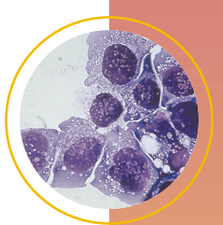
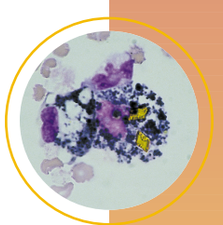
CHAPTER 7





Quality Assurance and Management in the Urinalysis Laboratory

LEARNING OBJECTIVES

Upon completion of this chapter, the reader will be able to:

1. Discuss the quality assurance procedures and documentation for quality control of specimens, methodology, reagents, control materials, instrumentation, equipment, and reporting of results in the urinalysis laboratory.
2. Define the preanalytical, analytical, and postanalytical components of quality assurance.
3. Distinguish between the components of internal and external quality control.
4. List the elements required for quality assurance as regulated by the Clinical Laboratory Improvement Amendments (CLIA '88).
5. Describe the four levels of the CLIA '88 complexity model and how they relate to urinalysis testing.
6. Discuss the importance of continuous quality improvement and total quality management, including the recommendations of the Joint Commission on Accreditation of Healthcare Organizations.

KEY TERMS

accreditation
continuous quality improvement
external quality control
internal quality control
outcomes
process
proficiency testing
quality assurance
quality control
total quality management
turnaround time

The term ***quality assurance*** (**QA**) refers to the overall process of guaranteeing quality patient care. In a clinical laboratory, a quality assurance program includes not only testing controls, referred to as ***quality control*** (**QC**), but also encompasses preanalytical factors (e.g., specimen collection, handling, and storage), analytical factors (e.g., reagent and test performance, instrument calibration and maintenance, personnel requirements, and technical competence), and postanalytical factors (e.g., reporting of results and interpretation), and documentation that the program is being meticulously followed.[8] Included in a QA program are procedure manuals, ***internal quality control*** and ***external quality control***, standardization, ***proficiency testing***, record keeping, equipment maintenance, safety programs, training and education of personnel, and a scheduled and documented review process. Essentially, QA is the continual monitoring of the entire test process from test ordering and specimen collection through reporting and interpreting results. Written policies and documented actions as they relate to the patient, the laboratory, ancillary personnel, and the health-care provider are required. Having written remedial actions mandating the steps to take when any part of the system fails is essential to a QA program.

During the discussion of the routine urinalysis in the preceding chapters, the methods of ensuring accurate results were covered on an individual basis for each of the tests. Because QA in the urinalysis laboratory—or any other laboratory department—is an integration of many factors, this section will provide a collection of the procedures essential for providing quality urinalysis.

Documentation of QA procedures is required for laboratory ***accreditation*** by either the Joint Commission on the Accreditation of Healthcare Organizations (**JCAHO**) or the College of American Pathologists (**CAP**) and for Medicare reimbursement. Guidelines published by CAP and the National Committee for Clinical Laboratory Standards provide very complete instructions for documentation and are used as a reference for the ensuing discussion of the specific areas of urinalysis QC and QA.[1,9] Documentation in the form of a procedure manual is required in all laboratories, and this format will be used as a basis for the following discussion.

Urinalysis Procedure Manual

A procedure manual containing all the procedures performed in the urinalysis section must be available for reference in the working area. The following information is included for each procedure: principle or purpose of the test, patient preparation, specimen type and method of collection, reagents, standards and controls, instrument calibration and maintenance protocols and schedules, step-by-step procedure, calculations, frequency and tolerance of controls and corrective actions, normal values and panic values, specific procedure notes, limitations of the method, method validation, references, effective date, author, and review schedule. Current package inserts should be available at the workplace.

St. JOSEPH HOSPITAL
PATHOLOGY DEPT
CLINICAL CHEMISTRY/ URINALYSIS SECTION

SPECIMEN ACCEPTABILITY/ LABELING

Prepared by: Carol Schmitt MT[ASCP]

Initial approval: Donna Wells MD

Procedure placed in use: June 1983

Revised: June 1999

Reason for Revision: Changes in format

Effective Date	Technical Approval	Medical Director Approval
Reviewed	Carol Schmitt 6/24/99	T Dwyer MD 6/22/99
Reviewed		
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FIGURE 7–1 Example of procedure review documentation. (From the Department of Pathology, St. Joseph Hospital, Omaha, NE, with permission.)

The evaluation of procedures and adoption of new methodologies is an ongoing process in the clinical laboratory. Whenever changes are made, the procedure should be reviewed and signed by a person with designated authority, such as the laboratory director or section supervisor (Figure 7–1). Documentation of an annual review of all procedures by the designated authority must also be substantiated.

PREANALYTICAL FACTORS

Preanalytical factors are the variables that occur before the actual testing of the specimen and include test requests, patient preparation, specimen collection, handling, and storage.[8] Health-care personnel outside the clinical laboratory control many of these factors such as ordering tests and specimen collection. Communication between departments and adequate training on the correct procedures for ordering a test and collecting the specimen will improve the ***turnaround time*** (**TAT**) of results, avoid duplication of test orders, and ensure a high-quality specimen.

Specimen Collection and Handling

Specific information on specimen collection and handling should be stated at the beginning of each procedure listed in the manual. Requisition forms and computerized entry forms should designate the type of urine specimen to be collected and the date and time of collection. The form should include space for recording 1) the actual date and time of specimen collection, 2) whether the specimen was refrigerated before transporting, 3) the time the specimen was received in the laboratory and the time the test was performed, 4) tests requested, 5) an area for specific instructions that might affect the results of the analysis, and 6) patient identification information.[9]

Patient preparation (e.g., fasting or elimination of interfering medications), the type and volume of specimen required, and the need for sterile or opaque containers must

TABLE 7–1 **Policy for Handling Mislabeled Specimens**

Do NOT assume any information about the specimen or patient.
Do NOT relabel an incorrectly labeled specimen.
Do NOT discard the specimen until investigation is complete.
Leave specimen EXACTLY as you receive it; put in the refrigerator for preservation until errors can be resolved.
Notify floor, nursing station, doctor's office, etc. of problem and why it must be corrected for analysis to continue.
Identify problem on specimen requisition with date, time, and your initials.
Make person responsible for specimen collection participate in solution of problem(s). Any action taken should be documented on the requisition slip.
Report all mislabeled specimens to the quality assurance board.

