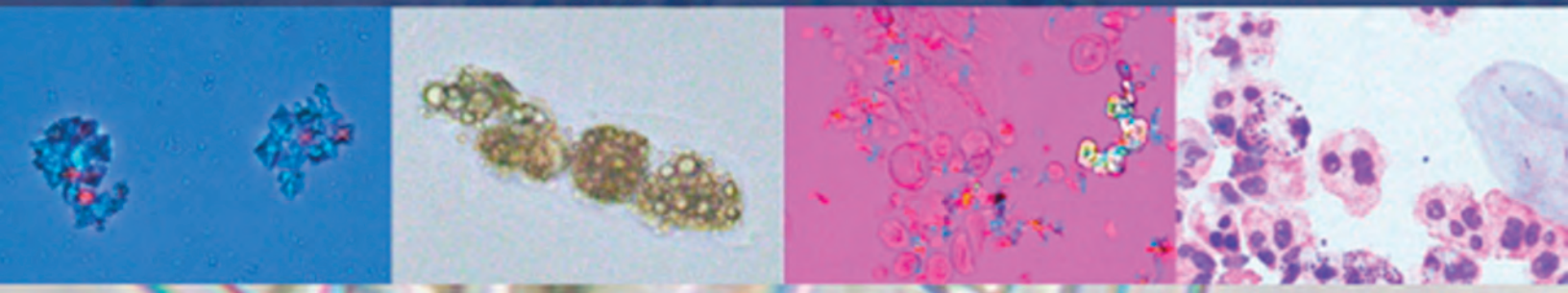
Fourth Edition

Fundamentals of URINE & BODY FLUID ANALYSIS



Nancy A. Brunzel

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QUICK GUIDE TO FIGURES

Blood Cells

Cell Type	Figure *(chapter.number)*	Image Gallery #
Red blood cells	7.13, 7.14, 7.15, (7.17, 7.23, 7.26, 7.27, 7.32, 7.46, 7.80, 7.92)	5, 7, 8, 11, (46), 74, 77, 83, (87, 88, 90)
Dysmorphic RBCs	7.14, 7.15, Table 7.5	8
White blood cells	7.6, 7.9, 7.13, 7.16, 7.17, 7.18, 7.19, 7.20, 7.21, 7.22, (7.23, 7.25), 7.92, (7.93, 7.94), 7.95	1, 4, 9, 10, 11, (67)
Macrophages	7.22	

( ), Numbers in parentheses indicates presence but not the predominant element in image.

Casts

Type	Figure *(chapter.number)*	Image Gallery #
Hyaline	7.34, 7.35, 7.37, 7.41, 7.42, 7.50, 7.58, (7.102, 7.108), (18.12)	31-33 (36)
Granular	7.38, 7.39, 7.40, 7.44, 7.47, 7.50, 7.51, 7.56	25-30
Cellular		
RBC	7.45, 7.46	(18), 19, 20, 21
WBC	7.48	17, 18
Renal epithelial cell	7.49, 7.57	13-16, 24
Mixed cell	7.40	12, 17, 18
Waxy	7.12, 7.36, 7.38, 7.39, 7.43, 7.44, 7.58, 18.21	34-38
Fatty	7.52, 7.53, 7.86	22-24, 75, 76, 80
Crystalline	7.54, 7.55	

( ), Numbers in parentheses indicates presence but not the predominant element in image.

Crystals (according to pH)

pH*	Crystal	Figure *(chapter.number)*	Image Gallery #
<5.7	Uric acid	7.63, 7.64, 7.65, 7.66, 7.67	(49), 61-64
≤5.8	2,8-Dihydroxyadenine	7.83	
≤7	Urates, amorphous	7.60	
	Urate, monosodium	7.62	60
	Urates, acid	7.61	59
	Bilirubin	7.79	40
	Cholesterol	7.84, 7.85, 7.86	45
	Leucine	7.82	
	Tyrosine	7.81	
	Radiographic contrast media	7.91	65
	Ampicillin (medication)	7.87	
	Sulfonamides (medication)	7.89, 7.90	48-49
5-8	Calcium oxalate	(7.55), 7.68, 7.69, 7.70	42-44
	Cystine	7.80	46-47
	Indinavir sulfate (medication)	7.88	50
(6)-8	Phosphate, calcium	7.73, 7.74, 7.75	54-57
≥7	Phosphate, amorphous	7.71	
	Phosphate, magnesium	7.76	58
	Phosphate, triple	7.72	51-53
	Carbonate, calcium	(7.74), 7.78	41
	Ammonium biurate	(7.74), 7.77	39

( ), Numbers in parentheses indicates presence but not the predominant element in image.
*Approximate pH value or range.

Epithelial Cells

Cell Type	Figure *(chapter.number)*	Image Gallery #
Squamous	7.4, 7.10, (7.16), 7.24, 7.25, 7.26, 7.98	(9, 11), 66-68
Clue cells	7.98, 13.4	66
Transitional	7.27, 7.28	68-70, 72
Renal	7.5, 7.20, 7.30, 7.31, 7.32	72-74, 78
Decoy cells	7.29	

( ), Numbers in parentheses indicates presence but not the predominant element in image.

Fat

Element	Figure *(chapter.number)*	Image Gallery #
Free fat globules	7.11	(75-76, 80)
Fatty casts—see Casts		
Oval fat bodies	7.7, 7.23, 7.33, (7.84, *A*) 7.104, 7.105	24, 76-81

( ), Numbers in parentheses indicates presence but not the predominant element in image.

Microorganisms (alphabetical order)

Organism	Figure *(chapter.number)*	Image Gallery #
Bacteria	7.8, 7.92, 13.1, 13.3	68, 82-83, (87, 95)
Giardia lamblia	7.100	
Pinworm eggs	7.99	
Schistosoma haematobium	7.101	
Trichomonads	7.96, 7.97, 13.7	84, 85, 86
Yeast and/or pseudohyphae	(7.13, 7.16, 7.17), 7.93, 7.94, 7.95	48, 87, 88, 89, 90

( ), Numbers in parentheses indicates presence but not the predominant element in image.

Miscellaneous Elements

Element	Figure *(chapter.number)*	Image Gallery #
Hemosiderin	7.106	91, 92
Mucus	(7.24, 7.34, 7.35, 7.37, 7.41), 7.102, (18.12)	93
Fibers	7.59, 7.108, 18.12	2, 3
Sperm	7.107	(80), 94, 95
Starch	7.109, 7.110	6

( ), Numbers in parentheses indicates presence but not the predominant element in image.

