of accuracy, and any special handling instructions for measuring devices;
- QC of reagents or media (e.g., pH testing or visual assessment);
- labeling requirements, including expiration;
- storage requirements, including containers and stability; and
- regulatory classifications where applicable.

6.2.1.4 Supplies

The procedure should include a list of the supplies used in performing the procedure. Examples of supplies that could be listed include:

- disposable pipettes;
- pipette tips;
- gauze;
- bibulous paper;

- immersion oil;
- test tube rack;
- test tubes;
- scissors; and
- other applicable supplies.

6.2.1.5 Special Safety Precautions

All laboratory personnel must receive training about precautions taken when handling biologic and other hazardous materials. Because all laboratory testing uses biologic specimens, it is redundant to repeat routine safety precautions, such as the requirement for wearing of gowns and gloves in every procedure. If no special precautions are required, the analytic procedure may refer the user to the safety policy manual for general safety requirements.

A special safety precautions section should be included in the analytic procedure when additional safety requirements—beyond the basic handling of biologic and other hazardous materials—are necessary. The special safety precautions section should include the following:

- Engineering controls (e.g., use of biohazard cabinetry);
- Personal protective equipment (e.g., respirators, gloves, and face shields); and
- Work practice controls (e.g., beginning a step only after certain conditions have been met or precautions have been taken).

6.2.1.6 Equipment Calibration and Maintenance

Instructions for calibration and maintenance should be included in the test performance procedure only for those activities that are performed each time the procedure is done. Instructions for equipment calibration, calibration verification, and maintenance that are performed at a time remote from the use of such equipment in the performance of a test procedure should be written as separate procedures. Directions for the preparation of calibration standards should be included in a separate calibration procedure.

Procedures for equipment calibration and maintenance should include the following information:

Calibration:

- Schedule for performing calibration—daily, weekly, monthly, semiannually;
- Schedule for performing calibration verifications (which are the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results);
- Calibration material specifications;
- Calibration material preparation and storage;

- Source of the calibration material;
- Step-by-step instructions for performing the calibration, including expected instrument readings;
- Troubleshooting guidelines; and
- Documentation methods and storage requirements for calibration data.

Maintenance:

- Schedule for performing maintenance—daily, weekly, monthly, semiannually, annually;
- Step-by-step instructions for performing maintenance activities;
- Troubleshooting guidelines; and
- Documentation methods and storage requirements for maintenance data.

6.2.1.7 Quality Control (QC)

Instructions for QC should be included in the test performance procedure only when the QC must be performed each time the test procedure is performed. Instructions for performing QC when it is performed at a time remote from the performance of the test procedure should be written as a separate procedure. For example, the instructions for testing the positive and negative controls for a rheumatoid factor test should be in the rheumatoid factor test procedure, because these controls are tested every time a batch of specimens is tested. On the other hand, the instructions for performing the QC of anti-A, anti-B, and anti-D reagents should be in a procedure separate from that of testing patients for ABO and Rh, because reagent QC testing is performed and recorded separately from patient testing.

QC procedures should include the following information:

- type of quality control material to be used;
- instructions for preparation and handling of control materials;
- frequency with which controls must be run;
- number of levels of controls to use;
- the location of QC expected values and/or ranges;
- explanation of control criteria (e.g., accept or reject runs or batch criteria);
- corrective action to be taken if controls exceed expected criteria;
- instructions for documentation of QC data; and
- alternate QC measures, such as procedural controls or clinical correlation.

Because proficiency testing specimens are to be handled as regular patient specimens, they do not need to be specifically mentioned in each analytic procedure. However, there should be separate written instructions for:

- receiving proficiency testing samples in the laboratory
- distributing and rotating samples for testing
- transcribing and submitting results
- reviewing reports, and
- taking any necessary follow-up action, as well as documenting such action.

6.2.1.8 Calculations for Quantitative Procedures

Quantitative analytic procedures should include the equations for calculations when they are applicable to the test. The calculation section should include:

- the full equation;
- step-by-step instructions to solve the equation; and
- an example of how to solve the equation.

This section may be omitted from qualitative analytic procedures (e.g., dipstick tests, slide tests, immunohematology tests, etc.)

Because verification of calculations made by the computer does not take place at the time of performing analytic testing, a separate written procedure is needed for periodically verifying calculations performed by the laboratory information system.

6.2.1.9 Expected Values

The analytic procedure should include the range of expected values for the analyte or test result. The expected values should be the reference range relevant to the:

- specimen type; and
- demographic variables such as sex, age, and race.

6.2.1.10 Interpretation of Results

The analytic procedure should include guidelines for interpreting test results if applicable. This section should include:

- comparison of the results to the expected values or diagnostic findings to determine if the result is normal, abnormal, or indeterminate;
- follow-up for indeterminate results;
- recognition of results that fall outside the reportable range, and reference back to the Method Limitations section; and
- recognition and follow-up of results that exceed critical limits (see Section 6.3).

6.2.1.11 Method Limitations

The analytic procedure should include details about the limitations of the test method. The limitations may be due to the method itself or interfering substances. Where applicable, the following should be included in the Method Limitations section:

- analytic sensitivity and specificity;
- reportable range;
- appropriate dilutions or reporting measures if the reporting range is exceeded; and
- interfering substances such as chemicals (e.g., preservatives) or *in vivo* substances (such as cold agglutinins or drugs).

Appendix G demonstrates a means to present this kind of information in a tabular format for easier comprehension.

6.2.2 Automated Procedures and Manufacturers' Procedure Manuals

Multitest, random-access quantitative analyzers require documents that reflect the instructions for setting up the analyzer; performing a batch of tests; performing scheduled calibration or calibration verification; performing required maintenance and function checks; and troubleshooting problems. Because automated testing is centered on preparing the instrument for testing; selecting the analytes to test; making decisions based on the values of controls and patient test results; and handling instrument problems, it is important that written procedures clearly and accurately describe what the operator needs to do and how to do it.

The laboratory may write its own procedures for performing these activities or may use instrument operators' manuals. The laboratory must review the manuals to determine if the procedures match the laboratory's practice. If there are differences, the procedures must be revised to reflect actual practice. When manufacturer procedure manuals are adopted as the written procedures, the guidance provided in this document for revision and approval should be followed.

In addition to the common elements, procedures for automated analytic testing should cover all of the information discussed in Sections 6.2.1.1 through 6.2.1.11.

Important information about analytes that are tested on analyzers can be presented in a table that summarizes this information for easy reference. An example of such a table is presented in Appendix G.

6.3 Postanalytic Procedures

Postanalytic procedures address the activities from reporting patient test results to archiving results and specimens. In addition to the common elements, postanalytic procedures should include the following, where applicable:

- how results are prioritized;
- entry of results into the laboratory reporting system;
- guidelines for notification of appropriate individuals of test results;
- archiving results and report documents; and

- specimen retention.

6.3.1 Prioritizing Results

Postanalytic procedures should include instructions for prioritizing results that:

- are normal;
- fall outside the reference range;
- exceed the critical limits;
- fall outside the reportable range (e.g., the use of greater than [>] and less than [<]); and
- use interpretative text. (Note: Examples of all text should be included in the document.)

Instructions should also be included for:

- rounding numbers; and
- the acceptable units for reporting (e.g., mL, mmol, µg, etc.).

Instructions should be included for supervisory and/or medical review of test results, where such review is required.

6.3.2 Entry of Results Into the Laboratory Reporting System

The laboratory should have postanalytic procedure documents for electronic and manual result reporting that describe all methods that are being used. These postanalytic procedures should include instructions for reporting results:

- by electronic transfer of data from an instrument or analyzer into a computer system;
- by manual entry of data into a computer system; and
- manually, on paper report forms.

Procedures that provide instructions for entering patient test results into the laboratory's information system (whether manually or by electronic transfer) should contain instructions for the user at each prompt in the computer program sequence.

Because periodic verification of the accuracy of electronic result transmission does not take place at the time of performing analytic testing, a separate written procedure is needed for periodically verifying the accuracy of electronic transmission of laboratory test results.

6.3.3 Guidelines for Notification of Appropriate Individuals of Test Results

Postanalytic procedures should include guidelines for notifying the appropriate individual(s) of results that exceed critical clinical limits. Instructions for documentation of the notification should also be included. If the laboratory has a separate written procedure for notification and documentation of notification, the postanalytic procedure may refer the user to the other procedure.

6.3.4 Archiving Results

The laboratory should have postanalytical procedures that address the archiving of patient results. The procedures should provide instructions for electronic and/or paper storage of patient records. Data storage procedures should provide instructions for the storage of patient records in a manner that prevents loss, damage, or unauthorized access, and promotes easy retrieval.

In addition, the laboratory should have a schedule for the duration of patient record retention as defined by regulatory or accreditation requirements, and organizational needs.

6.3.5 Specimen Retention

Postanalytic procedures for specimen retention should include step-by-step instructions for archiving materials such as compatibility testing specimens, hematology slides, and histology and cytology tissue blocks and slides.

In addition, the laboratory should have a schedule for the duration of specimen retention as defined by regulatory or accreditation requirements, and organizational needs.

7 Procedures Manuals

Procedures manuals should be organized in a way that can be easily followed by laboratory personnel and should contain the following elements:

- table of contents;
- process descriptions (optional: see Appendix J);
- procedures; and
- associated forms.

Appendixes H and I provide examples of procedures manual content. These appendixes suggest that procedures could be organized into subgroups that represent the sequence of work activities, rather than arranging in alphabetical order, but that is entirely at the discretion of each laboratory. The organization of procedures by the sequence of work activities (i.e., work processes) makes information easier for staff to find and also provides a useful training tool for orienting new employees to "how we do it in our laboratory." An alphabetized index could also be included in the manual for easy location of individual procedures.

8 Form Documents

Forms are the blank documents (or computer screens) on which the results generated from the performance of a given procedure are recorded. Form documents should include:

- a title that describes the form's purpose;
- facility name and location;
- effective date;

- fields in which to record information generated from performing the procedure (e.g., results, interpretations, date, time, initials, etc.); and

- a means to link the form to its respective procedure document.

Examples of properly completed forms, labels, tags, and registers should be included with their respective procedures in the procedures manual.