From Schweitzer, Schumann, and Schumann,[10] p. 568, with permission.

be included with the specific procedure. All specimens should be examined within 2 hours. If this is not possible, written instructions for the preservation of the specimen must be available.

Instructions of a general nature, such as procedures for the collection of clean-catch and timed specimens, processing of specimens, and any printed materials given to patients, are also included in the manual.

Criteria for specimen rejection for both physical characteristics and labeling errors must be present. In Table 7–1, an example of a policy for handling mislabeled specimens is provided. Written criteria for rejection of specimens must be documented and available to the physician and nursing staff.

Laboratory personnel must determine the suitability of a specimen and document any problems and corrective actions taken (Figure 7–2). An acceptable specimen requires verification of the patient's identification information on the requisition form and the container label, timely transport to the laboratory, the presence of refrigeration or recommended preservative if transport was delayed, and collection of an adequate amount of the correct urine specimen type in a noncontaminated, tightly closed container. After receipt in the laboratory, the specimen must be processed immediately or, if necessary, stored in a refrigerator and protected from light.[9]

ANALYTICAL FACTORS

The analytical factors are the processes that directly affect the testing of specimens. They include reagents, instrumentation and equipment, testing procedure, QC, **preventive maintenance (PM)**, access to procedure manuals, and competency of personnel performing the tests.[8]

Reagents

The manual should state the name and chemical formula of each reagent used, instructions for preparation, when necessary, or company source of prepared materials, storage requirements, and procedures for reagent QC. The type of water used for preparing reagents and controls must be specified. A bold-type statement of any safety or health precautions associated with reagents should be present. An example of this would be the heat produced in the Clinitest reaction.

All reagents and reagent strips must be properly labeled with the date of preparation or opening, purchase date, expiration date, and appropriate safety information. Reagent strips should be checked against known negative and positive control solutions on each shift or at a minimum once a day, and whenever a new bottle is opened. Reagents are checked daily or when tests requiring their use are requested. Results of all reagent checks are properly recorded.

Instrumentation and Equipment

Instructions regarding the operation, performance and frequency of calibration, limitations, and procedures to follow when limitations or linearity are exceeded, such as dilution procedures, must be clearly stated in the procedure manual. Instructions detailing the appropriate recording procedures must be included.

The most frequently encountered instruments in the urinalysis laboratory are refractometers, osmometers, automated reagent strip readers, and automated microscopy instruments. Refractometers are calibrated on each shift against distilled water (1.000) and a known control, such as 5 percent saline (1.022 ± 0.001) or 9 percent sucrose (1.034 ± 0.001), is run. Both the high and low commercial controls are available for the osmometer. All control values are recorded. Automated urinalysis systems and reagent strip readers are calibrated using manufacturer-supplied calibration materials following the protocol specified by the manufacturer. Both positive and negative control values must be run and recorded (Figure 7–3).

Equipment found in the urinalysis laboratory commonly includes refrigerators, centrifuges, microscopes, and water baths. Temperatures of refrigerators and water baths should be taken daily and recorded. Calibration of centrifuges is customarily performed every 3 months, and the appropriate relative centrifugal force for each setting is recorded. Centrifuges are routinely disinfected on a weekly basis. Microscopes should be kept clean at all times. A routine PM schedule for instruments and equipment should be prepared, and records are kept of all routine and nonroutine maintenance performed (Figure 7–4).

Deionized water used for reagent preparation is quality controlled by checking pH and purity meter resistance on a weekly basis and the bacterial count on a monthly schedule. All results must be recorded on the appropriate forms.

Testing Procedure

Detailed, concise testing instructions are written in a step-by-step manner. Instructions should begin with specimen preparation, such as time and speed of centrifugation, and include types of glassware needed, time limitations and stability of specimens and reagents, calculation formulas and a sample calculation, health and safety precautions, and procedures. Additional procedure information including reasons for special precautions, sources of error and interfering

Month/year ________/____

Core Laboratory Errors/Corrections

				Origin of Error - place a check mark in one box																Check one								
				Collection				Processing			Mis-info			Tech sec.			Result rpt			Discov		When						
Error by: Initials	Recorded by: Initials	Date	Major Error/Incident rpt	Patient Identification	Specimen Identification	Specimen Integrity	Document Status	Aliquot ID	Requisition/Order	Specimen Processing	Nursing	Respiratory Therapy	Client	Performance	Interpretation	Math	Entry (tech)	Transcription (tech)	Clerical Personnel	By Lab	Non-lab	Immediately	Same Shift	After Shift	nrbc	Other non-error	Comments	Patient Name, Test
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FIGURE 7–2 Sample of errors and corrections documentation form. (From the Department of Pathology, Methodist Hospital, Omaha, NE, with permission.)

QUALITY CONTROL - CLINITEK ATLAS **MONTH:____________20____**

			KOVATROL LOT #:									SALINE								
			GLU	BIL	KET	SP GR	BLD	PH	PROT	NIT	LEU EST	GLU	BIL	KET	SP GR	BLD	PH	PROT	NIT	LEU EST
			mg/dl		mg/dl	1.0			mg/dl			mg/dl		mg/dl	1.0			mg/dl		
KOVATROL ASSAY VALUES																				
	TECH	DATE																		
REAGENT PACK																				
LOT #																				
EXP																				

FIGURE 7–3 Sample instrument QC recording sheet. (From the Department of Pathology, Methodist Hospital, Omaha, NE, with permission.)