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Fourth Edition

Fundamentals of URINE & BODY FLUID ANALYSIS

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To Medical Laboratory Scientists around the world—for it is by your work
and expertise (i.e., quality laboratory results)
that diseases are diagnosed and managed.
Hats off to you!

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PREFACE

This book is designed as a teaching and reference text for the analysis of urine and body fluids. The intended audience is students in medical/biomedical laboratory science programs and practicing laboratory professionals. However, other health care professionals—physicians, physician assistants, nurse practitioners, and nurses—can also benefit from the information provided.

As with previous editions, the task of achieving a balance in depth and breadth of content to meet all needs is challenging. I believe that to gain a true understanding of a subject requires more than the mere memorization of facts. Therefore a guiding principle in the format and writing of this book is to present comprehensive information in a manner that arouses interest, enhances learning, and facilitates understanding and mastery of the content. Although the content is comprehensive and detailed, educators can easily adapt it to the level of content desired.

ORGANIZATION

A few organizational changes have been made with this, the 4th edition. Note that although a chapter number may have changed, the format and content within each chapter remain true to previous editions and include topical updates. The text now begins with *Quality Assessment and Safety* as Chapter 1 because of their paramount importance in laboratories, and this chapter focuses specifically on the analysis of urine and body fluids.

Chapters 2 through 8 focus on renal function, the analysis of urine, and the role a urinalysis can play in the diagnosis and monitoring of renal and metabolic disorders. In Chapter 2 is a thorough discussion of urine specimen collection, handling, and preservation; Chapters 3 and 4 review the anatomy and physiology of the urinary system. Together, these three chapters set the stage for an in-depth discussion of the three components of a complete urinalysis—namely, the physical examination (Chapter 5), chemical examination (Chapter 6), and microscopic examination (Chapter 7). In Chapter 6, *Chemical Examination of Urine*, the Protein section was reorganized, and the discussion and performance of some methods have been moved to a new Appendix E, *Manual and Historic Methods of Interest*. Located between Chapters 7 and 8 is the *Urine Sediment Image Gallery*, containing *more than 100* urine sediment photomicrographs to be used as a teaching tool and reference for the identification of urine sediment elements. Chapter 8 completes the study of urine with a discussion of the clinical features of renal and metabolic disorders and their associated urinalysis results.

Chapters 9 through 15 are dedicated to the study of body fluids (other than urine) frequently encountered in the clinical laboratory. In this edition, these chapters have been reordered, with the most common specimens submitted for analysis in hospital-based laboratories being presented first; for example, cerebrospinal fluid analysis is first as it predominates among other body fluids analyzed in laboratories. Each chapter describes the physiology, normal composition, and clinical value associated with laboratory analysis of the body fluid. Preanalytic factors in specimen collection and handling are discussed along with the significance of specific tests that provide clinically useful information. Note that laboratory tests routinely performed on one body fluid may not have clinical value when analyzing another body fluid.

Chapter 16 provides a snapshot of automation currently available for the analysis of urine and body fluids. Because of the robust and dynamic nature of laboratory instrumentation, the content of this chapter can change dramatically and quickly outdate. However, the intent is to provide an understanding of the analytic principles used in automated instruments. In this regard, the basic analytic principles for urine chemical (reflectance photometry) analysis have stood the test of time and will endure. The arena of automated microscopic analysis of urine is broadening with three alternatives: digital flow microscopy, flow cytometry, and cuvette-based digital microscopy. Future developments in the analysis of urine and body fluids will undoubtedly bring to the marketplace new analyzers and manufacturers.

For a variety of reasons, manual cell counts of body fluids using a hemacytometer persist today. Therefore Chapter 17 and Appendix D are provided as resources for the preparation of dilutions and the performance of manual body fluid cell counts. Pretreatment solutions and a variety of diluents for body fluids are discussed; step-by-step instructions and calculations for performing manual cell counts are included. This chapter closes with a discussion of cytocentrifugation and the preparation of slides for a leukocyte differential.

Microscopy is now the concluding chapter, Chapter 18. The importance of familiarity with and the ability to optimize the microscope cannot be overemphasized when analyzing urine and body fluids. Note that the detection and proper identification of microscopic elements in body fluids are adversely affected when the microscope is not properly adjusted. Chapter 18 describes the various types of microscopy used for body fluid analysis, as well as proper microscope handling and care, including important dos and don'ts. Step-by-step instructions are provided (1) to properly adjust a brightfield microscope for optimal viewing using Köhler illumination (Box 18.1) and (2) to convert a brightfield microscope for polarizing microscopy including directions for synovial fluid crystal analysis (Box 18.3, Fig. 18.18).

Five appendices are provided to complement the chapters. Appendix A, *Reagent Strip Color Charts,* supplements the chemical examination of urine (see Chapter 6) by providing figures of manufacturer color charts used to manually determine reagent strip results. These figures are a useful reference

and assist in highlighting differences in reagent strip brands, such as physical orientation of strip to chart and variations in result reporting. Appendix B, *Comparison of Reagent Strip Principles, Sensitivity, and Specificity,* gathers the information for each chemical reaction discussed in Chapter 6 into one location. Here, a table summarizes the test principles employed on reagent strips from three popular brands. Similarly, a tabular comparison is provided of the sensitivity and specificity of each test. Appendix C serves as a handy resource and single location for the *Reference Intervals* of all body fluids that are provided in the various chapters. As previously stated, Appendix D, *Body Fluid Diluent and Pretreatment Solutions,* supplements Chapter 17 (manual hemacytometer counts) by providing detailed instructions for the preparation and use of diluents and pretreatment solutions. Last, Appendix E provides information for the performance of manual and historic methods of interest. These methods are valuable tests that are no longer routinely performed in some regions, are used only under rare circumstances, or are of historical interest. Note that this section provides detailed information that enables test performance, including specifics for reagent preparation.

The book concludes with two additional sections, the Answer Key and a Glossary. The Answer Key provides the answers and explanations (when necessary) to the end-of-chapter study questions and cases in a convenient, readily accessible location. The glossary includes the key terms that are bolded in each chapter and additional important clinical and scientific terms that may be new to readers.