9 Document Management

The laboratory should have a document management system in place to ensure that all documents in use are written in the approved formats, reflect the current version, and are reviewed and approved by appropriate individual(s) in a timely manner. The document management system may be either paper-based or electronic-based.

9.1 Document Identification

To facilitate the document management system, it is recommended that the laboratory have a document identification system that enables the reader to determine the type of document, its location, and how it is used.

Document identification tells the individual what type of document it is (e.g., policy, process, procedure, or form.) A combination of alpha and numeric characters can be used to identify appropriate placement or ordering of the document within the laboratory operational workflow. In addition, version identification provides a means to ensure that only the latest approved version of a laboratory document is in use. Version identification also enables the tracking of changes to documents over time. Procedure names and effective dates can also serve as identification of documents stored electronically.

Creative applications of the document identification system can be used to link documents to:

- laboratory location (e.g., in a region or system);

- laboratory section (e.g., a clinical discipline or division);

- work bench (e.g., microbiology enterics, anaerobes, respiratory, etc);

- analyzer (e.g., chemistry, hematology, or coagulation); or

- operations process (e.g., compatibility testing, blood component modification).

9.2 Master File

Each document should have a master file that contains the current and all previous versions of the document. Documents can be either stored as electronic files in “virtual” folders or as the original paper copy in a paper file folder. The master file serves as the original paper or electronic source from which working copies of the current version can be generated. The master file is the historic record of the document and includes master copies of previous versions as required. The laboratory may decide to include in the master file the signature file for all the author, reviewer, and approval signatures for each version.

9.3 Review and Approval of New Documents

Laboratory services should establish a process for the timely review and approval of new documents. This process should specify:

- who is responsible for the review (e.g., laboratory director, supervisors, senior staff, etc.);
- who has the approval authority; and
- how the review is recorded.

9.4 Review and Approval of Changes to Approved Documents

The laboratory services should have a process for the timely modification, review, and approval of formerly approved documents. The process should include the following activities:

- establishing the need for modification;
- modifying the document and any related documents that must also be changed;
- reviewing the revised document;
- approving the revisions and recording the approval;
- notifying staff of the changes; and
- providing copies of the approved, revised master document to all appropriate personnel.

Laboratory control over changes to documents provides a means to ensure that:

- only authorized changes are made to approved documents;
- all changes are reviewed and approved before being placed in service; and
- all copies of the document in use reflect the change.

All signed approvals of new and changed documents must be dated.

Appendixes K1 and K2 describe the document control process.

When changes to a particular document are made, the laboratory service should also determine what other documents will be affected by the change. This is facilitated by review of the appropriate process documents. If associated documents need to be revised, the change process should be initiated for those documents as well. One mechanism that can be used to accomplish this is to adopt the use of a document request form. The completed document change request form should then be kept in the changed document's master file.

Appendix L is an example of a document change request form for approving new documents or changing previously approved documents.

Note: This change request form has a place for signature approval of the document. If this type of form is used and retained for each document, working copies of the document do not need to be signed, because the change control process is such that only approved current versions are available to staff.

9.5 Job Aid Documents

If any additional job aids are used (such as index card files; posted diagrams, forms, or instruction sheets; wall charts; etc.), they should also be reviewed to be sure that they are current, complete, correct, and traceable to the "parent" document. If changes need to be made, a document change process should be initiated.

9.6 Annual Review of Unchanged Documents

If documents are managed using a document control process such as that described in this section, annual review is unnecessary. However, periodic review of unchanged documents may be useful to detect errors, oversights, or work practices that have diverged from the written procedures. In the absence of an effective document control process, however, annual review of documents is required.

9.7 Master Index

The master index is a spreadsheet, database, or hard copy log that lists all documents currently in use in the laboratory. The master index can be kept for the entire laboratory, or it can be subdivided into the laboratory's defined work units.

At a minimum, the elements of the master index should include document name and effective date. In addition, the master index could include a document number and version and the locations of all working copies of the document.

The master index provides laboratory staff with the means to identify the most current version of the document. Whenever a document is changed and updated to a new version, the master index should be updated.

9.8 Distribution

Revised documents should be made available to all appropriate personnel. The laboratory should have a document master index to locate the active working copies of the documents. If paper copies or non-linked electronic copies of the document are used, the master copy is used to make new working copies that are distributed to the locations listed on the master index. Old working copies should be destroyed.

9.9 Archiving, Storage, and Retention of Documents

The current version and all previous versions of a laboratory document should be stored in its respective master file. When a document is changed, the current version becomes the new master document, and the previous version is retired and archived in the master file.

Document master files must be stored in a manner that prevents loss, damage, or unauthorized access, and promotes easy retrieval. Duration of retention of archived laboratory documents is defined in regulations, accreditation requirements, and by the organization. The laboratory should have documented processes for short-term and long-term storage for both on-site and off-site locations.

Appendix A. Suggested Contents of Laboratory Procedures

	Procedure		
	Analytical		Pre- and Post-Nonanalytical
	Quantitative	Qualitative	
Section			
Purpose	X	X	X
Policy	Insert specific requirements where applicable in the document		
Reagents	X	X	
Equipment	X	X	As needed
Supplies	X	X	As needed
Specimen	X	X	
Special safety precautions	As needed	As needed	As needed
Quality control	X	X	
Procedure	X	X	X
Interpretation / Results	X	X	
Calculations	X		
Expected Values	X		
Method limitations	X	X	
Procedure notes	X	X	As needed
References	X	X	X
Related documents	Other procedures	Other procedures	Other procedures
Appendixes (forms, labels, tags, tables)	As used	As used	As used

Note: If there are separate procedures for any of these sections, then that section does not need to be included in the procedure.

Appendix B. Sample Preanalytic Procedure

Identifying the Patient for Specimen Collection Effective Date: mm/dd/yy
Document # / version #

Identifying the Patient for Specimen Collection

Purpose

This procedure provides instructions for correctly identifying patients for specimen collection.

Policy

- A patient's name and a second identifier (e.g., medical record number or date of birth) are required.
- Exceptions are not allowed.

Supplies

Patient identification band (see example in Appendix 1)

Procedure A: Inpatients

Follow the steps in the table below to properly identify inpatients.

Step	Action	
1	Ask the patient to state his or her last name when able.	
2	Verify that the patient is wearing an identification band.	
3	Follow the directions in the table below for identifying the patient.	
	If	**Then**
	there is no ID band anywhere in the room	• do not proceed, and • notify the patient's nurse. Note: During disasters or codes, refer to the emergency identification procedure.
	the ID band is attached to the bed	• do not proceed • ask the patient's nurse to identify the patient, and • ask the nurse to document the verification on the collection list, labels, or requisition.
	the ID band is present but not attached to the patient	• do not proceed, and • notify the patient's nurse.
4	Match the ID band to the requisition, collection list, or labels.	
5	*Proceed with specimen collection only when patient identification is verified.*	

Continued on next page

Appendix B. (Continued)

Identifying the Patient for Specimen Collection Effective Date: mm/dd/yy
Document # / version #

Identifying the Patient for Specimen Collection (cont.)

Procedure B: Outpatients

Follow the steps in the table below to properly identify outpatients.

<table>
<tr><th>Step</th><th colspan="2">Action</th></tr>
<tr><td>1</td><td colspan="2">Ask the patient to
• spell his or her first and last names, and
• give his/her date of birth.</td></tr>
<tr><td>2</td><td colspan="2">Verify the spelling and date of birth against the
• label, and
• requisition.</td></tr>
<tr><td>3</td><td colspan="2">Proceed with specimen collection only when patient identification is verified. If identification cannot be verified, proceed to step 4.</td></tr>
<tr><td>4</td><td colspan="2">Follow the directions in the table when steps 1 and 2 cannot be followed.</td></tr>
<tr><td></td><td>If</td><td>Then</td></tr>
<tr><td></td><td>the patient is unable to provide information for whatever reason</td><td>• get the information from a family member or caregiver, if present, or
• if not present, notify the person in charge.</td></tr>
<tr><td></td><td>the identifiers do not match</td><td>• contact the registration desk, and
• resolve the discrepancies before proceeding.</td></tr>
<tr><td></td><td>the ID band is present but not attached to the patient</td><td>• do not proceed, and
• notify the patient's nurse.</td></tr>
<tr><td>5</td><td colspan="2">Proceed with specimen collection only when patient identification is verified.</td></tr>
</table>

Related Procedures

Procedure ID. XXX: Emergency Identification Procedure

Appendixes

Appendix 1: Example of Patient Identification Band

End

Anytown Hospital Laboratory, Anytown USA 12345 Page 2 of 2
[filename and path]

Appendix C. Sample Analyzer Procedure

Loading Samples for Testing on *Instrument X* Effective Date: mm/dd/yy
Document # / version #

Loading Samples for Testing on "*Instrument X*"

Purpose This procedure provides instructions for prioritizing and loading the samples to be run on *"Instrument X."*

Procedure A: Rack Selection Use the table below to select the correct rack for loading samples.

Specimen Type	Rack Color	Rack ID	Details
Calibrator	Black	C	
Quality control	White	Q	
Serum/plasma/body fluid (not urine)	Red (stat)	10-50	Most often used for exceptional samples.
Serum/plasma/body fluid (not urine)	Gray (routine)	21-200	Most often used for: • stat • routine
CSF	Red with blue stripes	1-9	
CSF	Gray with blue stripes	1-9	
Urine	Gray with yellow stripes	10-20	

Procedure B: Loading Samples Follow the steps in the table below to load samples.

Step	Action	
1.	• Prioritize samples to be loaded 1. ER 3. Priority 2. Priority 1 4. Routine	
2.	• Load ER and Priority 1 samples into a gray rack with bar code facing the open slot. • Load ER / Priority 1 rack onto *Instrument X*.	
	If *Instrument X* is	Then
	• in operation	• load the rack into the stat position. Note: The stat position is located on the left side of the instrument.
	• "Standby" or "Rack Supply Complete"	• load racks to the front of the tray.

Continued on next page

Appendix C. (Continued)

Loading Samples for Testing on *Instrument X* Effective Date: mm/dd/yy
Document # / version #

Loading Samples for Testing on "*Instrument X,"* (cont.)

Procedure B: Loading Samples (cont.)