IRIS 900 UDx BOEHRINGER MANNHEIM Super UA
MAINTENANCE LOG

DAILY	OM SECTION	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Check Waste Tray	4.2																															
Check Transport Tray	4.2																															
Execute Daily Wash	5.2																															
Empty Waste Tank	5.3																															
Check Water Level																																
Clean Instrument Surfaces																																
TECH INITIALS																																

WEEKLY	OM SECTION	1	2	3	4	5
Clean Rinse Bath	5.5					
Clean Sorter Stage	5.7					
Clean Mixing Rod/Displacement Rod	5.8					
Clean Di Water Reservoir	5.14					
BIWEEKLY						
Calibrate Reader	4.3					
TECH INITIALS						

OM = Operator's Manual

AS NEEDED	OM SECTION	DATE
Clean Transport Plate	5.4	
Clean Sorter Drum	5.6	
Replace Waste Tray	5.9	
Floppy Disk Replacement and Disk Drive Cleaning	5.10	
Clean Sample Disk Compartment	5.11	
Replace Printer Paper	5.12	
Clean Sample Drip and Sample Disk Drip Trays	5.13	
Decontamination of Tubing Lines	5.15	
TECH INITIALS		

FIGURE 7–4 Sample preventive maintenance documentation form. (Courtesy of International Remote Imaging Systems, Chatsworth, CA.)

substances, helpful hints, clinical situations that influence the test, alternative procedures, and acceptable TATs for STAT tests are listed under the title of Procedure Notes following the step-by-step procedure.[11]

Reference sources should be listed. Manufacturer's package inserts may be included but cannot replace the written procedure.

Quality Control

Quality control refers to the materials, procedures, and techniques that monitor the **accuracy**, **precision**, and **reliability** of a laboratory test.[5] QC procedures are performed to ensure that acceptable standards are being met during the process of patient testing. Specific QC information regarding the type of control specimen preparation and handling, frequency of use, tolerance levels, and methods of recording should be included in the step-by-step instructions for each test. QC is performed at scheduled times, such as at the beginning of each shift or prior to testing patient samples, and it must always be performed if reagents are changed, an instrument malfunction has occurred, or if test results are questioned by the physician. Both internal quality control and external quality control processes are practiced in the urinalysis laboratory.

Internal quality controls are used to verify the accuracy (ability to obtain the expected result) and precision (ability to obtain the same result on the same specimen) of a test and are exposed to the same conditions as the patient samples. Reliability is the ability to maintain both precision and accuracy. Commercial controls are available for the urine chemistry tests, specific gravity, and for certain microscopic constituents. Analysis of two levels of control material is recommended. Documentation of QC includes dating and initialing the material when it is first opened, recording the manufacturer's lot number and the expiration date each time a control is run and the test result obtained. Food and Drug Administration standards require that control material must test negative for the human immunodeficiency virus and hepatitis B virus. Internal controls are tested and interpreted in the laboratory by the same person performing the patient testing.

Control data are evaluated prior to release of patient results. Data obtained from repeated measurements will have a gaussian distribution or spread in the values that will indicate the ability to repeat the analysis and obtain the same value. The laboratory, after repeated testing, establishes the value for each analyte and the mean and standard deviation is calculated. The **control mean** is the average of all data points and the **standard deviation (SD)** is a measurement statistic that describes the average distance each data point in a normal distribution is from the mean. The **coefficient of variation (CV)** is the SD expressed as a percentage of the mean. The CV indicates whether the distribution of values about the mean is in a narrow versus broad range and should be less than 5 percent. Confidence intervals are the limits between which the specified proportion or percentage of results will lie. **Control ranges** are determined by setting confidence limits that are within ± 2 SD or ± 3 SD of the mean which indicates that 95.5 percent to 99.7 percent of the values are expected to be within that range.

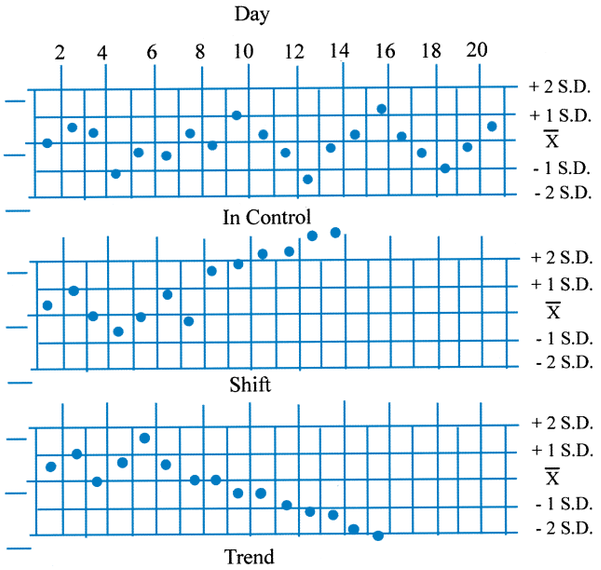

FIGURE 7–5 Levy-Jennings charts showing in-control results, trend, and shift.

Values are plotted on Levy-Jennings control charts to visually monitor control values. Immediate decisions about patient results are based on the ability of control values to remain within a preestablished limit. Changes in accuracy of results are indicated by either a **trend** that is a gradual changing in the mean in one direction or a **shift** that is an abrupt change in the mean (Figure 7–5). Changes in precision are shown by a large amount of scatter about the mean and an uneven distribution above and below the mean that are most often caused by errors in technique.

Corrective action, including the use of new reagents, reagent strips or controls and the verification of lot numbers and expiration dates, must be taken when control values are outside the tolerance limits. All corrective actions taken are documented. A protocol for corrective action is shown in Figure 7–6. A designated supervisor reviews all QC results.

External quality control is the testing of unknown samples received from an outside agency. It provides unbiased validation of the quality of patient test results. Proficiency testing such as that offered by the CAP provides this external quality control. Laboratories subscribing to this program receive lyophilized specimens for routine urinalysis and transparencies for sediment constituent identification. The results are returned to the CAP, where they are statistically analyzed with those from all participating laboratories, and a report is returned to the laboratory director. The laboratory accuracy is evaluated and compared with other laboratories using the same method of analysis. Corrective action must be taken for unacceptable results.