NEW TO THIS EDITION

- Throughout the text, content has been updated, and numerous tables have been revised or added to supplement and enhance mastery of the material.
- Over 200 photomicrographs of urine sediment components. In Chapter 7, *Microscopic Examination of Urine Sediment,* they accompany the discussion of each sediment component and the alphabetized *Urine Sediment Image Gallery* provides additional images for reference when performing microscopic examinations.
- The *Quick Reference Guide* on the inside front cover has been expanded and assists in locating figures of urine sediment elements (i.e., photomicrographs) for quick reference.
- In Chapter 6, each reagent strip test section has additional tables that summarize the test principle, sensitivity, and specificity for three popular brands of reagent strips.
- In Chapter 7, *Microscopic Examination of Urine Sediment,* the discussion of various forms of red blood cells found in urine sediment is expanded and images provided. A brief section on decoy cells and other cell types encountered with bladder diversions is now present. In addition, new figures were added and others replaced with better examples.
- Chapter 16, *Automation of Urine and Body Fluid Analysis,* has been updated and now includes discussion of "cuvette-based digital microscopy," another technique for automated microscopic analysis of urine sediment.
- Chapter 18, *Microscopy,* now includes step-by-step instructions to convert a brightfield microscope for polarizing microscopy, as well as directions for synovial fluid crystal identification, which supplements Chapter 11, *Synovial Fluid Analysis.*
- The new Appendix B provides a tabular comparison of the *Reagent Strip Principles, Sensitivity, and Specificity* of three commonly used reagent strip brands in a single location for reference.
- The new Appendix E, *Manual and Historic Methods of Interest,* provides detailed information about tests that have clinical value but are infrequently performed in most settings. This appendix provides detailed information for reagent preparation as well as test performance.

LEARNING AIDS

Each chapter includes the following aids to enhance mastery of the content:

- *Learning Objectives* at three cognitive levels (Recall, Application, Analysis)
- *Key Terms* that are bold in the chapters and defined in the Glossary
- Many *Tables* that capture and summarize content
- Numerous high-quality *Figures* in full color
- *Study Questions* at three cognitive levels (Recall, Application, Analysis)
- *Case Studies,* when applicable to content

EVOLVE INSTRUCTOR RESOURCES

New for this edition, downloadable instructor content specific to this text is available on the companion Evolve site (http://evolve.elsevier.com/Brunzel). This includes the following ancillary material for teaching and learning:

- *PowerPoint presentations* for all chapters to aid in lecture development
- *Test Banks* that tie exam questions directly to book content, making exam development easier and faster
- *Image Collection* that includes all illustrations in the book in various formats, offering a closer look at hundreds of microscopic slides

ACKNOWLEDGMENTS

I want to acknowledge all the laboratory scientists at the University of Minnesota Medical Center over the years who have saved innumerable "interesting" specimens or have called me about unusual findings. I dare not begin to name them all for fear that I should make a terrible omission. But I thank each of you for your love of the profession and for taking the time out of your busy days on the bench. I also want to thank the many students for their questions, as well as colleagues who have provided feedback or made suggestions.

As with previous editions, I want to especially honor my mentor and friend, Karen Karni, PhD. It was under her tutelage that I became a writer. She helped birth the author within and helped develop and refine me as an educator. I am deeply grateful.

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Nancy A. Brunzel

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1

Quality Assessment and Safety

LEARNING OBJECTIVES

After studying this chapter, the student should be able to:

1. Define and explain the importance of quality assessment in the laboratory.
2. Identify and explain preanalytical, analytical, and postanalytical components of quality assessment.
3. Differentiate between internal and external quality assessment and discuss how each contributes to an overall quality assessment program.
4. Define and discuss the importance of the following:
   - Critical values
   - Documentation
   - Ethical behavior
   - Preventive maintenance
   - Technical competence
   - Test utilization
   - Turnaround time
5. Discuss the relationship of the Occupational Safety and Health Administration to safety and health in the workplace.
6. Define and give an example of the following terms:
   - Biological hazard
   - Chemical hazard
   - Decontamination
   - Personal protective equipment (PPE)
7. Describe a Standard Precautions policy, and state its purpose.
8. Discuss the three primary routes of transmission of infectious agents and a means of controlling each route in the clinical laboratory.
9. Describe appropriate procedures for the handling, disposal, decontamination, and spill control of biological hazards.
10. Discuss the source of potential chemical and fire hazards encountered in the laboratory and the procedures used to limit employee exposure to them.
11. State the purpose of and the information contained in a material safety data sheet.

CHAPTER OUTLINE

KEY TERMS*

biological hazard
Chemical Hygiene Plan (CHP)
critical value
decontamination
documentation
external quality assessment
infectious waste disposal policy
Occupational Safety and Health Administration (OSHA)
personal protective equipment (PPE)
preventive maintenance
quality assessment (QA)
quality control materials
safety data sheet (SDS)
Standard Precautions
technical competence
test utilization
turnaround time (TAT)
Universal Precautions (UP)

*Definitions are provided in the chapter and glossary.

QUALITY ASSESSMENT

Quality Assessment: What Is It?

Quality assessment (QA) is a system designed to ensure the quality of a laboratory's services (i.e., test results). All laboratory personnel must be aware of the effects that their test results and services have on the diagnosis and treatment of patients. These services must be monitored to ensure that they are appropriate and effective and that they meet established standards for laboratory practice. The Clinical Laboratory Improvement Act enacted by the US Congress in 1988 (CLIA '88) was in direct response to growing concern about the quality of laboratory test results and the need to impose external standards to ensure quality results.[1] Clinical laboratories in the United States must be certified by the Centers for Medicare and Medicaid Services (CMS) or by a private certifying agency (e.g., College of American Pathologists [CAP]) or a CMS-approved state regulatory agency. Certification is an ongoing process to ensure that laboratories are maintaining compliance with federal regulations through periodic on-site inspections. QA provides a mechanism for detecting problems and provides an opportunity to improve services. In reality, all components of health care, including physicians, nurses, clinics, hospitals, and their services, are involved in QA; the laboratory is only part of this larger program to ensure quality health care services.

Ensuring the quality of test results was an important part of the clinical laboratory long before CLIA '88; the first external laboratory surveys were developed in the 1940s. These early surveys revealed that not all laboratories reported the same results on identical blood specimens submitted for hematologic and chemical analyses. Since the time of those first surveys, all sections of the clinical laboratory have become involved in ensuring the quality, accuracy, and precision of the laboratory results they generate. The urinalysis laboratory is no exception.

A QA program encompasses all aspects of the urinalysis laboratory. Specimen collection, storage, and handling; instrumentation use and maintenance; reagent quality and preparation; and the laboratorian's knowledge and technical skills must meet specific minimum criteria to ensure the quality of the results generated. To achieve the goals set forth in a QA program, a commitment by all laboratory personnel, including those in administration and management, is necessary. This dedication must be evident in managerial decisions, including the allocation of laboratory space, the purchase of equipment and supplies, and the budget. Without adequate resources, the quality of laboratory services is compromised. Properly educated and experienced laboratory personnel with a high level of evaluative skills are essential to ensure the quality of laboratory results. "Many studies have shown that the standards of specimen collection technique and analytical performance are generally inferior to those obtained by skilled laboratorians."[2] Because of the dynamic environment of clinical laboratory science, it is imperative that laboratorians have access to reference books and opportunities for continuing education to assist them in skill maintenance and development. Not only do continuing education opportunities provide intellectual stimulation and challenges for laboratorians, they also facilitate the development of quality employees and ensure that the urinalysis laboratory is kept abreast of technological advances.

