Biochemistry of biological fluids (BIOCH 472)

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Class 2:

laboratory Quality assessment and management

Urine analysis and body fluids by susan king strasinger

Objectives for this lecture

- Discuss the quality control of specimens, methodology, control materials, instrumentation.
- Define the preanalytical, analytical, and postanalytical components of quality assessment.

Definitions

- **Quality Control** (QC): the measures that must be included during each assay run to verify that the test is working properly, and it is regulated throughout the total testing system.
- **Quality Assurance** (QA) (Quality System): the overall laboratory programs that ensures that the final results reports are correct.
- "The aim of quality control is simply to ensure that the results generated by the test are correct. However, quality assurance is concerned with much more: that the right test is carried out on the right specimen, and that the right result and right interpretation is delivered to the right person at the right time"

- **Quality Assessment** - (also known as proficiency testing) is a means to determine the quality of the results generated by the laboratory. It is the overall process of guaranteeing quality patient care.

- Quality Assessment program can have under it the procedure manuals, internal quality control and external quality control, standardization, proficiency testing, record keeping equipment maintenance, safety programs, training, education and competency assessment of personnel.

Quality Assessment program consists of three pincipal:

1. preanalytical factors: (e.g., specimen collection, handling, and storage).
2. analytical factors: (e.g., reagent and test performance, instrument calibration and maintenance, personnel requirements, and technical competence).
3. postanalytical factors: (e.g., reporting of results and interpretation).

- documentation that the program is being meticulously followed. It is required by all laboratory accreditation agencies.

Preanalytical Factors

- variables that occur before the actual testing of the specimen:
- ✓ Test requests
- ✓ Patient preparation (fast, medication,..)
- ✓ Specimen collection (date, refrigerated, time received, test request, patient inf.)
- ✓ Handling
- ✓ Sample storage (ursin sample should be examined within 2 h)

Preanalytical Factors

- Adequate communication (laboratorian and physicians), collecting and transporting the specimen improves the *turnaround time* of results and avoid duplication of test.

- Physical characteristics and labeling errors must be present. Written criteria for rejection of specimens must be documented.
- Specimen must be processed immediately or, if necessary, stored in a refrigerator and protected from light

Preanalytical Factors

- The procedure the staff should follow involves:
  1. Correlation of patient name on request slip and sample.
  2. Evaluation of elapsed time between collection and receipt of the specimen in lab.
  3. suitability of specimen preservation
  4. Acceptability of the specimen (e.g., volume collected, container used, cleanliness, contamination)

Analytical Factors

- It is the processes that directly affect the testing of specimens.
- They include:
  - ✓ Reagents (name, instructions, company, storage, QC)
  - ✓ Instrumentation and Equipment
  - ✓ Testing procedure
  - ✓ Quality control *(accuracy, precision and reliability)*
  - ✓ Preventive maintenance
  - ✓ Procedure manuals
  - ✓ Competency of personnel performing the test

Analytical Factors

- Water used for preparing reagent and controls must be distilled or deionized water.
- Precautions associated with reagents should be present (heat produced by reaction).
- Follow procedure manual instructions for laboratory instrumentation.
- QC procedures are performed to ensure that standards are met during the test.

External Quality control monitoring

We use QC material to assess and monitor:

- Accuracy (ability to obtain the expected result).
- Precision (ability to obtain the same result on the same specimen)
- Standard deviation (SD) (measurement statistic that describes the average distance each data point in a normal distribution.
- Coefficient of variation (CV) (the SD expressed as a percentage of the mean.