Step	Action
3	• Load samples such as body fluids into red racks. • Program the samples. See Procedure ID. XXX, "Manually Programming Samples, " if needed. • Load rack onto tray.
4	• Load remaining samples into the appropriate racks with bar code facing the open slot. • Load racks onto trays.
5	Load the tray into an open position on *Instrument X.* - Lift the metal flap - Remove the empty tray - Load sample tray - Lower the metal flap Note: If instrument is taking samples from track 2, instrument will not go to track 1 when finished with 2. Wait for "rack supply complete" to restart.

Procedure C: Starting *Instrument X* Operation

Follow the steps in the table below to start operation of ***Instrument X.***

Step	Action	
1	Check the status of the instrument in the upper left corner of the monitor screen.	
	If the status is	**Then**
	• in operation	• continue to load samples onto the instrument.
	• "Standby" or "Rack Supply Complete"	• touch the Start button on the monitor screen and the Start button on the following screen. Note: If instrument is taking samples from track 2, instrument will not go to track 1 when finished with 2. Wait for "rack supply complete" to restart.

Continued on next page

Appendix C. (Continued)

Loading Samples for Testing on "*Instrument X,"* (cont.)

References	Daily Operations Guide for *Instrument X*
Related Procedures	Procedure ID. XXX Manually Programming Samples
Appendixes	None

End

This example was contributed by the Central Clinical Laboratory of the Mayo Clinic Department of Laboratory Medicine and Pathology, Rochester, Minnesota.

This page is intentionally blank.

Appendix D. Sample Microbiology Procedure

Urine Culture: Reading and Interpreting Effective Date: mm/dd/yy
Document # / version #

Urine Cultures: Reading and Interpreting

Purpose

This procedure provides instructions for reading and interpreting a urine culture.

Policy

- Examine the first read of all cultures that were set up before midnight.
- For cultures set up after midnight [enter facility-specific directions here].

Procedure

Follow the steps in the table below to read and interpret urine cultures.

If there is	Then
• no growth	• reincubate an additional day, and • enter a preliminary report of "No growth at 24 hours." (See Procedure ID. XXX: Generating Reports: Preliminary and Final)
• growth of 1-3 organisms	• follow instructions in Appendix 1: Urine Culture Workup Guidelines, • follow instructions in Appendix 2: Definitive Identification and Susceptibility Criteria, and • enter a preliminary report.
• growth of 4 or more organisms	• report as [facility-specific comment on mixed flora], and • enter a final report. (See Procedure ID. XXX: Generating Reports: Preliminary and Final.)
• a urine screen policy	• [follow facility-specific requirements for reporting.]

References

Essential Procedures for Clinical Microbiology, ASM, [year]

Related Documents

Procedure ID. XXX: Generating Reports: Preliminary and Final

Appendixes

Appendix 1: Urine Culture Workup Guidelines
Appendix 2: Definitive Identification and Susceptibility Criteria

End

Anytown Hospital Laboratory, Anytown USA 12345 Page 1 of 3
[filename and path]

This example was contributed by the Microbiology Technical Work Group, Sutter Health Laboratory Integration Project, Sacramento, California.

Appendix D. (Continued)

Urine Cultures: Reading and Interpreting Effective Date: mm/dd/yy
Document # / version #

Appendix 1: Urine Culture Reading and Interpreting Guidelines

Specimen	Sex	WBCs	Species	Count	Workup	Sens
• Voided • Clean catch • Catheterized	F all ages or M < 5 years	No < 10	Single (pure isolate)	< 50 K	Descriptive ID	No
				> 50 K	Definitive ID	Yes
			Multiple	< 50 K	Descriptive ID	No
				50 – 100 K	Definitive ID predominant ≤ 2	Yes
					Descriptive others and mixed flora	No
				> 100 K	Definitive ID predominant ≤ 3	Yes
					Descriptive others and mixed flora	No
		Yes > 10	Single (pure isolate)	< 1 K	Descriptive ID	No
				> 1 K	Definitive ID	Yes
			Multiple	< 10 K	Descriptive ID	No
				10 – 50 K	Definitive ID predominant ≤ 2	Yes
					Descriptive others and mixed flora	No
				> 50 K	Definitive ID predominant ≤ 3	Yes
					Descriptive others and mixed flora	No
	M > 5 years	N/A	Single (pure isolate)		Descriptive ID	No
					Definitive ID	Yes
			Multiple		Descriptive ID	No
					Definitive ID predominant ≤ 3	Yes
					Descriptive others and mixed flora	No
Suprapubic puncture	All	N/A	All	Any count	Definitive ID	Yes

Reference

Anytown Hospital Laboratory, Anytown USA 12345
[filename and path] Page 2 of 3

Appendix D. (Continued)

Urine Cultures: Reading and Interpreting Effective Date: mm/dd/yy
Document # / version #

Appendix 2: Urine Cultures—Definitive Identification and Susceptibility Criteria

Organism Group	Description (Presumptive/Definitive Identification)	Set Up Susceptibility?
Staphylococcus	• *Staphylococcus aureus*	• yes
	• *Staphylococcus* coagulase-negative	• yes
	• *Staphylococcus saprophyticus*	• s/p [facility-specific]
Streptococcus	• beta streptococcus	• no
	• enterococcus	• s/p [facility-specific]
	• *Streptococcus viridans*	• no
Gram-positive rods	• *C. ureolyticum*	• no
	• diphtheroids	• no
	• Lactobacillus	• no
Gram-negative rods	• presumptive identification	• yes
	• definitive identification	• yes
Yeast	[facility-specific] presumptive vs. definitive	• no

Reference

Anytown Hospital Laboratory, Anytown USA 12345
[filename and path] Page 3 of 3

This page is intentionally blank.

Appendix E. Sample Transfusion Service Procedure

Weak D (D^u) Testing Effective Date: mm/dd/yy
Document # / version #

Weak D (D^u) Testing

Purpose

This procedure provides instructions for performing the Weak D (D^u) test.

Background

Weak forms of the Rho(D) antigen can be detected only after incubating the red cells with the anti-D reagent and using the antiglobulin technique.

Specimen

Test red cells
- anticoagulated (e.g., EDTA), or
- from a clot

Materials

Reagents	Supplies	Equipment
• Isotonic saline • Anti-D Reagent • IgG Antiglobulin Reagent	• 12 x 75-mm test tubes • control drop pipettes • test tube rack	• calibrated centrifuge

Quality control

Reagents must be tested each day of use with appropriate controls. Verify that testing has been performed. If not, see Procedure ID. XXX: "Daily Reagent Quality Control."

Procedure

Note: If the original direct test with the anti-D was performed by tube testing, the same tube may be used for the weak D test providing the manufacturer's directions so state. In this case, proceed directly to step 4, after recording the original anti-D tube test as negative.

Step	Action
1	Place 1 drop of anti-D serum into a clean, labeled test tube.
2	Place 1 drop of 6% albumin control reagent into a second labeled test tube.
3	Add 1 drop of a 2-5% suspension in saline of the red cells to be tested to each tube.
4	Mix and incubate both tubes for 15 minutes at 37 °C.
5	Centrifuge for the saline spin time of the calibrated centrifuge.
6	Gently resuspend the cell button and examine for agglutination.

If the test red cells are	Then
strongly agglutinated in the anti-D tube but not in the control tube,	• record the test sample as D-positive, and • do not proceed with the antiglobulin test.
not agglutinated, or results are doubtful	proceed with step 7.

Continued on next page

Appendix E. (Continued)

Weak D (D^u) Testing Effective Date: mm/dd/yy
Document # / version #

Weak D (D^u) Testing (cont.)

Procedure (cont.)

Step	Action
7	Wash the cells 3 times in the automatic cell washer.
8	Add 2 drops of anti-IgG reagent.
9	Centrifuge for the saline spin time of the calibrated centrifuge.
10	Resuspend each cell button and examine for agglutination.
11	Grade and record the test results.
12	To each tube with a negative test result, add 1 drop of IgG-sensitized (check) cells.
13	Centrifuge for the saline spin time of the calibrated centrifuge.
14	Resuspend each cell button and examine for agglutination.
15	Grade and record the test result. Note: Agglutination of the check cells confirms the presence of active antiglobulin reagent in the test mixture and indicates that the test results obtained in step 14 are valid.

Interpretation

+ = agglutination of the red cells
0 = no agglutination

Anti-D	Control	Rh interpretation
+	0	D Positive
0	0	D Negative*
+	+	Invalid Perform and interpret the Direct Antiglobulin Test Procedure ID. XXX

Result Reporting

Enter results into the computer.

References

- Manufacturer's direction circulars for anti-D
- AABB Technical Manual, current edition

Related Documents

Procedure ID. XXX: Direct Antiglobulin Test
Procedure ID. XXX: Daily Reagent Quality Control

End

Anytown Hospital Laboratory, Anytown USA 12345
[filename and path] Page 2 of 2

Appendix F. Sample Pathology Procedure

Receiving Surgical Pathology Specimens After Hours Effective Date: mm/dd/yy
Document # / version #

Receiving Surgical Pathology Specimens After Routine Business Hours

Purpose

This procedure provides instructions for receiving and properly delivering surgical pathology specimens between 3:00 p.m. and 6:00 a.m.

- Monday through Saturday,
- all day Sunday, and
- holidays.

Definition: *Surgical pathology specimen*

A *surgical pathology specimen* is defined as anything surgically removed from the patient, including:

- appendages such as arms, legs, etc.;
- pieces of human body removed during surgery;
- products of conception such as fetuses etc.; and
- foreign materials removed from body such as surgical screws, etc.

Equipment

Histology refrigerator "Fisher"

Specimen Requirements

Surgical pathology specimens

- not in fixative
- in fixative. (e.g., labeled with "formalin" label)

Procedure

Follow the steps in the table below to receive and deliver surgical pathology specimens.

Step	Action
1	Time stamp and initial all paperwork (e.g., requisition, consent forms, etc.).
2	Compare the patient's name and medical record number (MRN#) on the requisition and any other paperwork with the patient's name on specimen container label.

Continued on next page

Appendix F. (Continued)

Receiving Surgical Pathology Specimens After Hours Effective Date: mm/dd/yy
Document # / version #

Receiving Surgical Pathology Specimens After Routine Business Hours (cont.)