Laboratories may participate in a commercial QC program. Results from the same lot of QC material are sent to the manufacturer for statistical analysis and comparison with other laboratories using the same methodology.

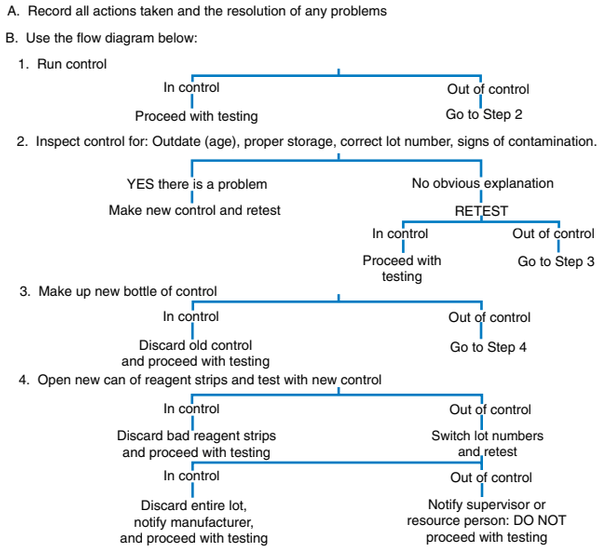

FIGURE 7–6 "Out-of-control" procedures. (From Schweitzer, Schumann, and Schumann,[10] with permission.)

MICROSCOPIC QUANTITATIONS

Quantitate an average of 10 representative fields. Do not quantitate budding yeast, mycelial elements, trichomonas, or sperm, but do note their presence with the appropriate LIS code.

Epithelial Cells/LPF	
None:	0
Rare:	0-5
Few:	5-20
Moderate:	20-100
Many:	>100
Casts/LPF	
None:	0
Numerical ranges:	0-2, 2-5, 5-10, >10
RBCs/HPF	
None:	0
Numerical ranges:	0-2, 2-5, 5-10, 10-25, 25-50, 50-100, >100
WBCs/HPF	
None:	0
Numerical ranges:	0-2, 2-5, 5-10, 10-25, 25-50, 50-100, >100
Crystals/HPF	
None:	0
Rare:	0-2
Few:	2-5
Moderate:	5-20
Many:	>20
Bacteria/HPF	
None:	0
Rare:	0-10
Few:	10-50
Moderate:	50-200
Many:	>200
Mucous Threads	
Rare:	0-1
Few:	1-3
Moderate:	3-10
Many:	>10

FIGURE 7–7 Sample standardized urine microscopic reporting format. (From University of Nebraska Medical Center, Omaha, NE, with permission.)

Personnel and Facilities

Quality control is only as good as the personnel performing and monitoring it. Personnel must understand the importance of QA, and the program should be administered in a manner such that personnel view it as a learning experience rather than as a threat.[10] Up-to-date reference materials and atlases should be readily available, and documentation of continuing education must be maintained.

An adequate, uncluttered, safe working area is also essential for both quality work and personnel morale. Universal precautions for handling body fluids must be followed at all times.

POSTANALYTICAL FACTORS

Postanalytical factors are processes that affect the reporting of results and correct interpretation of data.[8]

Reporting of Results

Standardized reporting formats and, when applicable, reference ranges should be included with each procedure covered in the procedure manual. A written procedure for reporting, reviewing, and correcting errors must be present.

Forms for reporting results should provide adequate space for writing and should present the information in a logical sequence. Standardized reporting methods will minimize health-care provider confusion when interpreting results (Figure 7–7).

Written procedures should be available for the reporting of critical values (Figure 7–8). In laboratories analyzing pediatric specimens, this should include the presence of ketones or sugars in newborns.

Summary of Quality Assurance Errors

Preanalytical

Patient misidentification
Wrong test ordered
Incorrect urine specimen type collected
Insufficient urine volume
Delayed transport of urine to the laboratory
Incorrect storage or preservation of urine

Analytical

Sample misidentification
Erroneous instrument calibration
Reagent deterioration
Poor testing technique
Instrument malfunction
Interfering substances present
Misinterpretation of quality control data

Postanalytical

Patient misidentification
Poor handwriting
Poor quality of instrument printer
Failure to send report
Failure to call critical values
Inability to identify interfering substances

ST.JOSEPH HOSPITAL
PATHOLOGY DEPT
CLINICAL CHEMISTRY/ URINALYSIS SECTION

CRITICAL RESULTS REPORTING IN URINALYSIS

Prepared by: Carol Schmitt MT[ASCP]

Initial approval: George McClellan MD

Procedure placed in use: January 1991

Revised: June 1999

Reason for Revision: format change

Effective Date	Technical Approval	Medical Director Approval
Reviewed	Carol Schmitt 6/22/99	T Duggan 6/22/99
Reviewed		
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Reviewed		
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POSITIVE KETONES:

All positive ketones on pediatrics less than or equal to two years old shall be called to the appropriate nursing unit. The time of the call, initials of the "tech", and the name of the person receiving the call are to be documented in the computer as a chartable footnote appended to the result.

POSITIVE CLINITEST;

All positive Clinitest results on pediatrics less than or equal to two years old shall be called to the appropriate nursing unit. The time of the call, initials of the "tech", and the name of the person receiving the call are to be documented in the computer as a chartable footnote appended to the result.

This policy shall be reviewed by the Chemistry Section Supervisor and Chemistry Section Director annually or whenever changes are made.

FIGURE 7–8 Sample critical results–reporting procedure. (From the Department of Pathology, St. Joseph Hospital, Omaha, NE, with permission.)

Interpretation of Results

The specificity and the sensitivity for each test should be included in the procedure manual for correct interpretation of results. All known interfering substances should be listed for evaluation of patient test data. A well-documented QA program will ensure quality test results and patient care.