A QA program for the urinalysis laboratory consists of three principal aspects: (1) preanalytical components—processes that occur before testing; (2) analytical components—aspects that directly affect testing; and (3) postanalytical components—procedures and policies that affect reporting and interpretation of results. Because an error in any component will directly affect the quality of results, each component must be monitored, evaluated, and maintained.

Preanalytical Components of Quality Assessment

The preanalytical components involve numerous laboratory and ancillary staff and, in many instances, multiple departments. Because of the importance of cost-effective practices in test ordering, the laboratory plays a role in monitoring **test utilization**—that is, avoiding duplicate testing and ensuring test appropriateness whenever possible. Each laboratory is unique, and procedures to intercept and eliminate unnecessary testing must be designed to fit the workflow of each laboratory.

The importance of timely result reporting cannot be overemphasized. A delay in specimen transport and processing directly affects specimen **turnaround time (TAT).** Keep in mind that the definition of TAT can differ for the laboratorian compared with physicians or nursing personnel. For example, a laboratorian defines TAT as the time from receipt of the specimen in the laboratory to reporting of results to a patient care area or into a data information system. In contrast, physicians view TAT as the time from when they write the order for the test until the result is communicated to them for action. To nursing personnel, TAT is the time that elapses from actual specimen collection until the results are communicated to them. Therefore to monitor and address potential delays that directly involve the laboratory, a consensus definition of TAT and realistic goals for test results must be established. This requires a policy for documenting the times of specimen collection, receipt, and result reporting.

Urine specimen collection techniques differ; they are often controlled by medical personnel outside the laboratory and can have a direct effect on the results obtained (see Tables 2.1 and 2.2). In addition, numerous physiologic factors can affect the urine specimen obtained (e.g., diet, exercise, hydration, medications), and depending on the test, appropriate patient preparation may be needed. To ensure an appropriate specimen, collection instructions (including special precautions and appropriate labeling) must be well written, as well as distributed to and used by all personnel involved in specimen collection.

Laboratory staff who receive urine specimens must be trained to identify and handle inappropriate or unacceptable specimens. In addition, they must document any problems encountered so that these problems can be addressed and corrected. The procedure the staff should follow involves

(1) ensuring that two unique patient identifiers (e.g., name, date of birth, medical record number) are on the request slip and on the specimen and that they correlate; (2) evaluation of elapsed time between collection and receipt of the specimen in the laboratory; (3) the suitability of specimen preservation, if necessary; and (4) the acceptability of the specimen (e.g., the volume collected, the container used, its cleanliness—any evidence of fecal contamination). If the urine specimen is unacceptable, a procedure must be in place to ensure that the physician or nursing staff is informed of the problem, the problem or discrepancy is documented, and appropriate action is taken. Written guidelines that list the criteria for specimen rejection (Box 1.1), as well as the procedure for the handling of mislabeled specimens, are required to ensure consistent treatment by all staff (Table 1.1).

The processing of urine specimens within the laboratory is another potential source of preanalytical problems. Specimens for a *routine urinalysis* should be tested within 2 hours of collection (see Chapter 2). If delay in transport to the laboratory or at the reception area is unavoidable, specimens should be refrigerated. Timed urine collections require a written protocol to ensure adequate mixing, volume measurement, recording, aliquoting, and preservation—when specimen testing is to be delayed or the analyte of interest is unstable. With a written procedure for specimen processing in place, all personnel will perform these tasks consistently, thereby eliminating unnecessary variables.

Because of the multitude of variables and personnel involved in urine specimen collection and processing, adequate training and supervision are imperative. Communication to personnel regarding any procedure changes or introduction of new procedures must be consistent. Written procedures must be available and personnel must perform and follow established preventative maintenance schedules. All personnel must have appropriate education regarding the biologic and chemical hazards in the laboratory. Preanalytical components are a dynamic part of the clinical laboratory and require adherence to protocol to ensure meaningful test results. In other words, *quality* testing cannot make up for a substandard specimen.

BOX 1.1 Criteria for Urine Specimen Rejection

- Insufficient volume of urine for requested test(s)
- Inappropriate specimen type or collection
- Visibly contaminated specimen (e.g., with feces, debris)
- Incorrect urine preservative
- Specimen not properly preserved for transportation delay
- Unlabeled or mislabeled specimen or request form
- Request form incomplete or lacking

TABLE 1.1 Definitions and an Example of Policy for Handling Unlabeled or Mislabeled Specimens

Definitions	
Unlabeled	No patient identification is on the specimen container or tube that contains the specimen. Placing the label on the plastic bag that holds the specimen is inadequate.
Mislabeled	The name or identification number on the specimen label does not agree with that on the test request form.
Policy Features	
Notification	Contact the originating nursing station or clinic and indicate that the specimen must be recollected. Document the name of the individual contacted.
Document	Order the requested test and write CANCEL on the request form with the appropriate reason for the cancellation, e.g., specimen unlabeled or specimen mislabeled, identification questionable. Initiate an incident report and include names, dates, times, and all circumstances.
Specimen	Do not discard the specimen. Process and perform analyses on those specimens that cannot be saved, but do not report any results. Properly store all other specimens. On specimens that cannot be recollected (e.g., cerebrospinal fluid): 1. The patient's physician must: • contact the appropriate laboratory supervisor and request approval for tests on the "questionable" specimen • sign documentation of the incident 2. The individual who obtained the specimen must come to the laboratory to: • identify the specimen • properly label the specimen or correctly label the test request form sign documentation of the incident • sign documentation of the incident
Reporting Results	All labeling and signing of documentation must occur before results are released (except in cases of life-threatening emergencies, such as, cardiac arrest, when verbal specimen identification is accepted and documentation is completed later). All reported results must include comments describing the incident. For example, "Specimen was improperly labeled but was approved for testing. The reported value may not be from this patient."
Quality Assessment Report	Forward a copy of the incident to the Quality Assessment committee and to the patient care unit involved (e.g., nursing station, clinic, physician's office).

Analytical Components of Quality Assessment

Analytical components are those variables that are directly involved in specimen testing. They include reagents and supplies, instrumentation, analytical methods, the monitoring of analytical methods, and the laboratory personnel's technical skills. Because each component is capable of affecting test results, procedures must be developed and followed to ensure consistent and acceptable quality.