Procedure (cont.)

Step	Action	
2 (cont.)	If	Then
	• no discrepancy is found	accept the specimen.
	• a discrepancy is found (e.g., any mismatched information, no label, etc.)	• notify the supervisor immediately, • document the discrepancy on the requisition, and • accept the specimen.
3	Deliver the specimen to Histology.	
4	If the specimen is	Then
	• in fixative	place specimen and paperwork on the Gross Room counter.
	• not in fixative	• place specimen on bottom shelf of "Fisher" refrigerator, and • place requisition and other paperwork in folder on refrigerator door.

References N/A

Related Procedures N/A

Appendixes None

End

Anytown Hospital Laboratory, Anytown USA 12345 Page 2 of 2
[filename and path]

This example was contributed by the Pathology section of Elmhurst Memorial Hospital Department of Pathology and Laboratory Medicine, Elmhurst, Illinois.

Appendix G. Comparison of Analyte-Specific Attributes by Analyzer Type

Creatinine Attributes by Analyzer Type Effective Date: mm/dd/yy
Document # / version #

CREATININE	Instrument 1 [Name]	Instrument 2 [Name]	Instrument 3 [Name]
Principle	Colorimetric rate reaction. Creatinine forms a yellow-orange complex with picrate in an alkaline solution.	Colorimetric rate reaction. Creatinine forms a yellow-orange complex with picrate in an alkaline solution.	Dry slide, 2-point colorimetric rate.
Clinical Utility	• Diagnosis and treatment of acute and chronic renal disease • Monitoring of renal dialysis		
Specimen **-Stability** **-Volume** (Preferred) (Minimum) **-Patient Prep**	• Serum; EDTA or sodium heparin plasma • 7 days; centrifuged, at 2 - 8 °C 0.5 mL 0.2 mL None	• Serum; EDTA or sodium heparin plasma • 7 days; centrifuged, at 2 - 8 °C 0.5 mL 0.25 mL None	• Serum; lithium and sodium heparin plasma • 7 days; centrifuged, at 2 - 8 °C 0.5 mL 0.2 mL None
Reagents	R1: NaOH R2: Picric Acid	R1: NaOH R2: Picric Acid	Slide ingredients: creatinine amidohydrolase, creatine amidohydrolase, sarcosine oxidase, peroxidase, and 2(3,5-dimethoxy-4-hydrophenyl)-4,5-bis (4-dimethylaminophenyl) imidazole.
Calculations	N/A	N/A	N/A
Interferences	Bilirubin >25.0 mg/dL Hemoglobin >150 mg/dL Triglyceride >1000 mg/dL	Bilirubin >25.0 mg/dL Cephalosporin (↑ bias) Hemoglobin > 1000 mg/dL Triglyceride >2000 mg/dL Acetoacetate >20 mmol/L β-Hydroxybutyrate >25 mmol/L Hemoglobin >5%	Proline (↑ bias) and Dobutamine (significant ↓ bias) from IV fluids Creatine >8 mg/dL Intravenous Lidocaine (↑ of 0.3 mg/dL or less) Dipyrone (↓ bias)
Method Limitations	Linear range of detection: 0.1 - 25.0 mg/dL	Linear range of detection: 0.1 - 25.0 mg/dL	Linear range of detection: 0.05 - 11.5 mg/dL

Anytown Hospital Laboratory, Anytown USA 12345 Page 1 of 2
[filename and path]

Appendix G. (Continued)

Creatinine Attributes by Analyzer Type Effective Date: mm/dd/yy
Document # / version #

Reporting - Reference Range

Male Age (Years)	mg/dL	Female Age (Years)	mg/dL
1 – 2	0.2 – 0.6	1 – 3	0.3 – 0.6
3 – 4	0.3 – 0.7	4 – 5	0.4 – 0.7
5 – 9	0.4 – 0.8	6 – 8	0.5 – 0.8
10 – 11	0.5 – 0.9	≥ 9	0.6 – 0.9
12 – 13	0.6 – 1.0		
14 – 15	0.7 – 1.1		
≥ 16	0.8 – 1.2		

-Alert Limits

Age	Creatinine Value, mg/dL
1 day – 30 days	>1.5 mg/dL
1 month – 23 months	>2.0 mg/dL
2 years – 11 years	>2.5 mg/dL
12 years – 15 years	>3.0 mg/dL
> = 16 years	>10.0 mg/dL

-Reporting Results

	Instrument 1 [Name]	Instrument 2 [Name]	Instrument 3 [Name]
Auto-release Low Recheck	• 0.4 - 25.0 mg/dL: Release results. • <0.4 mg/dL: Check for clots and bubbles. Instrument will rerun as ↑ volume and calculate results.	• 0.4 - 25.0 mg/dL: Release results. • <0.4 mg/dL: Check for clots and bubbles. Instrument will rerun as ↑ volume and calculate results.	• 0.3 - 25.0 mg/dL: Release results. • <0.3 mg/dL: Check for clots and bubbles and rerun.
Dilutions	• >25.0 mg/dL: Instrument will rerun as ↓ volume and calculate results. • Rerun dilution ≤ 50.0 mg/dL: Report result. • Rerun dilution ≥50.0 mg/dL: Make manual dilution (0.9% NaCl) and rerun. • Document calculations and report.	• >25.0 mg/dL: Instrument will rerun as ↓ volume and calculate results. • Rerun dilution ≤ 69.0 mg/dL: Report result. • Rerun dilution ≥69.0 mg/dL: Make manual dilution (0.9% NaCl) and rerun. • Document calculations and report.	• >11.5 mg/dL: • Program on-board dilution x2 and rerun. Instrument performs calculations. • Rerun dilution ≤ 23.0 mg/dL: Report result. • Rerun dilution ≥23.0 mg/dL: Make manual dilution with saline and rerun. • Document calculations and report.

Anytown Hospital Laboratory, Anytown USA 12345 Page 2 of 2
[filename and path]

This example was contributed by the Central Clinical Laboratory, Mayo Clinic Department of Laboratory Medicine and Pathology, Rochester, Minnesota.

Appendix H. Sample Table of Contents for a Preanalytic Procedures Manual

Section 1. Test Ordering Process
Test Ordering Process Flowchart
Test Ordering Procedures
• Taking and Scheduling Verbal Physician Orders • Ordering Tests in the Hospital Computer System
• Registering Patients in the Hospital Computer System • Registering Patients in the Laboratory Information System (LIS)
• Preparing a Manual Test Requisition
• Ordering Tests in the LIS • Adding an Order to a Test in LIS • Verifying Physician Orders • Obtaining Special Consent Forms • Managing Standing Orders
• Generating a Blood Specimen Collection List for Rounds • Reprinting Labels • Handling Collection Lists and Labels for Priority Draws
Section 2. Specimen Collection
Specimen Collection Process Flowchart
Specimen Collection Procedures
• Identifying Patients for Specimen Collection • Identifying Patients for Emergencies • Collecting a Blood Specimen by Venipuncture • Collecting a Blood Specimen by Capillary Technique • Collecting a Blood Specimen by Arterial Puncture
• Labeling Collected Blood Specimens • Following Chain of Custody
• Providing Nonblood Specimen Instructions to Patients • Collecting a Nonblood Specimen
Section 3. Specimen Transport
Specimen Transport Procedures
• Tubing Specimen to the Laboratory • Transporting Specimens to the Laboratory
Section 4. Specimen Receiving and Processing
Specimen Receiving and Processing Flowchart
Specimen Receiving and Processing Procedures
• Receiving Specimens in the Laboratory
• Changing Specimen Status in LIS as Received • Generating a Specimen Unreceived List
• Determining Specimen Acceptability
• Bar-code Labeling of Specimens at Processing
• Sending Tests to the Core Laboratory • Sending Tests to XYZ Reference Laboratory(ies)
• Processing In-House Tested Specimens • Operating the Centrifuge • Aliquoting Specimens • Delivering Specimens to Testing Sections

This example was contributed by the Client Services Workgroup, Sutter Health Laboratory Integration Project, Sacramento, California.

Appendix I. Sample Table of Contents for the ABC Analyzer Procedures Manual

Section 1. ABC Analyzer Set-Up and Run Process
Analyzer Set-Up and Run Process Flowchart
Analyzer Set-Up and Run Procedures
• Starting Up the ABC Analyzer • Performing Daily Maintenance on the ABC Analyzer • Performing and Evaluating Daily Calibration on the ABC Analyzer • Performing and Evaluating Controls on the ABC Analyzer
• Generating a LIS Pending Log for the ABC Analyzer • Programming Patient Samples on the ABC Analyzer • Loading Routine and Stat Racks on the ABC Analyzer
• Evaluating Patient Test Results • Calling Alert Values • Following Up on Delta Checks • Following Up on Technical Limit Flags
• Verifying Results in the LIS
• Storing Patient Test Specimens
Section 2. Analyte-Specific Information Table [see example in Appendix G]
• Analyte-Specific Information Table(s)
Section 3. Troubleshooting Process
Troubleshooting Process Flowchart [from manufacturer's manual]
Troubleshooting Process Procedures
[Troubleshooting Procedures from the manufacturer's manual in the order in which they are to be performed]
Section 4. Preventive Maintenance Process
Preventive Maintenance Schedule [from manufacturer's manual]
[Preventive Maintenance Procedures from the manufacturer's manual in the order in which they are to be performed]
Section 5. Calibration Process
Calibration Schedule [from manufacturer's manual]
Calibration Procedures
[Calibration Procedures from the manufacturer's manual • Installation Calibration • Periodic Calibration • Recalibration After Service or Repair]

Ideas for this example were contributed by the

- Client Services Workgroup, Sutter Health Laboratory Integration Project, Sacramento, California, and
- Central Clinical Laboratory, Mayo Clinic Department of Laboratory Medicine and Pathology, Rochester, Minnesota.

This page is intentionally blank.

Appendix J. Process vs. Procedure—An Important Distinction

Process—How Something Happens

The laboratory's key work processes interlink to transform a test order into a result report on a patient's health status. Ideally, the laboratory should document its key processes, because these documents describe the sequence of specific activities that take place across time and identify the specific organizational units (departments, services, sections) and individuals involved. Process documents can be created for all aspects of preanalytical, analytical, and postanalytical laboratory operational workflow and provide valuable information to help prevent medical errors.

