"External Quality Assessment in Medical Laboratories" - differences with other PT testing programs

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EQA versus PT

- The term PT in laboratory medicine is commonly used in North America
  - Proficiency testing (PT) focus essentially on laboratory performance evaluations especially for regulatory purposes

From EQAS to EQAP

- EQAS: External Quality Assessment Schemes
- EQAP: External Quality Assurance Programs

Olafsdottir E, Hellsing K, Steensland H, Terhunen R, Uldall A. Adding new scopes to traditional EQA schemes emphasizig quality improvement. Upsala J Med Sc 1994: 187-183

EQAP

- EQAP is an interlaboratory comparison designed and operated to assure one or more of following aspects:
  - Participant performance evaluation (analytical performance, test interpretation, advice to the clinician on laboratory requests and on diagnosis
  - Vigilance of IVD's
  - Continuous education, training and help

The primary intention of the activities of an EQAP in laboratory medicine shall be to support quality improvements of the service provided by participating laboratories for the benefits of the patients.

(IFCC Guidelines for the Requirements for the Competence of EQAP organizers 2002)

Interlaboratory comparison ISO 15189

- **5.6.4** The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not furfilled. Interlaboratory comparison shall be in substantial agreement with ISO/IEC Guide 43-1.

- External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

INTERNATIONAL STANDARD

ISO 15189

Second edition
2007-04-15

Medical laboratories — Particular requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières concernant la qualité et la compétence

contributing to patient care

« Patient care in ISO 15189 »

- Introduction: *Medical laboratory sevices are essential to patient care…*
- 4.1.2: *Medical laboratory services, including appropriate interpretation and advisory servies, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care*

« Patient care in ISO 15189 »

- 4.12.4: *Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient care…….. Laboratory management shall ensure that the medical laboratory articipates in quality improvement activities that deal with relevant areas and outcomes of patient care*

« Patient care in ISO 15189 »

- 4.14.1: *……..The internal audit shall progressively address these elements and emphasize areas critically important to patient care*
- 4.15.1: *In order to ensure their continuing suitability and effectiviness in support of patient care,…*
  - i) quality indicators for monitoring the laboratory's contribution to patient care

« Patient care in ISO 15189 »

4.15.3: *The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, be monitored and evaluated objectively.*

5.2.1: *The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel or patient care services*

« Patient care in ISO 15189 »

5.8: Reporting of results:

e) Date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory

5.8.7 The laboratory shall have procedures for immediate notification of a physician (or other clinical responsible for patient care) when examination results for critical properties fall within established « alert » or « critical » intervals.

« Patient care in ISO 15189 »

- 5.8.11 Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

  ….

  This does not mean that the clinical personnel are to be notified of all delays in examinations, but only in those situations where the delay could compromise patient care.

« Patient care in ISO 15189 »

- Annex B: Recommendations for protection of laboratory information systems (LIS)

Reference to « patient care » 4X

EQA/PT ORGANIZERS

- Medical laboratories
  - Professional organisations
  - Scientific societies
  - Governmental organisations
  - IVD manufacturers
- Other type of laboratories
  - International and national scientific organisations (institutions)
  - Commercial organisations
  - Accreditation bodies

Professional & Scientific EQA organizers versus commercial EQA organizers

- Is there a specific role to play by professional and scientific EQA organisations?
- Is there a specific role to play by IVD manufacturers organizing EQA schemes?

EQA from IVD manufacturers (1)

- Organizer of regular EQA schemes with several materials
- Link with the producer of kits and reagents
- Extra service for users of the same internal QC material
- Only own QC materials are used
- No real patient material

EQA from IVD manufacturers (2)

- Especially activity in clinical chemistry and immunoassays
- Large groups, in general good service
- Free participation
- Educational, no sanctions
- Feedback from a steering committee (expert board) ?
- THESE SCHEMES FOCUS ON ANALYTICAL QUALITY

"Non-commercial" EQA schemes

PT schemes

- Mandatory
- Linked to a licence
- Repressive (sanctions)
- Acceptability limits based on "state of the art"
- Static: no incentive for quality improvement
- Follow-up: "the bad and the good boys"

External quality assessment => external quality assurance schemes

- Can be mandatory or free
- Can be linked to a license
- Essentially educational
- Dynamic: incentives for quality improvement – tools for problem related schemes
- (EQAP approach)

Inconvenience of PT schemes

- "Bad boys" are punished
- Everybody is happy with the "good boys"
  - But: are the good boys as good as they look?