Regulatory Issues

Clinical Laboratory Improvement Amendments '88 stipulate that all laboratories that perform testing on human specimens for the purposes of diagnosis, treatment, monitoring, or screening must be licensed. This includes all independent and hospital laboratories, physician-office laboratories, rural health clinics, mobile health screening entities such as health fairs, and public health clinics. CLIA '88 defined categories of diagnostic laboratory tests and specified the training and educational levels required of personnel performing the tests. Tests are assigned to the following categories: waived, provider-performed microscopy, moderate complexity, and high complexity.

Waived tests are considered easy to perform and interpret, require no special training or educational background, require only a minimum of standardization and QC, and are not considered critical to immediate patient care. Urinalysis tests in this category are manual dipstick/chemical tablet testing and urine pregnancy tests. In Table 7–2, the current tests in this category are listed. Tests continue to be modified, enabling them to be approved for waived testing.

TABLE 7–2 **CLIA '88 Waived Tests**

Dipstick/chemical tablet urinalysis
Ovulation pregnancy tests (visual color comparison)
Urine pregnancy tests (visual color comparison)
Erythrocyte sedimentation rate (nonautomated)
Hemoglobin by copper sulfate and Hemocue
Fecal occult blood
Spun hematocrit
Blood glucose (using FDA-approved home-use instruments)
Group A streptococcus, mononucleosis, and *Helicobacter pylori* kits
Point-of-care cholesterol screening instruments
Prothrombin time

A modification of the CLIA categories created a new certificate category for provider-performed microscopy (**PPM**) procedures. This category includes certain microscopic procedures that can be performed in conjunction with any waived test to avoid disruption in the patient visit. Personnel standards authorize only physicians, physician's assistants, nurse practitioners, and dentists to perform the tests. Laboratories performing PPM must meet the moderate-complexity requirements for proficiency testing, patient test management, QC, and QA. Urine sediment examinations, wet mounts, and KOH preparations are examples of the tests in this category. A complete listing is provided in Table 7–3.

Moderate-complexity tests are more difficult to perform than are waived tests and require documentation of training in testing principles, instrument calibration, periodic proficiency testing and on-site inspections. In a hospital setting, even waived tests must adhere to the moderate-complexity test standards. Most chemistry and hematology tests are assigned to this category. Automated or semiautomated urinalysis tests and urine microscopic procedures are considered moderate-complexity tests.

High-complexity tests require sophisticated instrumentation and a high degree of interpretation by the testing per-

TABLE 7–3 **Provider-Performed Microscopy Category**

Urine sediment examination
Wet mounts (vaginal, cervical, skin, or prostatic secretions)
KOH preparations
Pinworm examinations
Fern test
Postcoital direct, qualitative examinations of vaginal mucus
Fecal leukocyte examination
Qualitative semen analysis
Nasal smear for granulocytes

sonnel. Many tests performed in microbiology, immunology, immunohematology, and cytology are in this category.

Clinical Laboratory Improvement Amendments '88 regulations specify required components for QA that include patient test management assessment, QC assessment, proficiency testing assessment, comparison of test results, relationship of patient information to patient test results, personnel assessment, communications, complaint investigation, QA review with staff, and QA records.[4]

Patient test management includes systems for patient preparation, correct specimen collection, sample identification, sample preservation, sample transportation, sample processing, and accurate result reporting. The testing facility must have available written procedures for each system to ensure that specimen integrity and identification are maintained throughout the entire testing process.

Quality control assessment requires that quality control records include date, results, testing personnel, and lot numbers for reagents and controls. Records must be retained for 2 years. Records should be reviewed daily and monthly to detect trends, shifts, inconsistent test systems, or operator difficulties.

Proficiency testing is required for all laboratories performing PPM moderate-complexity or high-complexity testing. An approved program will involve three events per year with five challenges per analyte that is regulated.[5] Samples must be tested in the same manner as patient samples. Communication or consultation with other laboratories is not permitted.

Personnel assessment includes education and training, continuing education, competency assessment, and performance appraisals. Each new employee must have documentation of training during orientation to the laboratory. A checklist of procedures must be documented with the date and initials of the person doing the training and of the employee being trained.

The qualifications of the personnel performing patient care are also regulated to ensure that only persons with appropriate education and training perform procedures. Health-care personnel become certified and/or licensed in their particular fields through the completion of specified educational requirements and/or satisfactory performance on standardized proficiency examinations. The level of education is documented in the employee personnel file. A record of all continuing education sessions should be kept in each personnel file. Currently no minimum hours of continuing education are mandated.

Technical competency assessment as mandated by CLIA '88 must be done for each employee for each procedure twice during the first year of employment and then annually. Methods for assessing competency include direct observation, review of QC records, review of proficiency testing records, and written assessments.[3]

Performance appraisals for each employee are done following the institution's protocol and evaluate the standards of performance as designated by the job description. The standards must be specific and measurable and may include evaluation of attitude as well as organizational and communication skills.

Clinical laboratory records must be maintained for 2 years. These records include patient test results, QC data, reagent logs, proficiency test data, competency assessment, education and training, equipment maintenance, service calls, documentation of problems, complaints, communication, inspection files, and certification records.

The Clinical Laboratory Improvement Amendments '88 are administered by the Health Care Financing Administration (**HCFA**). Accrediting agencies that have been approved by the federal government after demonstrating equivalency with CLIA '88 standards include the Commission on Laboratory Assessment (**COLA**), which is popular with physician office laboratories; the JCAHO; and CAP, which serves large laboratories. Compliance with accreditation regulations is ensured by periodic on-site visits to facilities by inspection teams and through performance on proficiency tests. If deficiencies are present, the facility must correct them within a specified time and be reinspected. Waived and PPM laboratories are not subject to routine inspection. Inspections must be scheduled and are done within the first 2 years of certification. The ultimate goal of these agencies is to promote ***continuous quality improvement*** (**CQI**).[3]

Continuous Quality Improvement

Quality control and QA programs are part of institutional CQI and ***total quality management*** (**TQM**). Whereas QA is designed to maintain an established level of quality, TQM and CQI are designed to develop methods to continually improve the quality of health care. Standards from the JCAHO address this concept by requiring documentation showing that effective, appropriate patient care is being provided, as shown by positive patient ***outcomes***. Areas addressed by the standards include availability of services, timeliness, continuity of care, effectiveness and efficiency of services, safety of service provided, and respect and care by the personnel providing services.