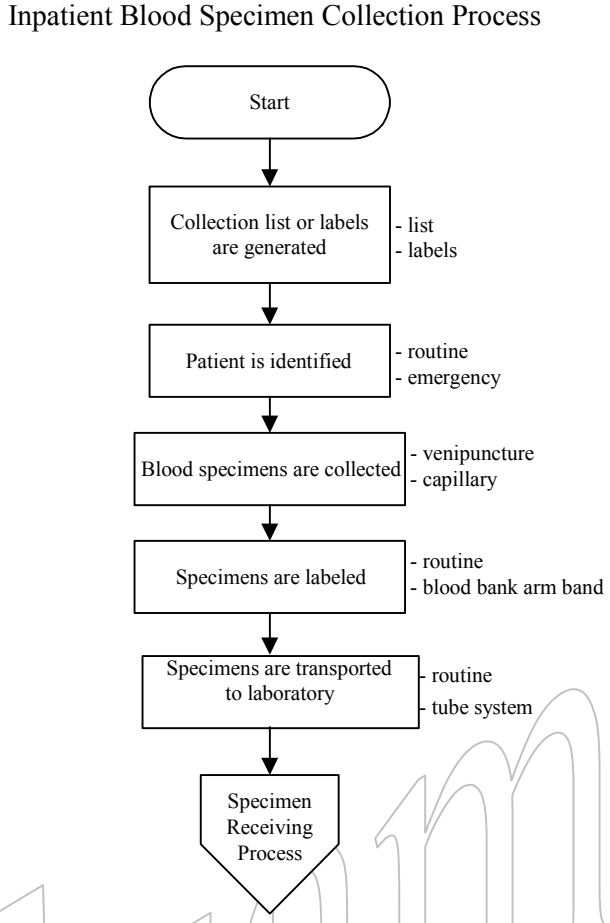
The main information in a process document depicts or describes "how something happens"—for example, the interrelated activities involved in the compatibility testing process. Flowcharts or tables are usually used to present process information. Process flowcharts and their respective tables are provided in this appendix as Attachments J1 through J10.

Process documents are also useful tools for identifying all the procedures necessary to successfully execute a process. Appendixes H and I are sample tables of contents of procedures manuals that have been organized by the sequence of procedures in their respective processes.

Procedure—How To Do It

Whereas process documents depict or describe how related activities happen across time, procedure documents present step-by-step instructions that a single individual must take to successfully complete one activity in the process. Therefore, one process document refers to a number of supporting procedure documents. Examples of procedures have been provided as Appendixes B through F.

Attachment J1. Inpatient Blood Specimen Collection Process Flowchart



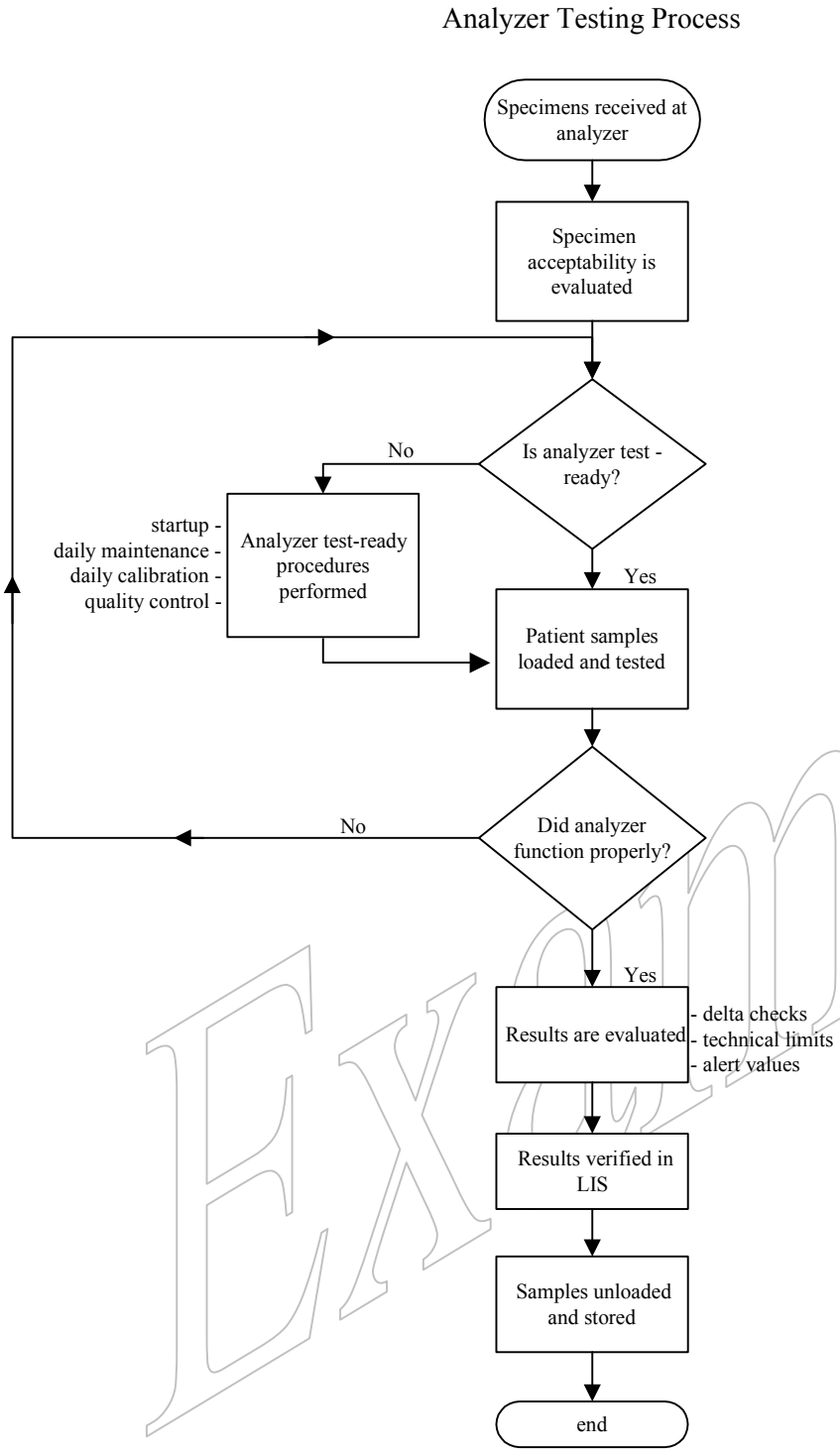
This example was contributed by the Client Services Workgroup, Sutter Health Laboratory Integration Project, Sacramento, California.

Attachment J2. Inpatient Blood Specimen Collection Process Table

Inpatient Blood Specimen Collection Process

What Happens	Who's Responsible	Procedures
Collection list or labels generated	• lab assistant • clerk • technician • technologist	• "Generating a Collection List for Rounds" • "Generating Collection Lists and Labels for Priority Draws" • "Reprinting Labels"
Patient is identified	• patient care technician • lab technician • lab technologist • nurse • other healthcare professional trained in blood collection	• "Identifying Patients for Specimen Collection" • "Identifying Patients for Emergencies"
Blood specimens are collected	• patient care technician • lab technician • lab technologist • nurse • other healthcare professional trained in blood collection	• "Collecting a Blood Specimen by Venipuncture" • "Collecting a Blood Specimen by Capillary Technique" • "Collecting a Blood Specimen by Arterial Puncture"
Blood specimens are labeled	• patient care technician • lab technician • lab technologist • nurse • other healthcare professional trained in blood collection	• "Labeling Collected Blood Specimens" • "Using the Blood Bank Armband/ Labeling System" • "Following Chain of Custody"
Specimens are transported to laboratory	• patient care technician • lab technician • lab technologist • nurse • other healthcare professional trained in blood collection	• "Tubing Specimens to the Laboratory" • "Transporting Specimens to the Laboratory"

Attachment J3. Analyzer Testing Process Flowchart



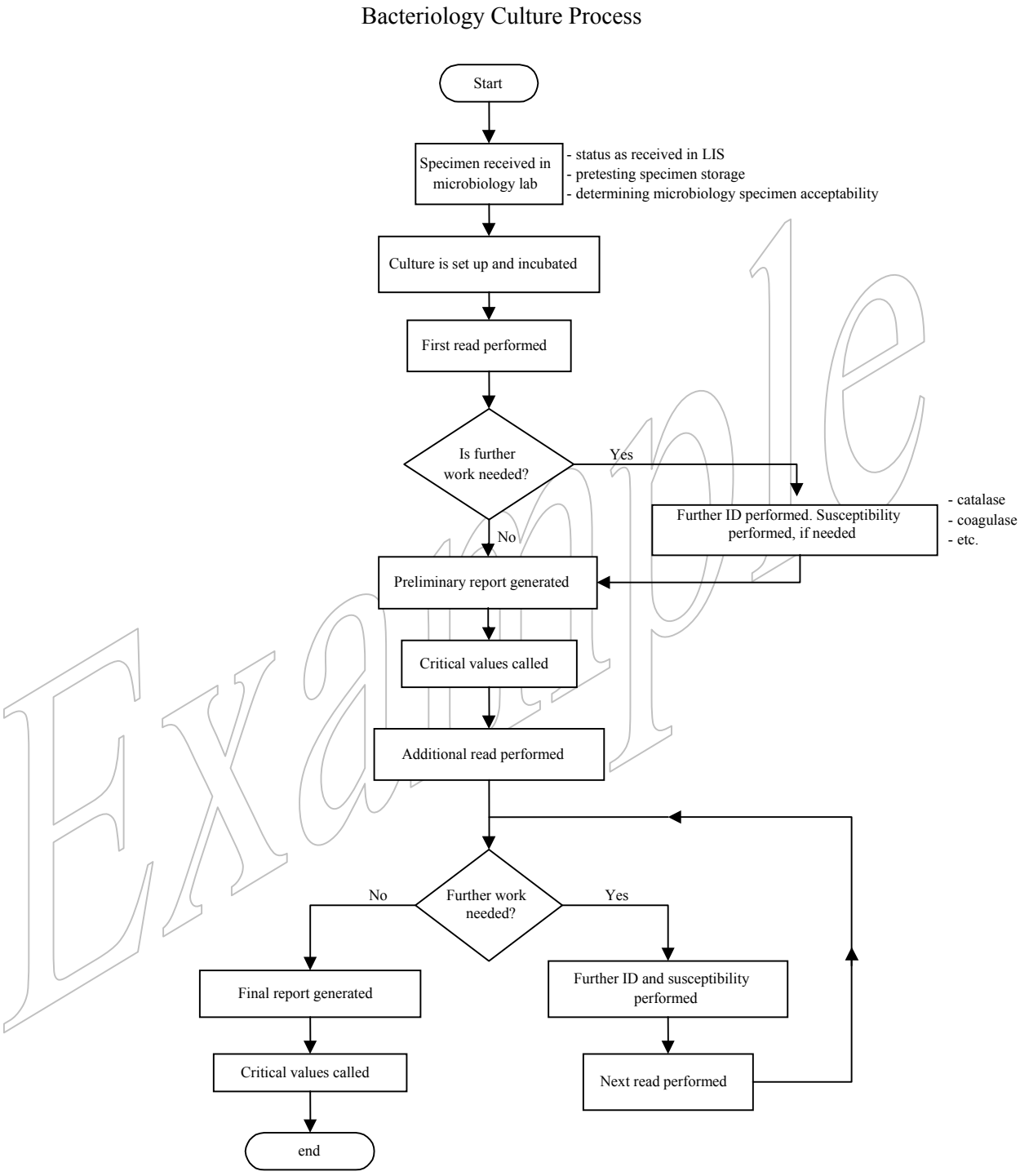
This example was contributed by the Central Clinical Laboratory of the Mayo Clinic Department of Laboratory of Medicine and Pathology, Rochester, Minnesota.