Equipment

All equipment—such as glassware, pipettes, analytical balances, centrifuges, refrigerators, freezers, microscopes, and refractometers—requires routine monitoring to ensure appropriate function, calibration, and adherence to prescribed minimal standards. **Preventive maintenance** schedules to eliminate equipment failure and downtime are also important aspects of QA and should be included in pertinent laboratory procedures. The use of instrument maintenance sheets for **documentation** provides a format to remind staff of daily, monthly, and periodic maintenance as well as to record unexpected failures and their resolution. Because the bench technologist is the first individual to be aware of an instrument failure, troubleshooting and "out-of-control" protocols need to be included in procedures, and historic service and repair documentation should be readily available for reference.

The required frequency of maintenance differs depending on the equipment used; the protocol should meet the minimal standards set forth in guidelines provided by The Joint Commission (TJC) (formerly the Joint Commission on Accreditation of Health Care Organizations [JCAHO]) or the College of American Pathologists (CAP). Table 1.2 lists equipment often present in the urinalysis laboratory along with the frequency and types of performance checks that should be performed. For example, temperature-dependent devices are monitored and recorded daily; refractometers and osmometers may be checked daily or whenever in use. Centrifuges should be cleaned regularly (e.g., weekly, as well as after spills), and the accuracy of their timers and speed (revolutions per minute) should be checked periodically. Automatic pipettes, analytical balances, and fume hoods also require periodic checks, which are determined by the individual laboratory, and the time interval depends on usage. Microscopes require daily cleaning and sometimes adjustments (e.g., illumination, phase ring alignment) to ensure optimal viewing. Microscopes and balances should undergo annual preventive maintenance and cleaning by professional service engineers to avoid potential problems and costly repairs. A current CAP inspection checklist is an excellent resource for developing an individualized procedure for performing periodic checks and routine maintenance on equipment and for providing guidelines on the documentation necessary in the urinalysis laboratory.

TABLE 1.2 Urinalysis Equipment Performance Checks

Equipment	Frequency	Checks Performed
Automatic pipettes	Initially and periodically thereafter; varies with usage (e.g., monthly)	Check for accuracy and reproducibility.
Balances, analytical	Periodically (e.g., quarterly)	Check with standard weights (National Bureau of Standards Class S).
	Annually	Service and clean.
Centrifuges	Weekly	Clean rotor, trunnions, and interior with suitable disinfectant.
	Periodically (e.g., annually)	Check revolutions per minute and timer.
	Periodically	Change brushes whenever needed; frequency varies with centrifuge type and usage.
Fume hoods (i.e., biosafety cabinets)	Periodically (e.g., annually)	Airflow.
Microscopes	Daily	Clean and adjust if necessary (e.g., Köhler illumination, phase ring adjustment).
	Annually	Service and clean.
Osmometers	Daily	Determine and record osmolality of control materials.
Reagent strip readers	Daily	Calibrate reflectance meter with standard reagent strip.
	Daily (or periodically)	Clean mechanical parts and optics.
Refractometers	Daily (or when used)	Read and record deionized water (SG 1.000) and at least one standard of known SG. For example, NaCl 3% (SG 1.015), 5% (SG 1.022), 7% (SG 1.035); or sucrose 9% (1.034). Acceptable tolerance: target ± 0.001.
Temperature-dependent devices, (e.g., refrigerators, freezers, water baths, incubators)	Daily (or when used)	Read and record temperature.
Thermometers	Initially and annually thereafter	Check against NIST-certified thermometer.

NIST, National Institute of Standards and Technology; *SG,* specific gravity.

Reagents

Reliable analytical results obtained in the urinalysis laboratory require the use of quality reagents. The laboratory must have an adequate supply of distilled water, deionized water, or clinical laboratory reagent water (CLRW), formerly called Type I water. Each urinalysis procedure should specify the type of water required for tasks such as reagent preparation or reconstitution of lyophilized materials. The quality of CLRW requires periodic monitoring for ionic and organic impurities as well as for microbial contamination.[3] In addition, because CLRW absorbs carbon dioxide, thereby losing its resistivity on storage, it should be obtained fresh daily. CLRW quality tolerance limits and the actions to be taken when these limits are exceeded must also be available in a written policy.

Today, manufacturers provide many "ready-to-use" reagents as well as the water required to prepare lyophilized materials. When this is not the case, reagent-grade or analytical reagent–grade reagents should be used to prepare reagent solutions for qualitative or quantitative procedures. Primary standards for quantitative methods must be made from chemicals of the highest grade available. These can be purchased from manufacturers or agencies such as the National Institute of Standards and Technology (NIST) (formerly the National Bureau of Standards [NBS]) or CAP and can be accurately weighed to produce a standard of a known concentration. From these primary standards, secondary standards or calibration solutions can be made. Any solvents used should be of sufficient purity to ensure appropriate reactivity and to prevent interfering side reactions.

A standard laboratory requirement is to check all newly prepared standards and reagents before using them. This is done by analyzing a control material using new and old standards or reagents. If performance of the new standard or reagent is equivalent to performance of the old, it is acceptable and dated as approved for use; if it performs inadequately, it should be discarded and the reagent or standard remade. New lot numbers of commercially prepared reagents (e.g., kit tests, reagent strip tests, tablet tests), as well as different bottles of a current lot number, must be checked against older, proven reagents before they are placed into use. Documentation of reagent checks must be maintained in the urinalysis laboratory. All standards, reagents, reagent strips, and tablets, whether made in the laboratory or commercially obtained, must be dated (1) when prepared or received, (2) when their performance is checked and determined to be acceptable, and (3) when put into use. Ensuring the quality of commercial reagent strips and tablet tests used in the urinalysis laboratory is discussed further in Chapter 6.

Procedures

Procedures for all tests and tasks performed must be available in the urinalysis laboratory. An excellent resource for creating and standardizing these documents is provided by the Clinical and Laboratory Standards Institute (CLSI)—for example, document QMS02-A6, Quality Management System: development and management of laboratory documents.[4] Each procedure should be comprehensive and include details of proper specimen collection and handling, test principles, reagent preparation, control materials and acceptance criteria, step-by-step performance, calculations, reporting of results, and references. Because procedures are vital to the test results obtained, they must be maintained and adhered to when each test is performed. Each procedure must include documentation of any procedural changes and must be reviewed regularly—for example, annually. A well-written procedure provides a ready and reliable reference for the veteran technologist, as well as an informational training tool for the novice. The importance of procedures cannot be overemphasized, because uniform performance of testing methods ensures accurate and reproducible results, regardless of changes in personnel.