Levy-Jenninges control charts

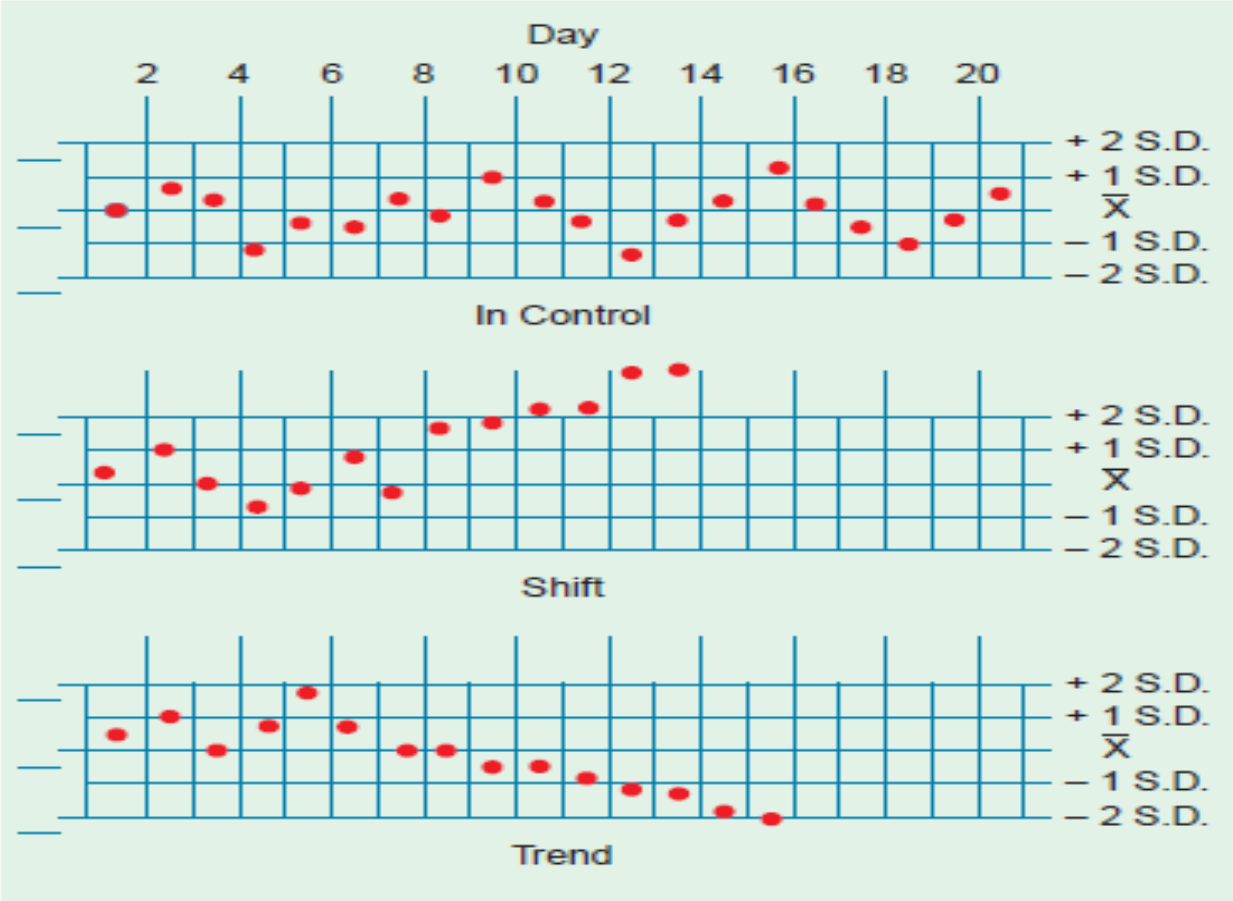

Figure 7–4 Levy-Jennings charts showing in-control, shift, and trend results.

External Quality control monitoring

- Corrective action, including the use of new reagents, reagent strips, or controls (expiration date)

Internal Quality control monitoring

- It is a procedural / electronic controls to monitor the correct addition of a patient specimen or reagents, instruments interaction, and test completion.

Postanalytical Factors

- It is the processes that affect the reporting of results and correct interpretation of data:
- ✓ Reporting of results (forms with reference ranges)… electronic is most common.
- ✓ Interpretation of results (specificity and sensitivity of test in manual)

Sample urine reporting format

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