Attachment J4. Analyzer Testing Process Table

Analyzer Testing Process

What Happens	Who's Responsible	Procedures
Specimen acceptability evaluated	• technician, or • technologist	• "Evaluating Specimen Acceptability"
Analyzer test-ready procedures performed	• technician, or • technologist	• "Starting Up the ABC Analyzer" • "Performing Daily Maintenance on the ABC Analyzer" • "Performing and Evaluating Daily Calibration on the ABC Analyzer" • "Performing and Evaluating Controls on the ABC Analyzer"
Patient samples loaded and tested	• technician, or • technologist	• "Generating an LIS Pending Log for the ABC Analyzer" • "Programming Patient Samples on the ABC Analyzer • "Loading Routine and Stat Racks on the ABC Analyzer"
Troubleshooting procedures performed	• technician, • technologist, or • supervisor	• [Troubleshooting procedures from the manufacturer's manual]
Results evaluated	• technologist, or • supervisor	• "Evaluating Patient Results" • "Calling Alert Values" • "Following Up on Delta Checks" • "Following Up on Technical Limit Flags"
Results verified in LIS	• technologist	• "Verifying Results in the LIS"
Samples unloaded and stored	• technologist, or • technician	• "Storing Patient Test Specimens"

Attachment J5. Bacteriology Culture Process Flowchart



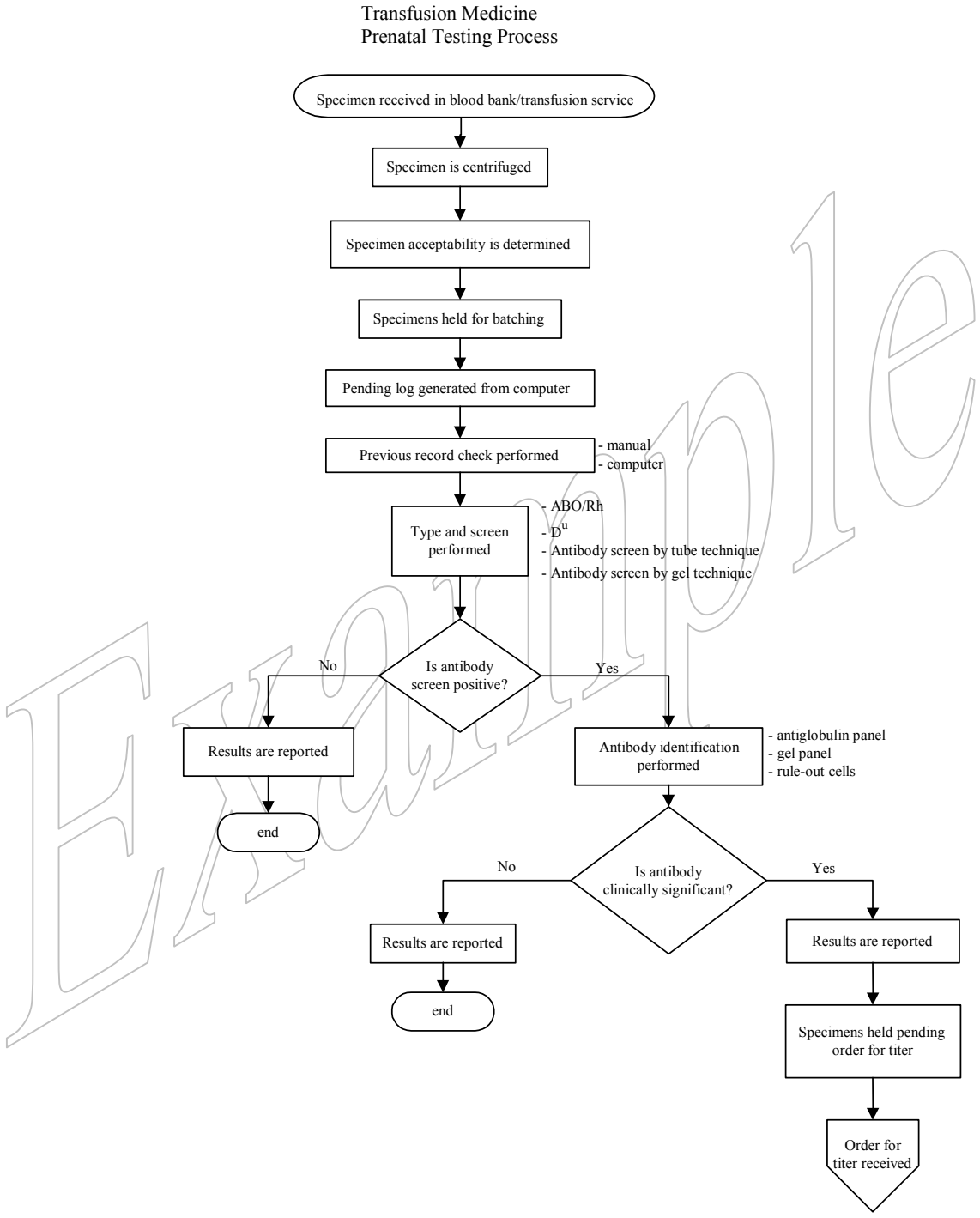
This example was contributed by the Microbiology Technical Work Group, Sutter Health Laboratory Integration Project, Sacramento, California.

Attachment J6. Bacteriology Culture Process Table

Bacteriology Culture Process

What Happens	Who's Responsible	Procedures
Specimens received in Microbiology	• lab assistant, • technician, or • technologist	• "Changing Microbiology Specimen Status to Received in the LIS" • "Storing Microbiology Specimens Before Processing/Testing" • "Evaluating Microbiology Specimen Acceptability"
Specimen is processed	• lab assistant, • technician, or • technologist	• "Centrifuging Specimens" • "Grinding Specimens"
Culture is set up	• lab assistant, • technician, or • technologist	• Media Selection Table • Incubating Cultures Table • "Streaking Agar Plates" • "Inoculating Tube Media" • "Making Specimen Smears" • "Postinoculation Microbiology Specimen Storage"
First read performed Second read performed	• technician, or • technologist	• "Urine Cultures: Reading and Interpreting" • "Enteric Cultures: Reading and Interpreting" • [Additional procedures for reading and interpreting other cultures]
Further identification made	• technician, or • technologist	• [instrument procedures] • [test-specific procedures such as catalase, gram stain, etc.]
Susceptibility performed	• technician, or • technologist	• [instrument and test-specific procedures]
Critical values called	• technician, or • technologist	• "Calling Alert Values"
Preliminary report Final report	• technician, or • technologist	• "Generating Microbiology Reports: Preliminary and Final"