A routine urinalysis procedure incorporates steps to ensure consistent quality in each of its components. It details each examination—physical, chemical, and microscopic—and includes quality control checks, acceptable terminology, and tolerances for each parameter. The procedure also provides steps to follow when tolerances are exceeded or results are questionable. Additionally, criteria for the correlation of the physical, chemical, and microscopic examinations, as well as follow-up actions are required if discrepancies are discovered. For instance, if the blood reagent strip test is negative and the microscopic examination reveals increased red blood cells, the specimen should be checked for ascorbic acid or the sediment closely reviewed—the "cells" could possibly be an RBC "look-alike," such as monohydrate calcium oxalate crystals or yeast. Reference materials such as textbooks, atlases, and charts must be available for convenient consultation.

Standardization of Technique

The manual microscopic examination of urine requires standardization of technique and adherence to the established procedure by all technologists to enable consistency in results obtained and in their reporting. Preparing urine for manual microscopy requires written step-by-step instructions that detail the volume of urine to use, the centrifuge speed, the time of centrifugation, the sediment concentration, and the volume of sediment examined, as well as the reporting format, terminology, and grading criteria (Box 1.2). Several standardized microscopic slides (e.g., KOVA [Hycor Biomedical Inc., Garden Grove, CA], Urisystem [Fisher Scientific, Waltham, MA]) are commercially available for manual microscopy, and all are superior to the traditional glass slide and coverslip technique.[5] See Chapter 7 for further discussion of manual microscopy and steps that must be taken when commercial standardized slides are not used.

In contrast, automated microscopy analyzers (see Chapter 16) require no specimen preparation (i.e., uncentrifuged urine is used), have good accuracy and precision, and are quick and easy to operate, and their performance is easily monitored and documented using **quality control materials.**

Qualified Personnel

The competence of personnel is an important determinant of the quality of the laboratory result.[6] Because many of the procedures performed in the urinalysis laboratory are done

BOX 1.2 Guidelines for Standardizing Microscopic Urinalysis

Procedural Factors

1. Volume of urine examined (10, 12, 15 mL)
2. Speed of centrifugation (400 × g, 600 × g)
3. Length of centrifugation (3, 5, 10 minutes)
4. Concentration of sediment (10:1, 12:1, 15:1)
5. Volume of sediment dispensed (6–15 uL)

Reporting Factors

1. Each laboratory should publish its own normal values (based on system used and patient population).
2. All personnel must use same terminology.
3. All personnel must report results in standard format.
4. All abnormal results should be flagged for easy reference.

From Schweitzer SC, Schumann JL, Schumann GB: Quality assurance guidelines for the urinalysis laboratory. J Med Technol 3:570, 1986.

manually, it is very important to monitor **technical competence.** Uniformity of technique by all personnel is necessary and can be achieved through (1) proper training, (2) adherence to established protocols, and (3) performance of quality control checks. New technologists should have their technical performance evaluated before they perform routine clinical tests and periodically thereafter to verify ongoing technical competence. Similarly, new procedures introduced into the laboratory must be properly researched, written, and proven before placed into use.

Before reporting results, technologists must be able to evaluate the results obtained, recognize discrepancies or absurdities, and seek answers or make corrections for those encountered. Performing and recording the results obtained, even when they differ from those expected or desired, is paramount. Because test results have a direct effect on patient diagnosis and treatment, the highest level of ethical behavior is required. Documentation of errors or problems and the actions taken to correct them is necessary to (1) ensure communication with staff and supervisory personnel, (2) prevent the problem from recurring, and (3) provide a paper trail of actual circumstances and corrective actions taken as a result. These policies should be viewed as a means of guaranteeing the quality of laboratory results.

Accurate results depend not only on the knowledge and technical competence of the technologist but also on the technologist's integrity in reporting what actually is obtained. Circumstances can arise in laboratory testing that appears to contradict expected test results. When these circumstances are appropriately investigated, legitimate explanations that expand the technologist's scope of experience can be obtained. For example, a patient's test results can differ greatly from those obtained previously. Investigation may reveal that a specimen mix-up occurred or that a drug the patient recently received is now interfering with testing. This highlights the need for good communication among all staff and supervisory personnel, as well as the need for staff meetings to ensure the dissemination of information.

Monitoring Analytical Components of Quality Assessment

For internal QA of testing methods, quality control (QC) materials are used to assess and monitor analytical error, that is, the accuracy and precision of a method. QC materials serve to alert the laboratorian of method changes that directly affect the quality of the results obtained. QC materials mimic patient samples in their physical and chemical characteristics, that is, they have the same matrix. They are usually obtained from commercial suppliers but can also be prepared by the laboratory, particularly for low-volume, esoteric tests. QC materials can be purchased with or without assigned expected values for each parameter. Assigned values should be confirmed and adjusted when necessary to reflect the method and conditions of each laboratory.

Numerous urinalysis control materials are commercially available. Some control materials monitor only the status of the qualitative chemical examination of urine using reagent strips, whereas other control materials include microscopic entities that can monitor the microscopic examination and the steps involved in processing urine specimens (e.g., centrifugation). The microscopic elements present vary with the manufacturer. Quantimetrix Corporation (Redondo Beach, CA) (Dip&Spin, QuanTscopics) uses stabilized human red blood cells, white blood cells, and crystals, whereas Hycor Biomedical Inc. (Garden Grove, CA) (KOVA-Trol) includes stabilized red blood cells, organic particles (mulberry spores) to simulate white blood cells, and crystals. Bio-Rad Laboratories, Inc. (Hercules, CA) (Liquichek Urinalysis Control, qUAntify Plus Control) includes stabilized human red blood cells, artificial white blood cells, and cystine crystals.

Another means of monitoring the entire urinalysis procedure as well as technical competence is to select a well-mixed urine specimen and have each technologist or one from each shift of workers perform the procedure. This provides an intralaboratory or in-house quality assessment. Results should be recorded and evaluated independently. When multiple laboratory sites within a facility perform urinalysis testing, personnel at each site can test an aliquot of the same urine specimen and compare results. If commercial control materials with sediment constituents are not used to evaluate the microscopic examination, in-house duplicate testing can be instrumental in detecting subtle changes in the processing procedure, such as alterations in centrifugation speed or time. The time and effort involved in intralaboratory testing are worthwhile because it ensures that each laboratory and all staff are consistently obtaining equivalent results.

Results obtained on control materials, as well as from duplicate specimen testing, are recorded daily in a tabular or graphic format. The tolerance limits for these results must be defined, documented, and readily available in the laboratory. When these tolerances are exceeded, corrective action must be taken and documented.

