Quality Control

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Introduction:

QC: Is defined as a system for verifying and maintaining a desired level of quality.

The quality of the tests performed in the lab depends on all subsequent steps:

- -Receiving the specimen
- -Adequate handling and staining of the sample.
- -Screening and interpretation of the slide
- -Reporting of the results.

The diagnosis is obstructed if one of the subsequent steps is inadequately performed.

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Cytopathology?

is the study of disease on the cellular level.

we have a problem!

 Visual examination of cells is a subjective procedure; it depends on the skills and experience of the cytotechnologist. This may lead to variation in results and incorrect diagnoses. As such, the test is imperfect and cannot be performed without errors.

Solution?

 Introduction of guidelines can reduce the rate of incorrect results and lower false test result rates (provide accurate laboratory testing)

Quality manual

The laboratory should have a quality manual in which all procedures are mentioned. The whole staff must use these procedures.

Receiving CERVICAL SAMPLES

All samples should be accompanied by a request form with:

- Full patient name
- Unique patient number
- Date of birth and age
- Date and time of specimen collection
- Source or site of the specimen
- Collection method
- Clinical information
- The ordering clinician's full name

Staining

- In this lab, the <u>progressive papanicoloau staining</u> method is useful for fixed <u>cytopreparations</u> and the <u>Diff-Quick staining method for Air-Dried staining</u>.
- Optimal staining is a fundamental prerequisite in cytology.
- the overall quality of staining must be reproducible and permanent.(y?)
- Accurate identification depend on the recognition of particular stained cellular entities. The diagnostic confidence is based on the 1)well stained and 2) technically controlled cytopreparations.

Assessment of the sample: screening

The cover slipped area should be investigated completely, in horizontal or vertical direction. The horizantal Z-sweep technique has proven to be effective. Smears are to be screened using at least 10x magnification. Unusual and / or abnormal cells are marked. Primary screening is performed by cytotechnologists.

Inadequate samples are given a repeat advice.
Repeat samples must always be compared with the sample on which the repeat advice is given

*Satisfactory for evaluations:

- *Appropriate labeling.
- *Relevant clinical information.
- *Adequate numbers of well preserved and well visualized squamous epithelial cells spread over more than 10% of the slide surface.

Fixation or preservation is one of the most important steps in the procedure. <u>Drying</u> of the cells prior to fixation will usually result in artifacts such as nuclear distortion and vacuolization.

*Unsatisfactory for evaluation:

This indicates that the specimen is unreliable for the detection of <u>cervical</u> <u>epithelial abnormalities.</u>

*It is used if any of the categorization criteria apply:

- Lack of patient ID on the specimen and/or requisition form.
- Technical unacceptable slides: broken, cannot be repaired, or if cellular material is inadequately preserved.
- Scant squamous epithelial spread over less than 10% of the slide surface.
- Completely obscuring with blood or inflammation.
- Thick specimen areas.
- Poor fixation.
- Air drying artifacts.

*If <u>abnormal cells</u> are present, a specimen cannot be called <u>unsatisfactory</u>. The diagnosis is based on the abnormal cell findings; the adequacy is evaluated as satisfactory.

Receiving reagents into the laboratory, labeling, usage, storage and disposal:

Receiving reagents into the laboratory:

- They are unpacked as soon as possible and checked against a shipping list to ensure all items are there.
- When unpacking, inspect for evidence of deterioration or damage. If the supplies are not in acceptable condition, report to the laboratory manager.

Labeling of reagents:

 When receiving reagents into the laboratory, record the date of receipt, lot number, and expiration date on the appropriate laboratory sheets. Also, reagent containers should be labeled with the date of receipt, and expiration date.

Reagent usage:

- Once opened, reagent containers are labeled by the date of opening.
- Check the expiration dates on all items each time they are used to ensure their stability.

Storing of supplies, reagents, and controls.

- Store reagents according to manufacturer's recommendations.
- Store reagents in designated storage areas of the laboratory (i.e., chemistry refrigerator, chemistry freezer, etc.). Generally, items are stored nearest to their point of usage.
- Always rotate stock by the putting the newest items (with the longest expiration dates) in the back and the oldest items (with the shortest expiration dates) to the front of the refrigerator or freezer.

Disposal of reagents:

Safety discard reagents once they become outdated.

Coverslippling procedure for fixed slide:

The objective of coversliping the slide evenly is to, preserve, protect and avoid drying-out of the stained cellular material.

- Wear protective gloves, work on clean, flat surface covered with a towel.
- The coverslip should be clean and dust free.
- Place a drop of mounting medium on the coverslip, remove the slide from xylene and wipe excess xylene present under the slide with clean tissue.
- To eliminate cellular cross contamination of slides or mounting medium, the <u>transfer pipette that is used to transfer mounting</u> medium onto coverslips must never come into contact with cellular material.

- Gently place the slide (cellular material) over the coverslip at an angle, to minimize bubble formation.
- Excess medium that may ooze out of the slide edges can be wiped off with a <u>xylene soaked tissue</u>.
- Place coverslipped slides on the slide warmer for quick medium hardening.
- Do not allow the <u>cells to dry</u> out at any stage of the process.
- The end result should be a presentable slide with the coveslip centered over the cellular material, with no mounting medium on the coverslip surface, and no air bubbles.
- Air bubbles formed while coverslipping compromise the technical quality of slides. No air bubbles should remain.

- If air bubbles exist or if there is excessive amount of medium, remove the coversilp by soaking the coverslipped slide in xylene until the coverslip loosens.
- Recoversliping maybe performed once the original coverslip is removed.
- Cover slipped slides must be allowed to dry adequately prior to filing to avoid slide adherence.

*Quality control issues:

- The overall quality is monitored and documented by the pathologist reviewing cases utilizing a QC feedback system.
- All reagents/stains must be maintained <u>clean</u>, <u>free of cellular</u>
 <u>contamination</u>, <u>covered when not used</u>, <u>and be properly labeled</u>.
- Whatman filter paper is recommended for filtering suspended contaminants or cells from reagent/stain solutions.
- All staff are required to understand the <u>safety issues</u> that apply when handling the reagents used in cytology as outlined in the <u>laboratory</u> safety manual.