- "Impression" of the potential capability of laboratories to perform these tests
- No link with patient samples analysis

EQAP covers more than EQA

- Participant performance evaluation
- Method performance evaluation
- Contineous education tool
- Analytical performance and clinical outcome evaluation
- Support for internal QC
- Training & help
- Promotion of standardisation efforts
- Quality improvement of patient results & interpretation
- .....

EQAP covers more than EQA: new item of interest

External Quality Assurance Programs

- Broad panel of schemes covering all aspects of laboratory medicine
  - Preparation of own control materials

    Or
  - Sharing sample preparation

  - Attention for new fields, new tests
  - Fields for which there is no interest from "commercial" organizers

External Quality Assurance Programs

- MUST FOCUS ON CLINICAL OUTCOME AND NOT ONLY ON ANALYTICAL RESULTS
  - Including pre- and post analytical EQA
  - Including difficult samples
  - Mimic as much as possible patient samples
  - Attention for quality management of new applications (POCT, NPT)
  - Acceptability limits may be based on EBM, biological requirements,..

Pre-analytical EQA: examples

- Examination of sample deficiencies based on data from participants (SEQC experience)
- EQA on appropriate sample package
- Paper challenges with a clinical case and evaluation of an appropriate tests request
- Distribution of not appropriate sample material (these samples are expected not to be analysed)

Preanalytical quality control program – an overview of results (2001–2005 summary)

- **105 LABORATORIES** : 4.715.132 tubes ➔ 32.977 (0.699 %) REJECTS

  - EDTA/SERUM (75.6% of all samples) ➔ 55.8 % of all rejects

  - 81% of rejects due to :
    - Specimen not received ➔ 37.5%
    - HEMOLYSIS ➔ 29.3% = **9.662 samples !**
    - Clotted sample ➔ 14.4%
    - **About 30% of ALL rejects due to HEMOLYSIS**

Cecília Martínez-Brú et al. Clin Chem Lab Med (2008); 46, 6; 849–854 (SEQC)

Paper Challenge of Accessioning Practices

- A nasal swab is submitted to the laboratory with clinical information "possible anthrax". No other information provided. What action would your laboratory undertake with this sample?

A	**Set-up and Culture.** **Read at 24 hours.**	22%
B	**Do not process.** **Destroy swab.** **Report: "Do not perform this test".**	0%
C	**Do not process.** **Contact physician.**	34%
D	**Do not process. Seal for public health. Contact Public Health.**	78%

CMPT M013; November 2001

Example of educational EQAS Cyclospora cayetanensis:

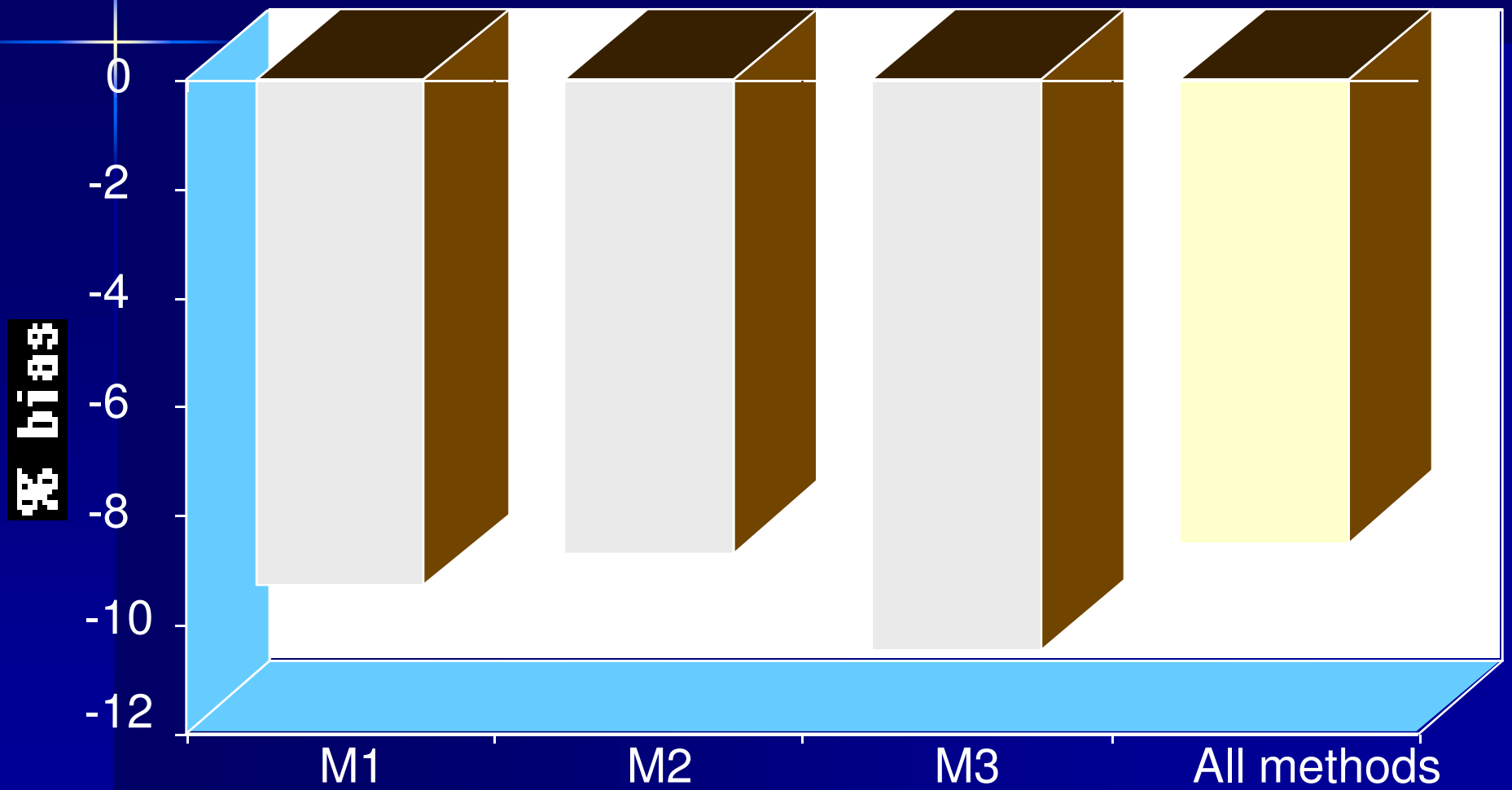
	1997	1998	2000
N labs	255	263	239
Cyclospora	135 (52.9%)	214 (81.4%)	192 (80.3%)
No parasites found	52 (20.4%)	10 (3.8%)	18 (7.8%)