Whether the urinalysis laboratory performs quantitative urine procedures (e.g., total protein, creatinine) depends on the facility. In some settings, the urinalysis laboratory

performs only the manual quantitative procedures, whereas the chemistry section performs those procedures that are automated. Regardless, a brief discussion of the QC materials used for quantitative urine methods is provided. The value assigned to commercial or homemade QC materials is determined in the laboratory by performing repeated analyses over different days. This enables variables such as personnel, reagents, and supplies to be represented in the data generated. After analyses are complete, QC data are tabulated and control limits determined by using the mean and standard deviation (SD). Initial control (or tolerance) limits can be established using a minimum of 20 determinations; as more data are accumulated, the limits can be revised. Because the error distribution is Gaussian, control limits are chosen such that 95% to 99% of control values will be within tolerance. This corresponds to the mean value $\pm$ 2 SD or $\pm$ 3 SD, respectively. Graphs of the QC values obtained over time are plotted and are known as *QC* or *Levey-Jennings control charts*. They provide an easy, visual means of identifying changes in accuracy and precision. Changes in accuracy are evidenced by a shift in the mean, whereas changes in precision (random error) are manifested by an increase in scatter or a widening of the distribution of values about the mean (standard deviation).

External quality assessment measures (e.g., proficiency surveys) monitor and evaluate a laboratory's performance compared with other facilities. These QA measures may take the form of proficiency testing or participation in programs in which each laboratory uses the same lot of QC materials. The latter is used primarily with quantitative urine methods. Monthly, the results obtained by each laboratory are reported to the manufacturer of the QC material. Within weeks, reports summarizing the analytical methods used and the results obtained by each laboratory are distributed. These reports are useful in detecting small continuous changes in systematic error in quantitative methods that may not be evident with internal quality assessment procedures.

For a laboratory to be accredited, periodic interlaboratory comparison testing in the form of a proficiency test (PT) is required by CLIA '88.[1] A PT program involves the performance of routine tests on survey samples provided for a fee to participating laboratories. Each laboratory independently performs and submits results to the survey agency (e.g., CAP, Centers for Disease Control and Prevention [CDC]) for assessment and tabulation. Before distribution of the PT samples, the target value of each sample is determined by testing at selected or reference laboratories. Using the reference laboratory target values and results submitted by the participant laboratories, the survey agency prepares extensive reports and charts for each analyte assessed, the method used, and the values obtained. A PT program provides valuable information on laboratory performance and testing methods—individually, by specific method, and as a whole.

Some urinalysis PT surveys include digital images or photomicrographs for the identification of urine sediment components, such as casts, epithelial cells, blood cells, and artifacts. These urine sediment images are reviewed and the sediment component identified by one randomly selected technologist in the laboratory. As with patient samples, the technologist can seek assistance from a lead tech, supervisor, or pathologist, provided that is the laboratory's standard protocol.[7] After submission and receipt of the PT results, group review of the sediment images provides an excellent opportunity to maintain and improve the competence of personnel.

Although QC materials and PT samples help to detect decreased quality in laboratory testing, they do not pinpoint the source of the problem, nor do they solve it. Only with good communication and documentation can analytical problems be pursued and continuing education programs developed. Some problems encountered in the laboratory are approached best by the involvement of laboratorians as a problem-solving team, which can reaffirm their self-worth and enhance their commitment to quality goals.

Postanalytical Components of Quality Assessment

Urinalysis results can be communicated efficiently and effectively using a standardized reporting format and terminology. The report should include reference ranges and the ability to add informative statements if warranted—for example, "glucose oxidase/reducing substances questionable due to presence of ascorbic acid" or "white blood cell clumps present." Results should be quantitative (e.g., 100 mg/dL or 10–25 RBCs/HPF [red blood cells per high-power field]) whenever possible. All personnel should use the same (i.e., standardized) terminology for test parameters (e.g., color and clarity terms).

Laboratory procedures should describe in detail the appropriate reporting format and should provide criteria for the reporting of any critical values. **Critical values** are significantly abnormal results that exceed the upper or lower critical limit and are life threatening. These results need to be relayed immediately to the health care provider for appropriate action. The laboratorian is responsible for recognizing critical values and communicating them in a timely fashion. Each institution must establish its own list of critical values. For example, the list might include as critical the presence of pathologic urine crystals (e.g., cystine, leucine, tyrosine); a strongly positive test for glucose and ketones; and in an infant the presence of a reducing substance, other than glucose or ascorbic acid.

Quality assessment measures, whether internal (QC materials) or external (proficiency tests), require documentation and evidence of active review. When acceptable tolerances are exceeded, they must be recorded and corrective action taken. In the clinical laboratory, documentation is crucial because an action that is not documented essentially was not performed. The goal of an effective QA program is to obtain consistently accurate and reproducible results. In achieving this goal, test results will reflect the patient's condition, rather than results modified due to procedural or personnel variations.

SAFETY IN THE URINALYSIS LABORATORY

For years the health care industry has been at the forefront in developing policies and procedures to prevent and control the

spread of infection in all areas of the hospital to ensure patient and employee safety. Because clinical laboratory employees are exposed to numerous workplace hazards in various forms—biological, chemical, electrical, radioactive, compressed gases, fires, and so on—safety policies are an integral part of the laboratory. With passage of the Occupational Health and Safety Act in 1970, formal regulation of safety and health for all employees, regardless of employer, officially began. This law is administered through the US Department of Labor by the **Occupational Safety and Health Administration (OSHA).** As a result of the law, written manuals that define specific safety policies and procedures for all potential hazards are required in laboratories. Guidelines for developing these written policies and procedures are provided in several Clinical and Laboratory Standards Institute (CLSI) documents.[8–10] An additional requirement of the law is that all employees must document annual review of the safety manual. The next section discusses hazards frequently encountered in the clinical laboratory when working with urine and other body fluids (e.g., feces, amniotic fluid, cerebrospinal fluid), as well as policies and procedures necessary to ensure a safe and healthy working environment.