Total quality management is based on a team concept involving personnel at all levels working together to achieve a final outcome of customer satisfaction through implementation of policies and procedures identified by the CQI program. This concept applies scientific principles to management and uses graphical and statistical analysis of data as a basis for decision making.[13] TQM is a systematic problem-solving approach using visual tools to identify the steps in the process for meeting customer satisfaction of quality care in a timely manner at reduced costs. In the health-care setting, the patient is the ultimate customer; customers also include health-care providers, personnel in other departments, and the patient's family and friends. TQM is far-reaching and encompasses the quality and performance assessment of the infrastructure (physical, personnel, and management), ***processes***, outcomes, and customer satisfaction.

The focus of CQI is to improve patient outcomes by providing continual quality care in a constantly changing health-care environment. Performance is defined as what is done and how well it is done to provide health care. The level of performance in health care is the degree to which

what is done is effective and appropriate for the individual patient and the degree to which it is available in a timely manner to patients who need it.[2] Characteristics of doing the right thing and doing the right thing well are termed the dimensions of performance.[12] Four phases of quality in doing the right things right can be demonstrated.[7] The first phase is "right things done wrong"—an example in urinalysis might be the acquisition of a very expensive and efficient instrument such as the 900 UDx Urine Pathology system but the personnel in the laboratory are not trained to use the instrument properly. The second phase is "wrong things done right"—an example would be the urinalysis instrument is insufficient for testing but the personnel in the laboratory make it work for them. The third phase is "wrong things done wrong"—an example would be an incorrectly calibrated 900UDx Urine Pathology system and no one in the laboratory knowing how to use the instrument. The fourth phase is "right things done right"—this is the ultimate goal and is represented by a properly calibrated 900UDx Urine Pathology system and all urinalysis laboratory personnel well trained to operate the instrument and interpret the results. The goal of CQI involves continuous performance improvement to ensure that "right things are done right" all of the time.

Helpful tools to assess CQI are flowcharts, cause and effect diagrams (fish-bone diagrams), pareto charts, histograms, run charts, and cause and effect diagrams. A flowchart is a picture of the process mapping out each individual step so that each group member can understand how it works. Cause and effect diagrams determine the cause of a problem and identify the different elements that contribute to the problem. They relate the interaction between equipment, methods, and customers. Pareto charts are based on the Pareto principle that states 80 percent of the trouble comes from 20 percent of the problems. Pareto charts are used to mainly identify the problems. The information in this type of graph displays the major contributors to a problem in descending order of importance. A run chart tracks individual data points recorded in a time sequence and compares the points to the average. It is useful to determine cyclic or seasonal differences. Control charts provide statistically determined limits drawn on both sides of the line indicating deviations from the average. Scatter diagrams are a visual plotting technique used to evaluate cause and effect correlations between two variables. Histograms display the shape of distribution of a variable indicating the amount of variation and are often used to summarize and communicate data.

Many models based on W. Edward Deming's 14 principles of CQI are available for implementing CQI. One example is the JCAHO 10-step process (Table 7–4). The most widely used plan for quality improvement in health care is the Plan-Do-Check-Act **(PDCA)** strategy.[7]

The "Plan" step is the process of making a change by identifying the customers and customer expectations, describing the current process, measuring and analyzing, focusing on improvement opportunities, identifying the root cause, and generating a solution. External customers are people such as the vendors or health-care providers who are not employed by one's organization. Internal customers are employees within the organization who are dependent on one's service. A nurse requesting a urinalysis result on a patient would be a customer of the laboratory. Customer needs and expectations are identified in the health-care field most often through complaint analysis, focus groups and interviews, satisfaction surveys, and JCAHO professional standards. An example would be "How to reduce the TAT for a patient's urinalysis test result?" Through the use of flowcharts, cause and effect diagrams, and Pareto charts (Figures 7–9 through 7–11), the data can visually be measured and analyzed, and the committee can arrive at a problem statement and focus on improvement opportunities. After generating theories of causes and collecting data, the root cause can be pinpointed, and, through focus groups with customers, discussions with staff, and brainstorming, a solution can be produced.

TABLE 7–4 **JCAHO 10-Step Process**

1. Appoint responsibility.
2. Outline the scope of care.
3. Identify key aspects of care.
4. Devise indicators.
5. Define thresholds of evaluation.
6. Collect and organize data.
7. Evaluate data.
8. Develop a corrective action plan.
9. Assess actions and document improvement.
10. Communicate relevant information.

The "Do" step is the process of testing the improvement by mapping out a trial run, implementing that run, collecting data, and analyzing the data. The person responsible for each step and the dates and time frames for the trial should be specified. Steps used to monitor implementation of the trial run and verification of results must be documented. As an example for the above urinalysis TAT, a trial run to shorten urinalysis testing TAT could be to transport the specimen from the patient location to the laboratory via a pneumatic tube system immediately upon collection.

The "Check" step involves evaluating the results and drawing conclusions as to the effect of the change. Tools to evaluate the solution are control charts, run or trend charts, simple observations, and surveys. From these results, it can be determined whether the process was a success, failure, or in need of minor modifications. An example would be to use a run chart to plot TATs from the time of collection of urine through the testing procedure to the time the report appeared in the patient chart for those specimens being transported by the pneumatic tube system.