Results in the Belgian EQAS programmes

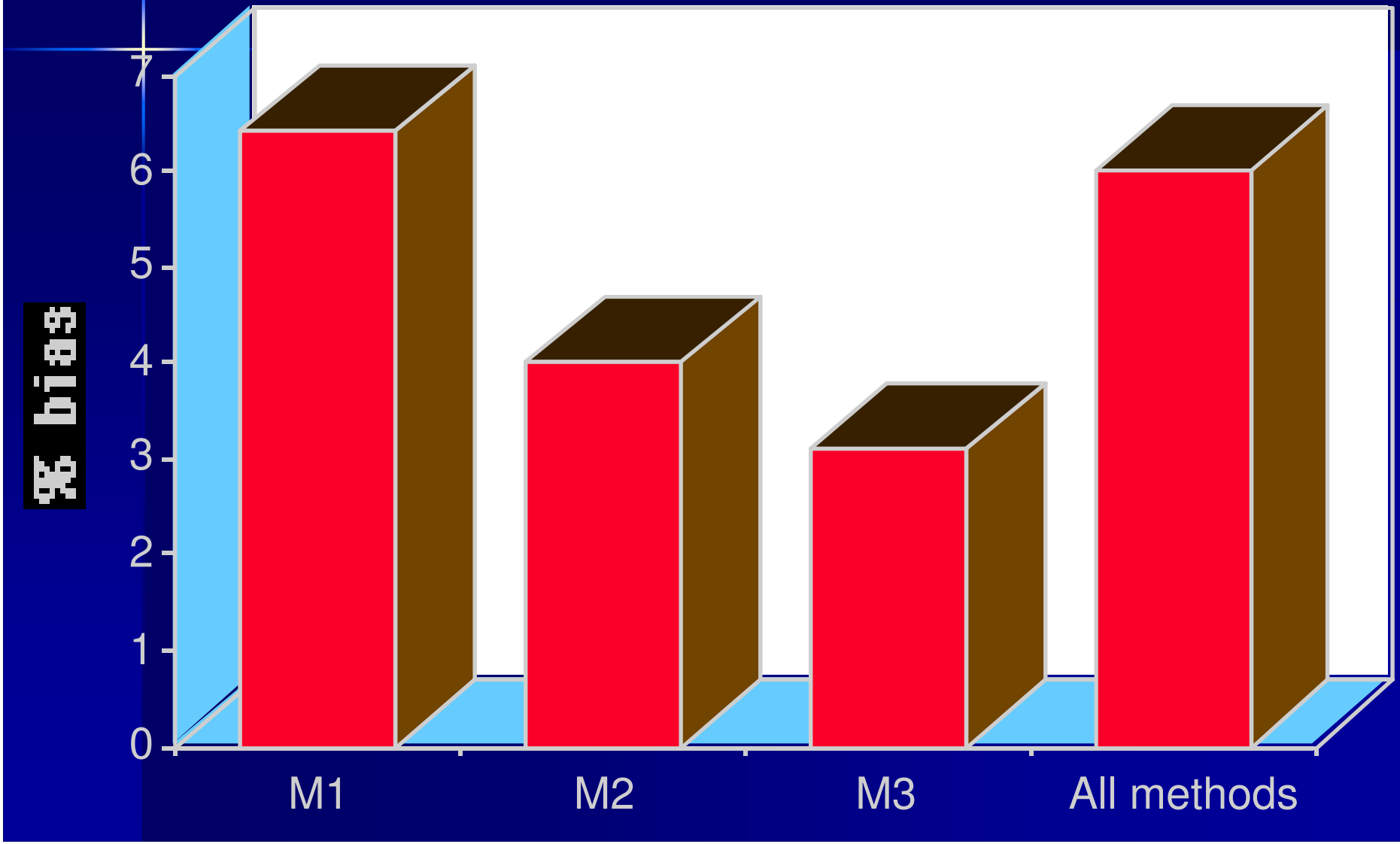
Appropriate EQA material

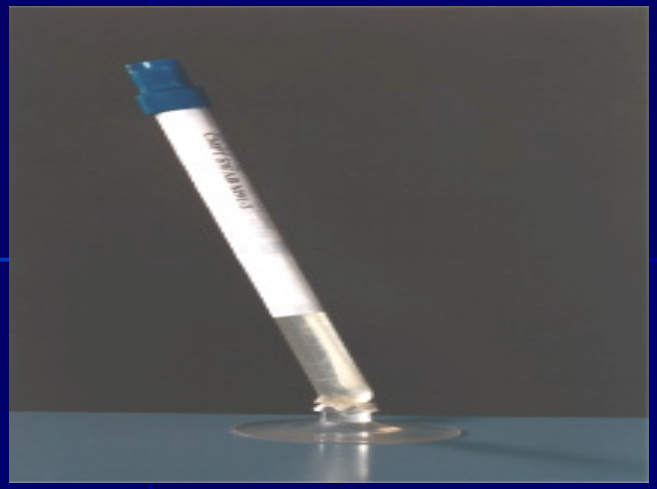
- Performances of lyophilized materials do not always reflect performances in patient samples
- Some materials are scarce (IgM samples for serology)
- Realistic patient material
- Virtual microscopy samples

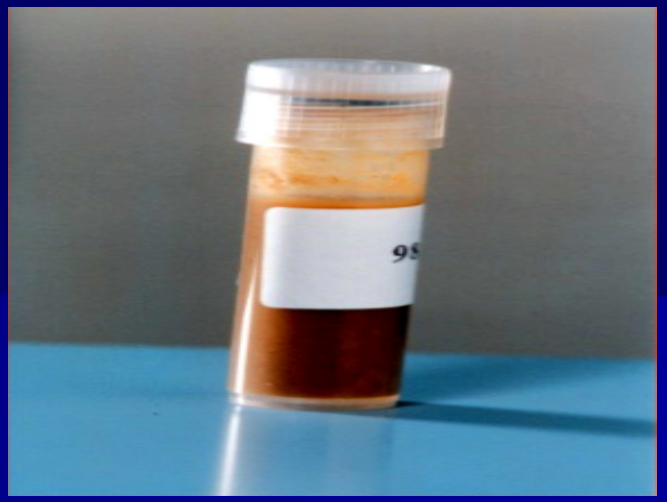
Bias of cholesterol methods against the RMV in lyophilised control samples



Bias of cholesterol methods against the RMV in frozen patient samples







PT/EQA Specimens Can be Realistic

Post-Analytical EQA

- Interpretation of analytical results
- Which information is given to the clinician?
- Correct use of reference values

Appropriate reference values check

- HbA1c: all methods in use are DCTT converted after IFCC calibration

  ⇒Reference values should be the same in all laboratories (4-6%)

Real life: reported reference values

3.0-5.8	**3.5-6.2**	**4.5-6.8**	**5.1-6.5**
0.1-5.4	**4.0-6.0**	**4.8-6.0**	**6.0-8.0**

Post-analytical EQAS

- Paper challenges on interpretation of results

Combined analytical and post-analytical exercice

NOKLUS

The Norwegian Quality Improvement of Primary Care Laboratories

The aim of the quality assurance system is that tests should be requested, analysed and interpreted in agreement with defined professional standards and in accordance with the patients needs for diagnosis, treatment and management.

EQAS for virology

Sample S/5339 and S/5340 were taken to the same patient with an interval of 4 weeks; Pregnancy wish in the scope of IVF for a woman, 35 years old. Request for CMV diagnosis

Requested results:

On each sample: total antibodies, IgG, IgG avidity, IgM

Test interpretation: positive,negative,borderline

Combined interpretation for both samples:

Negative
Seroconversion
Recent infection (< 3 months)
Infection > 3 months
Reactivity
Others

EQAS for hemato-oncology: example

- Paper challenge with
- Patient history and clinical context
- Results of cell counting
- Results of flow cytometry
- Translocations

Problem-related EQA schemes

- Schemes focus on different aspects of the test so that participants can have information on these aspects were there is a problem

Problem related EQA: sperm staining procedure

- Send two smears for morphology
- Collect stained smears
- Define criteria for acceptable results
- Evaluation of staining by 3 experts
- Report to participants

No “commercial” scheme will do this!