Attachment J7. Transfusion Medicine Prenatal Testing Process Flowchart



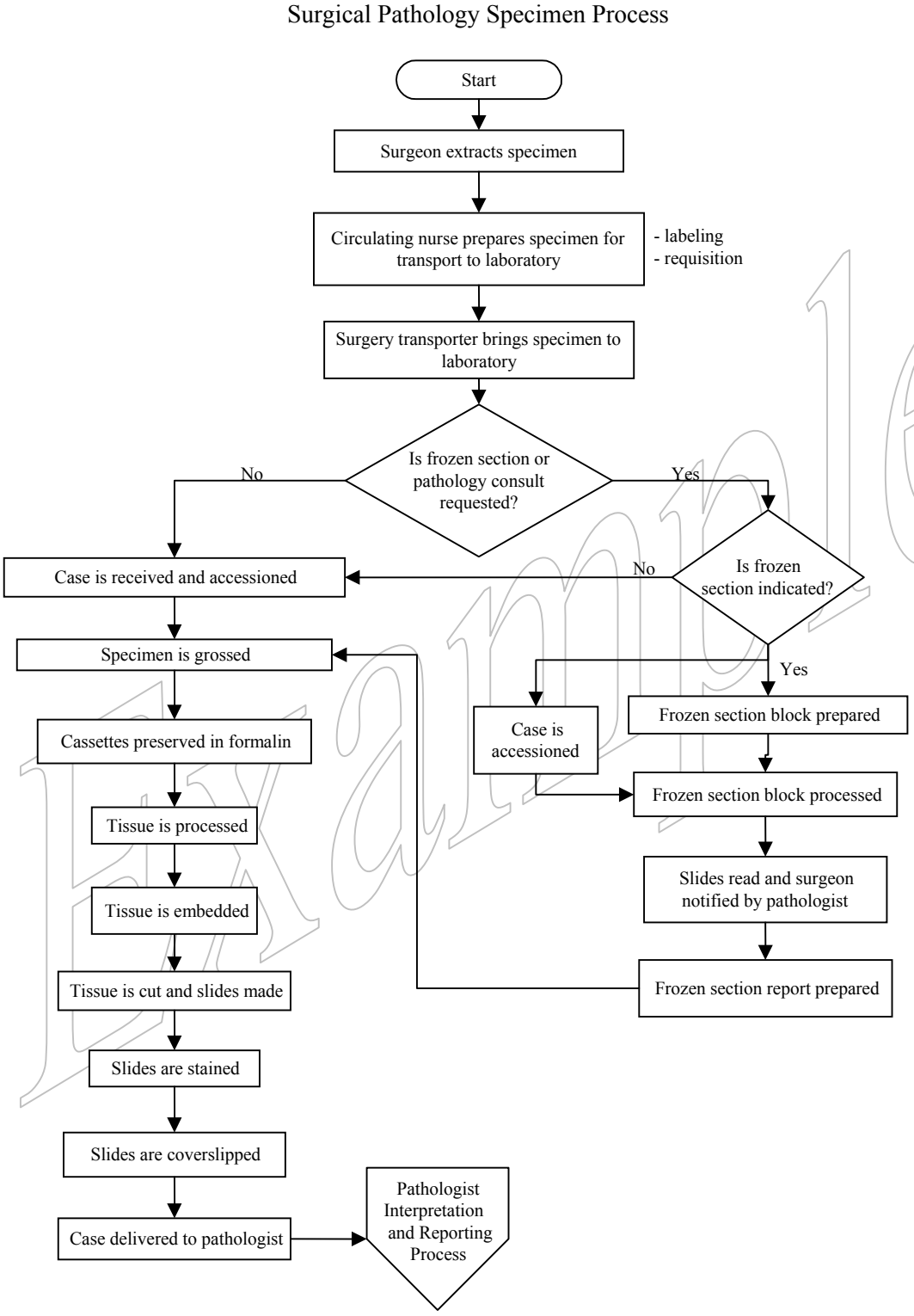
This example was contributed by the Blood Bank Technical Work Group, Sutter Health Laboratory Integration Project, Sacramento, California.

Attachment J8. Transfusion Medicine Prenatal Testing Process Table

Transfusion Medicine Prenatal Testing Process

What Happens	Who's Responsible	Procedures
Specimen acceptability determined	• technician • technologist	• "Evaluating Blood Bank Specimens"
Specimen held for batching	• lab assistant • technician • technologist	• "Batching Blood Bank Specimens for Future Testing"
Computer pending log generated	• lab assistant • technician	• "Generating a Pending Log from the LIS"
Previous record check performed	• technician • technologist	• "Checking Blood Bank Patient History Files"
Type and screen performed	• technician • technologist	• "ABO and Rh by Tube Testing" • "Weak D (D^u Testing)" • "Antibody Screen by Gel Technique" • "Antibody Screen by Tube Technique"
Antibody identification performed, when necessary	• technologist	• "Identifying Antibodies by the Antiglobulin Panel" • "Identifying Antibodies by the Gel Technique" • "Using Rule-Out Cells in Antibody Identification" • [Additional specific antibody identification procedures]
Results are reported	• technologist	• "Reporting Blood Bank Results in the LIS" • Antibody Identification Report Form
Specimens stored	• lab assistant	• "Storing Blood Bank Specimens"

Attachment J9. Surgical Pathology Specimen Process Flowchart



This example was contributed by the Department of Pathology and Laboratory Medicine, Elmhurst Memorial Hospital, Elmhurst, Illinois.

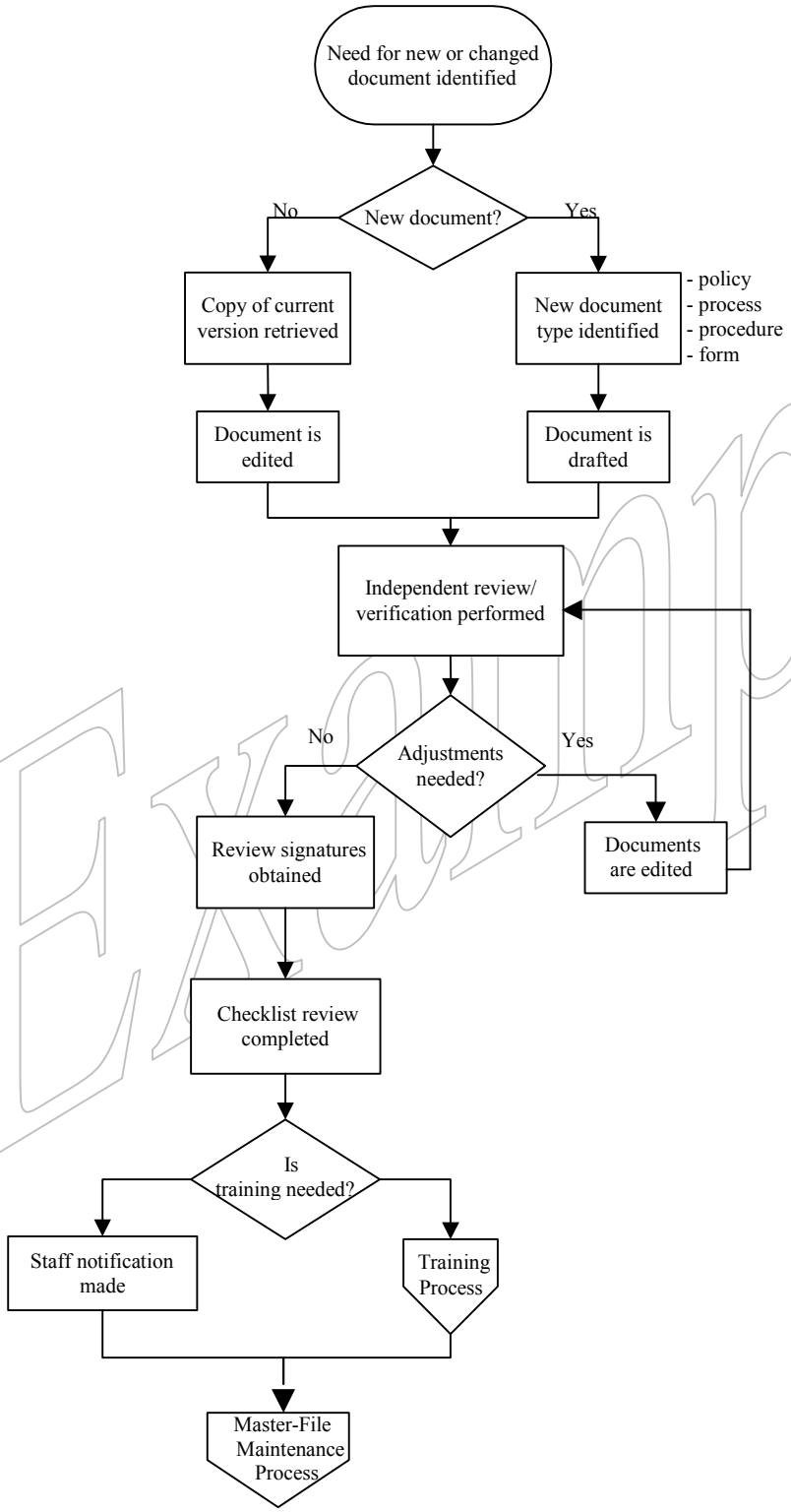
Attachment J10. Surgical Pathology Specimen Process Table

Routine Surgical Pathology Specimen Process

What Happens	Who's Responsible	Procedures
Surgical specimen prepared for transport to laboratory	• circulating nurse	• "Labeling Surgical Pathology Specimens" • "Preparing Surgical Pathology Requisitions"
Specimen brought to laboratory	• surgery transporter	• "Delivering Surgical Specimens to the Laboratory"
Case received and accessioned	• gross room assistant • resident	• "Accessioning Routine Surgical Specimens" • "Accessioning Frozen Section/ Intraoperative Consult Specimens"
Frozen section block prepared and processed into slides	• pathologist	• "Preparing Frozen Section Blocks" • "Processing Frozen Section Blocks" • "Cutting Frozen Section Blocks" • "Staining Frozen Section Slides"
Pathologist reads frozen section slides, prepares report	• pathologist	• "Reporting Frozen Section Results to Surgeon" • "Preparing Frozen Section Report"
Routine specimens grossed	• pathologist • pathologist assistant • resident	• [guidelines for grossing different specimen types] • "Labeling and Reconciling Specimens"
Cassettes in formalin	• Histology technician or technologist	• "Preserving Cassettes in Formalin"
Tissue is processed	• Histology technician or technologist	• "Readying the ABC Tissue Processor" • "Loading the ABC Tissue Processor" • "Unloading the ABC Tissue Processor"
Tissue is cut and slides made	• Histology technician or technologist	• "Embedding Tissues" • "Cutting Tissue and Making Slides"
Slides are stained	• Histology technician or technologist	• "Loading ABC Slide Stainer"
Slides are coverslipped	• Histology technician or technologist	• "Coverslipping with the ABC Instrument" • "Coverslipping by Manual Technique"
Case delivered to pathologist	• Histology technician or technologist	• "Assembling Folders for Pathologist Case Reading"

Appendix K1. Document Creation, Review, and Approval Process Flowchart

Document Creation, Review, and Approval Process



This example was contributed by St. Joseph Mercy Hospital Blood Bank, Ann Arbor, Michigan.

Appendix K2. Document Creation, Review, and Approval Process Table

Document Creation, Review, and Approval Process

What Happens	Who's Responsible	Procedures
Need for new document identified OR Need for changed document identified	• anyone	• "Selecting the Correct Document Type" • "Selecting the Correct Document Format" • New/Changed Document Request Form
	• anyone	• "Retrieving Current Document Version for Editing" • New/Changed Document Request Form
New document is drafted OR Current version is edited	• assigned or volunteer author	• "Writing Policy, Process, and Procedure Documents" • "Designing Form Documents"
	• supervisor	• "Editing Documents in Microsoft Word 2000"
Independent review and verification performed	• assigned staff reviewer	• "Reviewing and Verifying New or Changed Documents"
Review signatures obtained	• supervisor • medical director • quality function (where applicable)	• New/Changed Document Request Form
Checklist review completed	• supervisor	• New/Changed Document Request Form
Staff notification made	• supervisor	• "Notifying Staff of Document Changes"

Appendix L. Sample Document Change Request Form

QSE: Documents and Records Effective Date: mm/dd/yy
Document # / version #

Change #:_____

Document Change Request Form

Document Name:	
Document Number:	Requestor:
Version Number	Date:

Check one: ☐ **New Document** ☐ **Changed Document**

Description of Document:

Rationale for New or Changed Document:

Are any related documents affected? _____**Yes** _____**No**
If yes, list here. Also, prepare additional Document Change Request Forms, if needed.