The "Act" step is standardizing the change by modifying the standard procedure, policies, and performance expectations to reflect the changed process. These changes must be communicated effectively to the customers to ensure implementation and to avoid resistance to change. A plan must indicate ways the new procedure will be incorporated and how the customers will be supported throughout the change process and provide training to the people involved. In the previous urinalysis example, proper training

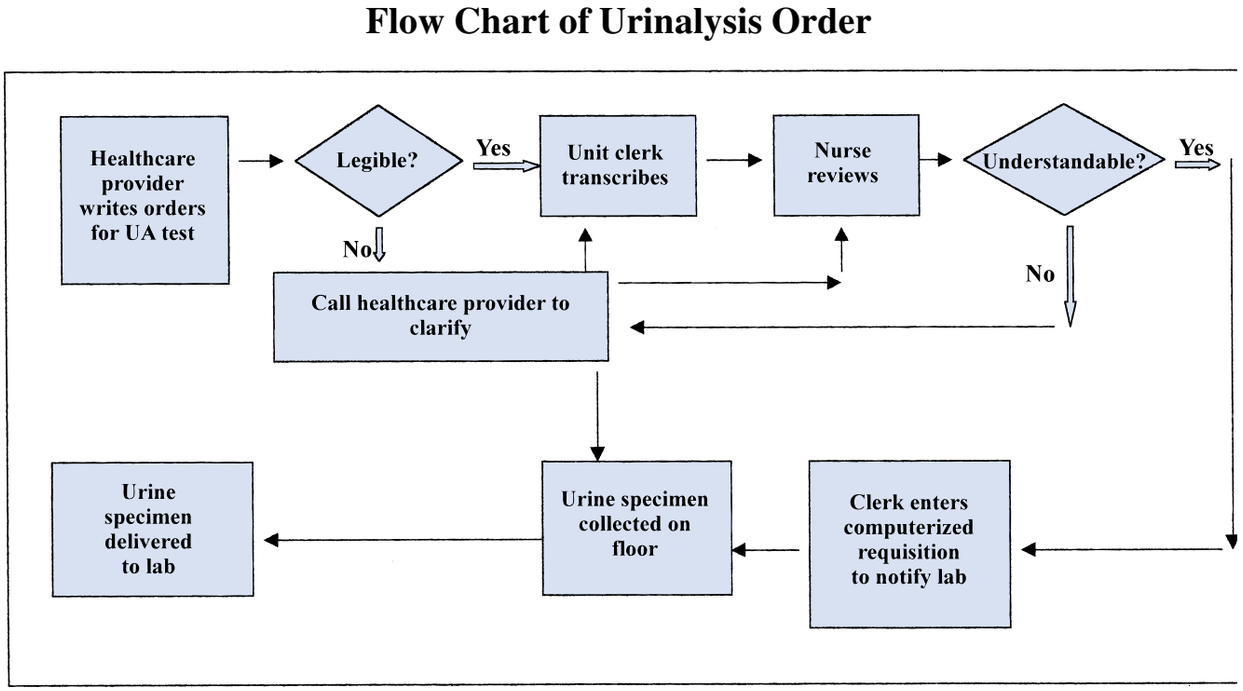

FIGURE 7–9 Flow chart demonstrating steps in the urinalysis collection procedure.

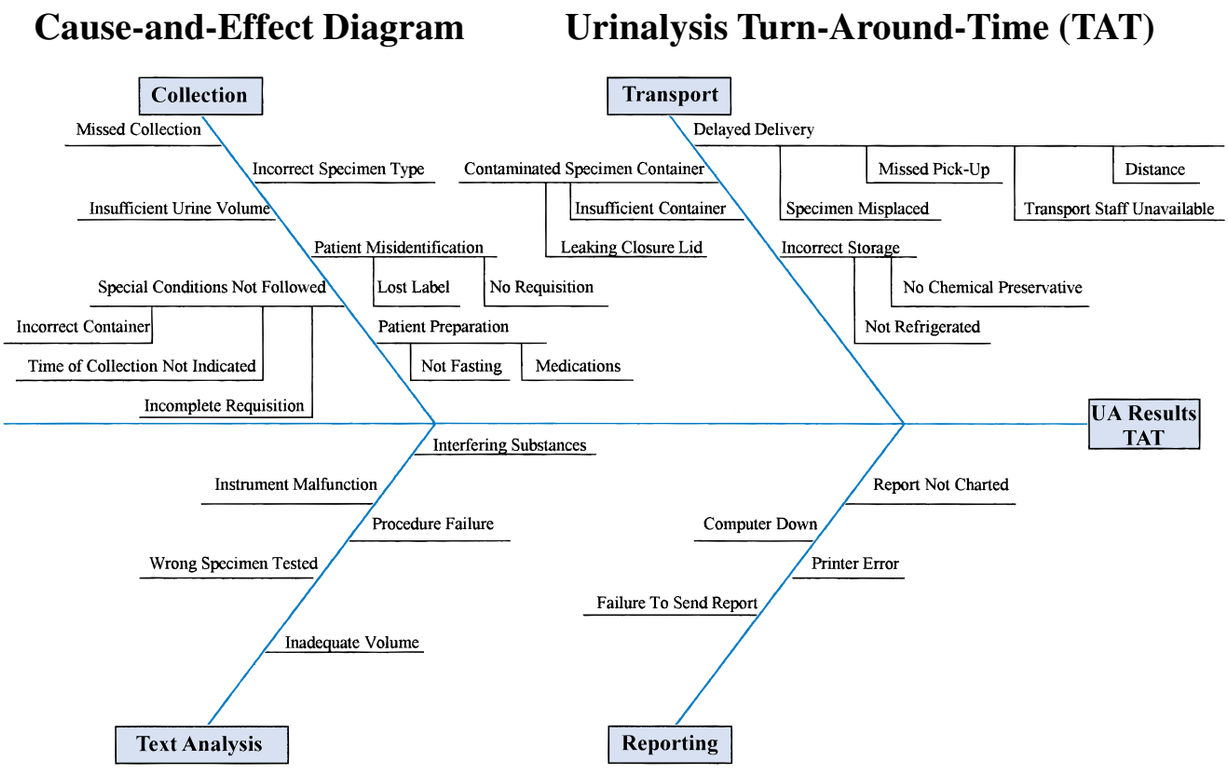

FIGURE 7–10 Cause-and-effect diagram for analyzing urinalysis TAT.

