

## Urinalysis and Body Fluids CP9

Unit 1 B

Quality Assessment

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## Laboratory Regulation

- Federal Regulations / Regulatory Organizations
  - Laboratory structure / operation
  - Quality test performed by qualified personnel to obtain quality results
  - Safe work environment
  - Protect environment from biohazards and pollution
  - Payment for services rendered.

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## Laboratory Regulation for Quality Assessment

- Federal Regulations / Regulatory Organizations
  - Public Health Service Act
  - Department of Health and Human Services
    - Centers for Medicare and Medicaid Services (CMS)
    - Commission on Office Laboratory Accreditation (COLA)
  - OSHA (Occupational Safety and Health Administration)
    - Worker safety issues, MSDS sheets
  - EPA (Environmental Protection Agency)
    - Regulates medical laboratory waste

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## Laboratory Regulation for Quality Assessment

- FDA (Food and Drug Administration)
  - Approval of diagnostic tests
- CDC (Centers for Disease Control)
  - Implements public health regulations, monitors reportable diseases and trends, categorizes lab tests
- DOT (Department of Transportation)
  - Regulates packaging and transport of biological hazards and HAZMATs
- NRC (Nuclear Regulatory Commission)
  - Regulates the handling and disposal of radioactive materials

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## Laboratory Regulation for Quality Assessment

- External accreditation agencies
  - CAP (College of American Pathologists)
  - COLA (Commission on Office Laboratory Accreditation)
  - JCAHO (Joint Commission on Accreditation of Healthcare Organizations) / aka "The Joint Commission"

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## Clinical Laboratory Improvement Act of 1988 (CLIA '88)

- (<http://www.cms.hhs.gov/clia/>)
- Actually implemented Sept 1, 1992
- Mandated quality assessment and categorized levels of clinical lab testing:
  - Provider performed microscopy (PPM)
  - Waived testing (WT)
  - Moderate complexity testing (MCT)
  - High complexity testing (HCT)

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## Laboratory Regulation for Quality Assessment

- Quality Assessment -
  - A process for guaranteeing quality patient care
- Clinical laboratories must continually assess, update, and adjust services to achieve optimal patient outcomes.

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## Quality Assessment (QA)

- Quality Assessment Program
  - Use of qualified personnel
  - Promotes effective communication
  - Establishment of clearly written policies

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## Quality Assessment (QA)

- Urinalysis Procedure Manual
  - Well written
  - Readily available in the work area
  - Covers all aspects of testing
    - Patient preparation,
    - Specimen type and collection,
    - Specimen acceptability, rejection criteria

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## Quality Assessment (QA)

- Urinalysis Procedure Manual
  - Principle, clinical significance of test
  - Reagents, standards, controls, procedure
  - Normal / Reference values
  - Critical Panic values
  - How to record the results
  - Instrument calibration, maintenance
  - Limits of controls, corrective actions, procedure limitations, specific notes
  - Effective date, author, review schedule

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## Quality Assessment (QA)

- Quality Assessment Program (con't)
  - Use of delta checks
  - Timely verbal reporting of all critical values
  - Participation in Proficiency Testing
    - Mandated by CLIA '88
    - External proficiency testing
      - The testing of 'unknown specimens'
    - Internal proficiency testing

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## Factors Affecting Test Quality

PRE-ANALYTICAL ERROR	ANALYTICAL ERROR	POST-ANALYTICAL ERROR
Patient was not prepared	Instrument not calibrated	Results not correctly entered into computer
Patient ID errors	Deteriorated reagents	Results do not get sent
Wrong test ordered	Control problems	Results are delayed
Wrong type of specimen	Pipetting / dilution errors	Results not properly interpreted
Specimen contaminated, hemolyzed, etc.	Instrument improperly operated	Critical / panic values not noticed, or acted upon in a timely manner.
	Tech runs wrong patient sample	

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## Quality Control (QC)

- **Quality Control**
- The methods utilized by the laboratory to ensure accurate test results
- QC is a set of procedures and practices to monitor the testing process
- QC monitors accuracy, precision, and reliability of tests
- All aspects should be evaluated, inc. controllable pre-analytical and analytical variables.
- Specimen collection & handling
- Testing process - reagents, etc
- Personnel performing test - are they qualified?
- Test reporting

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## Quality Control (QC)

- **Quality Control**
- Accuracy: a measure of how close a value is to the true result
- Precision: a measure of reproducibility
- Reliability: ability to maintain both accuracy and precision

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## Quality Control (QC)

- **Standards and Controls**
- Standard - a solution with a known concentration of a substance; that can be used as a reference.



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## Quality Control (QC)

- Standards and Controls"
  - Control - a solution with a determined range of values for one or more substances; used to determine validity of test results.
  - Controls have the same matrix as does the patient specimen.

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## Running Controls

- Control levels
  - Level 1 control
    - Best monitors patient samples that are 'normal'
    - Sometimes called the 'normal control'
  - Level 2 control
    - Best monitors the patient samples that are in 'abnormal' ranges
    - Sometimes called 'abnormal control'

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## Running QC

- Using control material
  - Record date of opening, manufacturer's lot number, expiration date each time control is run
  - The person doing the testing, MUST be the one running the controls.
- Control results must be evaluated before releasing patient results
  - If controls do not produce the expected result, no patient results released
  - Must investigate reason

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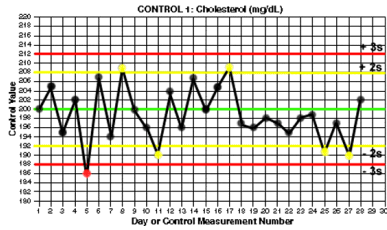
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# Levy Jennings Chart




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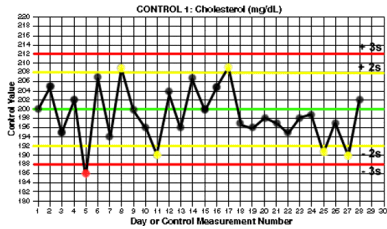
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# Levy Jennings Chart

OBJECTIVE Given a series of quality control results evaluate the results for validity, state the corrective actions to be taken on results which are out of range as well as possible causes of invalid results. CRg




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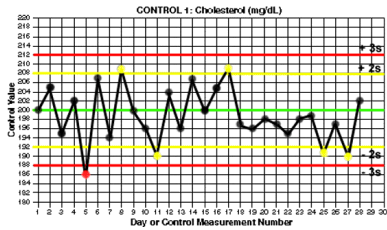
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