Biological Hazards

Biological hazards abound in the clinical laboratory. Today, any patient specimen or body substance (e.g., body fluid, fresh tissue, excretions, secretions, sputum, or drainage) is considered infectious, regardless of patient diagnosis. Table 1.3 provides a brief history and key points of safety guidelines and regulations implemented to prevent the transmission of infectious agents in hospitals. In the 1980s, the transmission of disease such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) became a major concern for health care workers. To address the issue, in 1987, the Centers for Disease Control and Prevention (CDC) issued practice guidelines known as **Universal Precautions (UP).** UP were intended to protect health care workers, primarily from patients with these bloodborne diseases. Under UP, body fluids and secretions that did not contain visible blood were exempt. At this same time, another system of isolation was proposed and refined; this was called *Body Substance Isolation* (BSI).[11,12] BSI and UP had similar features to prevent the transmission of bloodborne pathogens but differed with regard to handwashing after glove use. UP recommended handwashing after the removal of gloves, whereas BSI indicated that handwashing was not required unless the hands were visibly soiled. Then in 1991, OSHA enacted the Bloodborne Pathogens Standard (BPS) to address occupational exposure of health care workers to infectious agents, primarily HIV, hepatitis viruses, and retroviruses. BPS requires laboratories to have an exposure control plan that regulates work practices such as handling of needles and sharps and requires hepatitis B vaccinations, training, and other measures.[13–15]

This became a time of confusion, with hospitals differing in their isolation protocols, as well as in the handling of body fluids and other substances. It was recognized that UP guidelines alone were inadequate because infectious body fluids do not always have or show visible blood. To resolve this conundrum, the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the CDC issued in 1996 a new two-tier practice guideline known as Standard Precautions and Transmission-Based Precautions.[16,17] **Standard Precautions** are infection prevention practices that are applied to all patients in all health care settings and that address not only the protection of health care personnel but also the prevention of patient-to-patient and health care worker-to-patient transmission (i.e., nosocomial transmission) of infectious agents. It combines the major features of UP and BSI into a single guideline with feasible recommendations to prevent disease transmission. Standard Precautions also dictate that standards or calibrators, quality control materials, and proficiency testing materials be handled like all other laboratory specimens.[8] The Transmission-Based Precautions of the guideline apply to specific patients with known or suspected infections or colonization with infectious agents (e.g., vancomycin-resistant enterococcus [VRE]). Three categories of Transmission-Based Precautions in the hospital are described: contact precautions, droplet precautions, and airborne precautions. These additional precautions are used when the potential for disease transmission from these patients or their body fluids is not completely interrupted by using Standard Precautions alone.

It is important to note that Standard Precautions do not affect other necessary types of infection control strategies, such as identification and handling of infectious laboratory specimens or waste during shipment; protocols for disinfection, sterilization, or decontamination; or laundry procedures.[8]

Traditionally, the three routes of infection or disease transmission are (1) inhalation, (2) ingestion, and (3) direct inoculation or skin contact. In the laboratory, aerosols can be created and inhaled when liquids (e.g., body fluids) are poured, pipetted, or spilled. Similarly, centrifugation of samples and removal of tight-fitting caps from specimen containers are potential sources of airborne transmission. Ingestion occurs when infectious agents are taken into the mouth and swallowed, as from eating, drinking, or smoking in the laboratory; mouth pipetting; or hand-to-mouth contact after failure to appropriately wash one's hands. Direct inoculation involves parenteral exposure to the infectious agent as a result of a break in the technologist's skin barrier or contact with the mucous membranes. This includes skin punctures with needles, cuts or scratches from contaminated glassware, and splashes of specimens into the eyes, nose, and mouth. Although it is impossible to eliminate all sources of infectious transmission in the laboratory, the use of protective barriers and the adherence to Standard Precautions minimize transmission.

Under Standard Precautions, *all body fluids, secretions, and excretions* (except sweat) are considered potentially infectious and capable of disease transmission. Key components of Standard Precautions are good hand hygiene and the use of barriers (physical, mechanical, or chemical) between potential sources of an infectious agent and individuals. All personnel must adhere to Standard Precautions; this includes

TABLE 1.3 Selected Evolution History of Isolation Precautions in Hospitals[9,10]

Year	Guideline or Regulation	Key Points
1985–1988	Universal Precautions (UP)	• Established in response to HIV/AIDS epidemic • Initiated the application of blood and body fluid precautions to *all* patients • Exempted some specimens from precautions, namely, urine, feces, nasal secretions, sputum, sweat, tears, and vomitus *unless visible blood present* • Included the use of PPE by health care workers to prevent mucous membrane exposures • Recommended handwashing after glove removal • Included recommendations for the handling and disposal of needles and other sharps

1987	Body Substance Isolation (BSI)[11,12]	• Emphasized the avoidance of contact with potentially infectious, moist body fluids (except sweat), *regardless* of the presence or absence of blood
		• Similar to UP recommendations for the prevention of bloodborne pathogen transmission
		• Handwashing after glove removal *not required* unless hands visibly soiled
		• Inadequate provisions to prevent:
		  • Some droplet transmissions
		  • Direct or indirect contact transmission from dry skin or environmental sources
		  • Airborne droplet nuclei transmission of infection (e.g., tuberculosis) over long distances

1991[13] (1999,[14] 2001[15])	Bloodborne Pathogens Standard[13–15]; OSHA	• Aimed at reducing health care worker exposure to bloodborne pathogens—HIV, hepatitis viruses, and retroviruses—when caring for patients with known infection
		• Requires *employer* to have an Exposure Control Plan to:
		  • Educate workers
		  • Provide necessary supplies and other measures (e.g., PPE, hepatitis B vaccination, signs and labels, medical surveillance)

1996,[16] 2007[17]	Standard Precautions and Transmission-Based Precautions; HICPAC/CDC	• Two-tier approach to prevent disease transmission that emphasizes prevention of nosocomial infection and worker safety
		• Tier 1: Standard Precautions
		  • A synthesis of UP, BSI, and 1983 CDC guidelines
		  • Applies to all body fluids, secretions, excretions (except sweat), and tissue specimens
		  • Applies to human-based standards or calibrators, quality control materials, and proficiency testing materials
		  • Applies to nonintact skin and mucous membranes of patient and health care worker
		• Tier 2: Transmission-Based Precautions
		  • Three categories: airborne, droplet, and contact
		  • Used when Standard Precautions alone are insufficient
		  • Used for patients with known or suspected infection
		• Lists specific syndromes that require temporary isolation precautions until a definitive diagnosis is made

PPE, Personal protective equipment; *CDC,* Centers for Disease Control and Prevention; *HICPAC,* Healthcare Infection Control Practices Advisory Committee; *OSHA,* Occupational Safety and Health Administration.

ancillary health care staff such as custodial and food service employees, as well as health care volunteers. It is a responsibility of each health care department to educate, implement, document, and monitor compliance with Standard Precautions. In addition, written safety and infection control policies and procedures must be readily available for reference in the laboratory.

Personal Protective Equipment

When contact with body fluids or other liquids is anticipated, appropriate **personal protective equipment (PPE)** or barriers must be used. Gloves should be worn when assisting patients in collecting specimens, when receiving and processing specimens, when performing any testing procedure, and when cleaning equipment or work areas. In addition, they