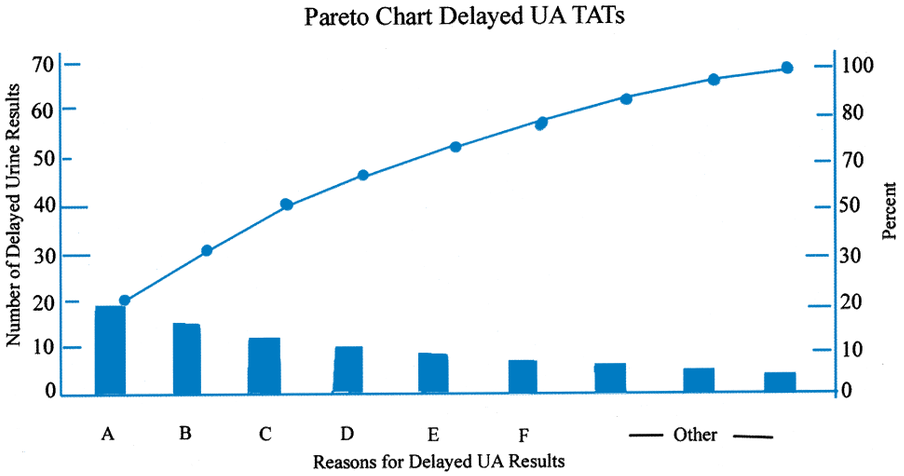

FIGURE 7–11 Pareto chart demonstrating causes of delayed urinalysis reporting.

on bagging the specimen to avoid leakage and on operating the pneumatic tube system would be necessary. Implementation of a regular schedule of measurement to monitor the change over an extended period confirms the success of the change or the gain.

The JCAHO *1996 Comprehensive Accreditation Manual for Hospitals* recommends a method for improving organizational performance (**IOP**). Known as PDMAI, the plan provides standards PI.1 through PI.5 (plan, design, measure, assess, and improve) to outline a specific cycle for improving performance.[2,6,12] The five essential elements for performance improvement are as follows:

Plan (PI.1): The hospital has a planned, systematic, hospital-wide approach to process design and performance measurement, assessment, and improvement.
Design (PI.2): New processes are designed well.
Measure (PI.3): The organization has a systematic process in place to collect data.
Assess (PI.4): The hospital uses a systematic process to assess collected data.
Improve (PI.5): The hospital systematically improves its performance.

With a constant focus on quality, the JCAHO standards are easily attained. By instituting the above quality improvement methodologies, a structured standardized format can be developed to systematically assess and document the quality of services to the customer.

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STUDY QUESTIONS

1. Explain the difference between QC and QA.
2. When the CAP inspects the urinalysis laboratory, what piece of documentation is always required?
3. Name two times when a laboratory-designated person must document a review of a procedure manual.
4. Indicate whether each of the following would be considered a 1) preanalytical, 2) analytical, or 3) postanalytical factor by placing the appropriate number in the space:
   _____ Reagent expiration date
   _____ Rejection of a contaminated specimen
   _____ Construction of a Levy-Jennings chart
   _____ Telephoning a positive Clinitest result on a newborn

_____ Calibrating the centrifuge
_____ Collecting a timed urine specimen

5. Can a test be precise and not be accurate? Explain your answer.
6. Under what conditions must internal and external quality control tests be performed?
7. Would a control sample that has accidentally become diluted produce a trend or a shift in the Levy-Jennings plot?
8. List three steps that are taken when the results of reagent strip QC results are outside of the stated confidence limits.
9. When a new bottle of QC material is opened, what information is placed on the label?
10. When a control is run, what information is documented?
11. When a new bottle of reagent strips is opened, what two controls should be run?
12. List the four categories of laboratory tests designated by CLIA '88.
13. State which of the above categories is assigned to each of the following: reagent strip urinalysis, urine culture, complete urinalysis using the Clinitek 200, urine microscopic, and urine pregnancy test.
14. What three categories of laboratory testing require documented proficiency testing of personnel as mandated by CLIA '88?
15. What documentation of new employees must the laboratory perform?
16. How often does CLIA '88 require documentation of technical competency?
17. How does QA differ from TQM andCQI?
18. List six areas relating to patient outcomes that are included in the JCAHO standards.
19. Who are the laboratory's "customers" in CQI?
20. What is the primary goal of CQI?
21. State the purpose for developing each of the following: flowcharts, cause and effect diagrams, Pareto charts, and run charts.
22. Briefly explain the four steps of the PDCA method for quality improvement.
23. What is the purpose of the JCAHO 10-step process?
24. List the five essential elements for performance improvement as stated by JCAHO.

CASE STUDIES AND CLINICAL SITUATIONS

1. State a possible reason for an accreditation team to report a deficiency in the following situations:
   a. The urine microscopic reporting procedure has been recently revised.
   b. An unusually high number of urine specimens are being rejected because of improper collection.
   c. A key statement is missing from the Clinitest procedure.
   d. Open control bottles in the refrigerator are examined.
2. A physician consults a medical technologist to answer the following questions regarding CLIA '88:
   a. Can I perform urine microscopics?
   b. If I purchase an automated urinalysis strip reader and a chemistry analyzer:

      Will my CLIA status be affected?
      Will my office be required to perform proficiency testing?
      Will my office be subject to COLA inspections?
3. A hospital laboratory outreach coordinator is asked to develop a method to decrease the number of rejected specimens for urinalysis received from physicians' offices.
   a. What accepted process could the coordinator follow?
   b. Briefly outline the steps the coordinator should take to address this problem, including the use of visual documentation.
4. As the new supervisor of the urinalysis section, you encounter the following situations. Explain whether you would accept them or take corrective action.
   a. You are told that the supervisor always performs the CAP proficiency survey.
   b. QC is not performed daily on the Clinitest tablets.
   c. The urinalysis section is primarily staffed by personnel assigned to other departments for whom you have no personnel data.