Method performance evaluation

- QCMD survey NG08: two samples with DNA from other Neisseria strains
- *N. lactamica* in sample NG08-06 en *N. cinerea* in sample NG08-09
- All participants using Roche Amplicor have false positive results for both samples

EQA ON INTERFERENCE BY HEMOLYSIS (B EQA)

- *Participants were asked to*

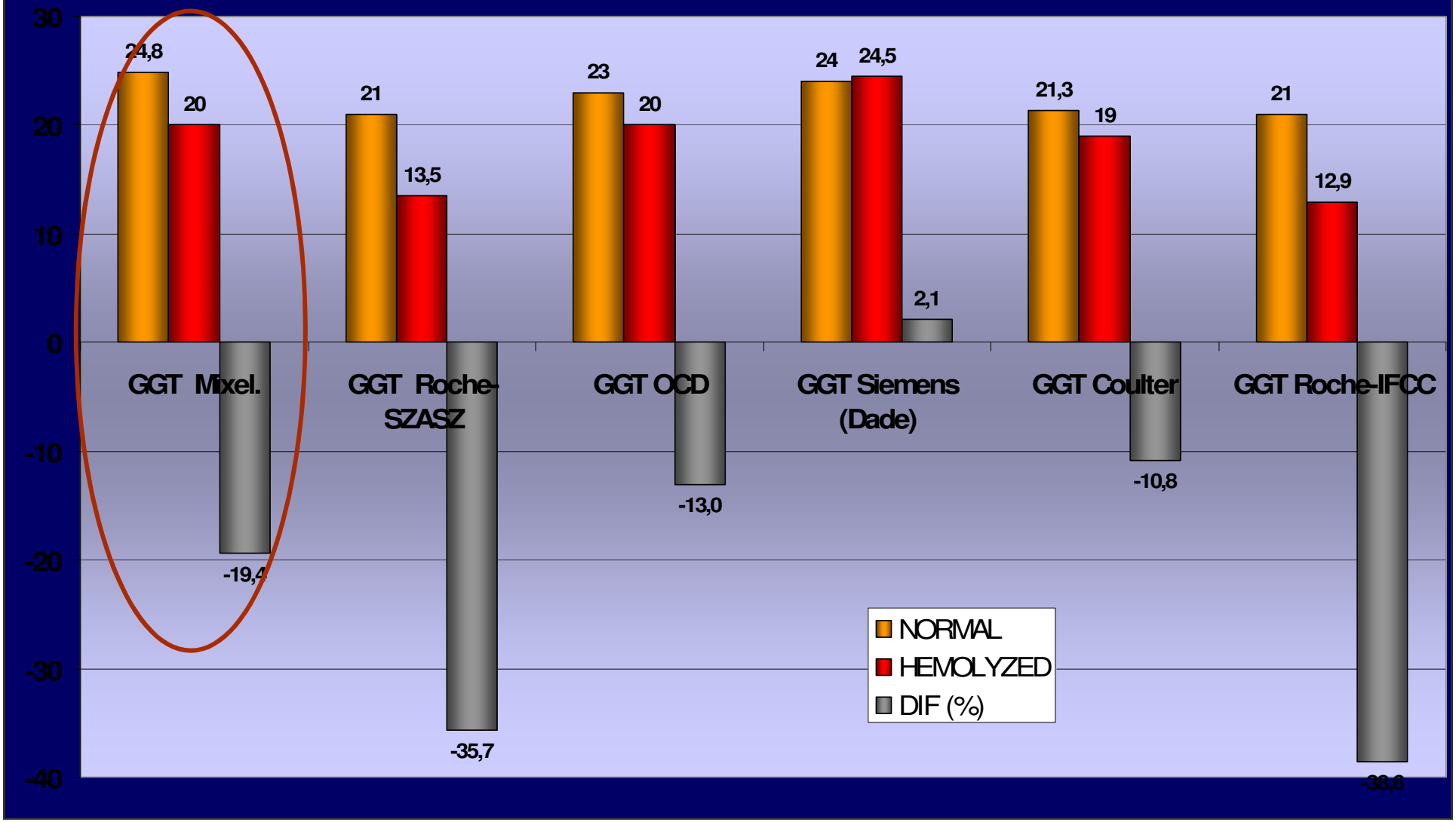
- score for the presence of hemolysis: *absent (-) – weak (+) – moderate (++) – strong (+++)*