Is process validation affected? _____**Yes** _____**No**
Why or why not?

Signature Approval

	Signature	**Date**
Document Author		
Supervisor		
Laboratory Director		
	Issue Date for Training	
	Effective Date for Lab Use	

Anytown Hospital Laboratory, Anytown USA 12345
[filename and path] Page 1 of 1

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 Working Group Responses

GP2-A3: *Clinical Laboratory Technical Procedure Manuals—Third Edition; Approved Guideline*.

General

1. While I find your guidelines thoughtfully constructed and generally replete with good examples, I did wish to comment on what I thought was an almost humorous omission: that is the omission of an example of an automated chemistry procedure.

   Many C.A.P. requirements and certainly the bulk of your guidebook seem to be more relevant to the more manual, sometimes home-grown, methods and not with the increasingly automated methods in wide use. Since the average hospital laboratory has automated chemistry analyzers, for instance, featuring large test menus with mostly proprietary commercial methods and use commercially supplied Q.C. materials, there is an increasing role for the product vendors in our method validation and Q.C. programs. Indeed, failure to meet Q.C. standards often requires vendor assistance. Yet, the company-supplied method documents, which are FDA-approved and really pretty good, are not in themselves considered adequate by C.A.P., and we feel compelled to recapitulate almost precisely the same information in a separate laboratory generated document. The thrust of my comments apply, of course, not just to chemistry but to other sections as well.

   I would suggest that you could do us all a great service by explicitly addressing this question as it applies to these highly automated methods and instruments. It would help clarify the issue both for C.A.P. inspectors and inspectees, neither of whom are entirely sure how this compromise should be negotiated.

- **The issue of writing documents for automated methods and instruments has been addressed, complete with examples, in this edition of GP2.**

Section 2.3.2

2. You may want to note which parts of each procedure could be part of a manufacturer's package insert.

- **This edition of GP2 provides manufacturers with guidance for what to include in test method procedures, as well as for organizing operators' manuals and presenting analyte information in tabular format rather than in each individual procedure. A manufacturer's package insert may be used to supplement a procedure but may not replace it.**

3. There is some concern that the word "interpretation"—when used to identify a section in a procedure—may be confused with the cognitive process performed by the pathologist or ordering clinician.

- **The bulleted examples provided in Section 6.2.1.10 define the meaning of "interpretation" as it is used in writing analytic procedures. A section for the interpretation of test results is commonly included in qualitative analytic procedures and is restricted solely to the activities of the person performing the test.**

Section 5.2

4. Computerized files: The guideline was very hazy on this area. A separate guideline for this event should be written.

    a) How will these be updated?
    b) If supplied by the various manufacturers, how will they be standardized?
    c) How will a signature page be provided?
    d) How will control access (or ability to change files) be handled?
    e) How can it be guaranteed that a file supplied by a manufacturer will not be changed (for liability purposes)?

- **The document has been revised to provide guidance for both paper and electronic document management**.

Section 6.1

5. CLIA requires that the laboratory director review and sign all procedures (or may use a cover sheet). The only person to whom this may be delegated is the technical supervisor. Procedures must be resigned and re-dated if the laboratory director changes.

- **This edition of GP2 addresses the issue of initial review, annual review, and the use of signature forms.**

Appendix B

6. Under quality control for the XYZ system, at least two external quality control samples should be tested per run, as well as examination of the alignment and linearity of the instrument as described in the sample procedure.

- **The sample procedure referred to in the above comment is no longer an example in this edition.**

Summary of Delegate Comments and Working Group Responses

GP2-A4: *Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition*

Section 5

1. Standardize the terminology in Section 5; one element mentioned is "Procedure Instructions," while the title of Section 5.3 for this element is "Procedure Information."

- **Section 5.3 has been renamed "Procedure Instructions."**

Section 5.6

2. Section 5.6, last sentence; where is Section 11?

- **The correct citation is Section 9.2; this change has been made.**

Section 6.1.7

3. Consider a reference to someone in addition to "physician" when discussing test orders. There are numerous instances, because all states do not require a physician to order tests, where patients self-order or other caregivers order tests.

- **The words "a physician order" have been changed to read "a proper order."**

Section 6.2.1.3

4. Specify in Section 6.2.1.3 that a QC procedure for commercial kits or products should include instructions on what information should be verified upon reception (lot numbers of the components of a kit, expiration date, temperature at which the product was maintained, etc.), on quarantine requirements when applicable, on inventory measures, etc. These elements could also be discussed in Section 6.2.1.7, "Quality Control."

- **This comment describes important information for which there definitely should be a written procedure. However, reagent receipt does not take place at the time of performing analytic testing. In one of the new concepts to come out of quality system thinking, instructions for activities which involve managing the infrastructure of laboratory operations should be separate from test performance procedures. These quality procedures can be included in a generic laboratory quality manual for use by all laboratory staff. Written procedures for receiving, inspecting, and appropriately testing laboratory reagents and test kits could be included in the quality manual under a section entitled: QSE: Purchasing and Inventory.**

  The following sentence has been added as the third paragraph of Section 6.2.1.3: "Because reagent receipt does not take place at the time of performing analytic testing, a separate written procedure is needed for receiving, inspecting, and appropriately testing laboratory reagents and test kits."

Section 6.2.1.7

5. We propose to add the following element either in Section 6.2.1.7, "Quality Control," or Section 6.2.1.8, "Calculations": QC of calculations performed by a computer to ensure the accuracy of the calculations made in such a way.

- **This comment describes important information for which there definitely should be a written procedure. However, verification of calculations made by the computer does not take place at the time of performing analytic testing. In one of the new concepts to come out of quality system thinking, instructions for activities which involve managing the infrastructure of laboratory operations should be separate from test performance procedures. These quality procedures can be included in a generic laboratory quality manual for use by all laboratory staff. The procedure described in the above comment is part of verifying and validating computerized analyzers and interfaces to laboratory information systems. A written procedure for periodically verifying calculations performed by a computer could be included in the quality manual under a section entitled QSE: Process Control.**

  The following sentence has been added to the end of Section 6.2.1.8: "Because verification of calculations made by the computer does not take place at the time of performing analytic testing, a separate written procedure is needed for periodically verifying calculations performed by the laboratory information system."

6. Include a subsection entitled "Proficiency Testing" under the "Quality Control (QC)" section.

- **The following text has been added to the end of Section 6.2.1.7: "Because proficiency testing specimens are to be handled as regular patient specimens, they do not need to be specifically mentioned in each analytic procedure. However, there should be separate written instructions for:**

  - **receiving proficiency testing samples in the laboratory**
  - **distributing and rotating samples for testing**
  - **transcribing and submitting results**
  - **reviewing reports, and**
  - **taking any necessary follow-up action, as well as documenting such action."**

Section 6.2.1.11

7. Details about the limitations of the test method should include such elements as sensitivity, specificity, etc.

- **The following text has been added as a first bullet to the list: "analytic sensitivity and specificity."**

  In addition, the following text has been added at the end of Section 6.2.1.11: "Appendix G demonstrates a means to present this kind of information in a tabular format for easier comprehension."

Section 6.3.1

8. There should be instructions regarding the hierarchic review and validation of the test result.

- **The following text has been added to the end of Section 6.3.1: "Instructions should be included for supervisory and/or medical review of test results, where such review is required."**

Section 6.3.2

9. We propose to include instructions for periodic verification of accuracy of result transmission, especially when there is electronic transfer of data.

Also, for laboratories that have satellite laboratories and report results electronically, instructions should include verification of accuracy of the electronic transmission (compatibility of the software, maintenance of the original report format after transmission, etc.).

- **This comment describes important information for which there definitely should be a written procedure. However, periodic verification of the accuracy of result transmission does not take place at the time of performing analytic testing. In one of the new concepts to come out of quality system thinking, instructions for activities which involve managing the infrastructure of laboratory operations should be separate from test performance procedures. These quality procedures can be included in a generic laboratory quality manual for use by all laboratory staff. The procedure described in the above comment is part of verifying and validating computerized analyzers and their interfaces to the laboratory information system. A written procedure for periodically verifying the accuracy of result transmission could be included in the quality manual under a section entitled QSE: Process Control.**

  The following text has been added to the end of Section 6.3.2: "Because periodic verification of the accuracy of electronic result transmission does not take place at the time of performing analytic testing, a separate written procedure is needed for periodically verifying the accuracy of electronic transmission of laboratory test results."

Section 8

10. You may find it helpful to describe different types of form documents. In our organization we use Forms and Registers. Both documents are used to record results generated from the performance of a procedure or to bring proof that a certain activity has been carried out according to a given procedure.

- **The last sentence of Section 8 has been modified to read: "…forms, labels, tags, and registers…"**

Section 9.6

11. The title of Section 9.6 should be Review of Documents. Also, it would be helpful if you could give an approximate length of time to describe (periodic review). What would be a reasonable time interval?

- **The title and content of Section 9.6 reflect quality system thinking. If a laboratory manages its documents in the controlled process described in this guideline, reviews are needed only when a document changes — unchanged documents would not require review or could be periodically reviewed based on laboratory policy.**

  Because there are no regulatory or accreditation requirements that define the term "periodic," a timeline for "periodic review" can be established by each organization or laboratory service.

  The following text has been added to the end of Section 9.6 for clarity: "In the absence of an effective document control process, however, annual review of documents is required."

Related NCCLS Publications*

GP17-A **Clinical Laboratory Safety; Approved Guideline (1996).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.

GP21-A **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.

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

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

* 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

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 1-56238-458-9