- to report the H – index if available and the instrument used

(Courtosy of Christel Van Campenhout and Nicole Hamers)

INFLUENCE OF HEMOLYSIS ON γGT (U/L)

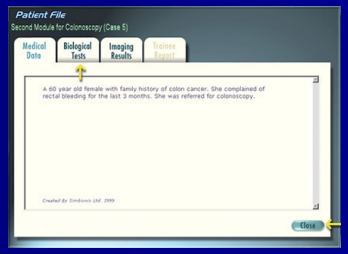
DIFFERENT SYSTEMS (d=20%)

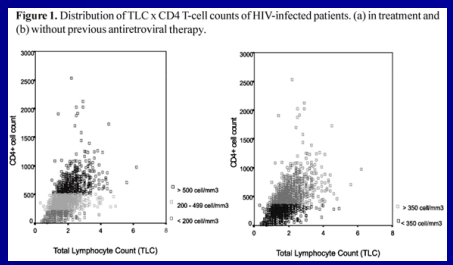


A dream for EQA schemes of the future?

EQA in hematology: case 2014/3

- Clinical history
- Samples
- Data
- Instructions for replying





Clinical history (example)

- All materials were drawn from the same patient: woman 79 years old.
- Since a few weeks abdominal pain. Routine examination revealed a lymphocytosis.

Question (example)

- Perform those analysis in order to give relevant clinical information for the clinician

Samples

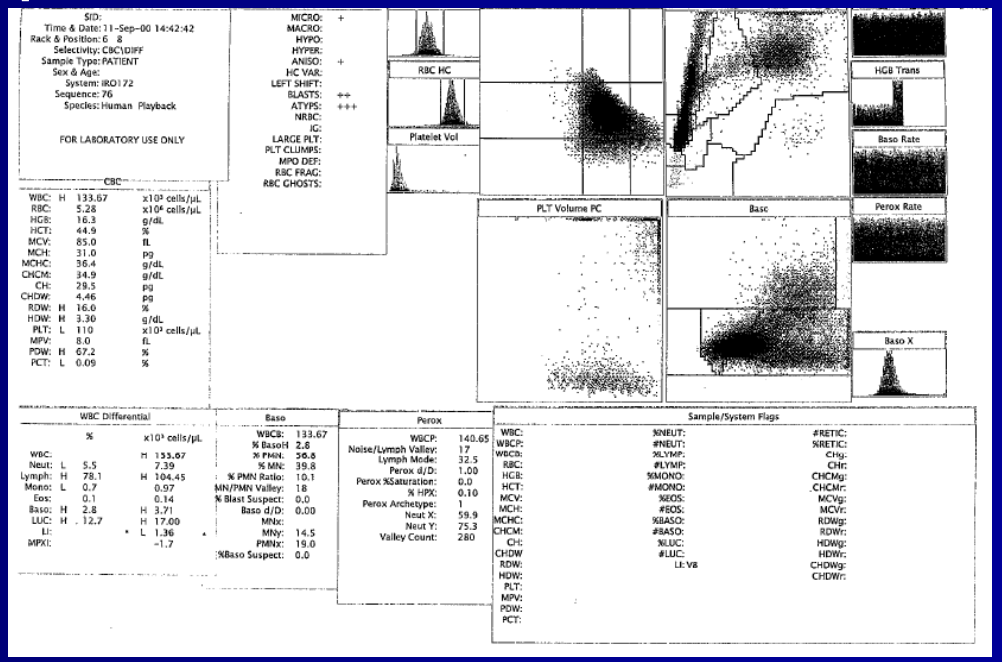
- (Serum tube)
- EDTA blood tube
- (Virtual samples)

EQA examinations

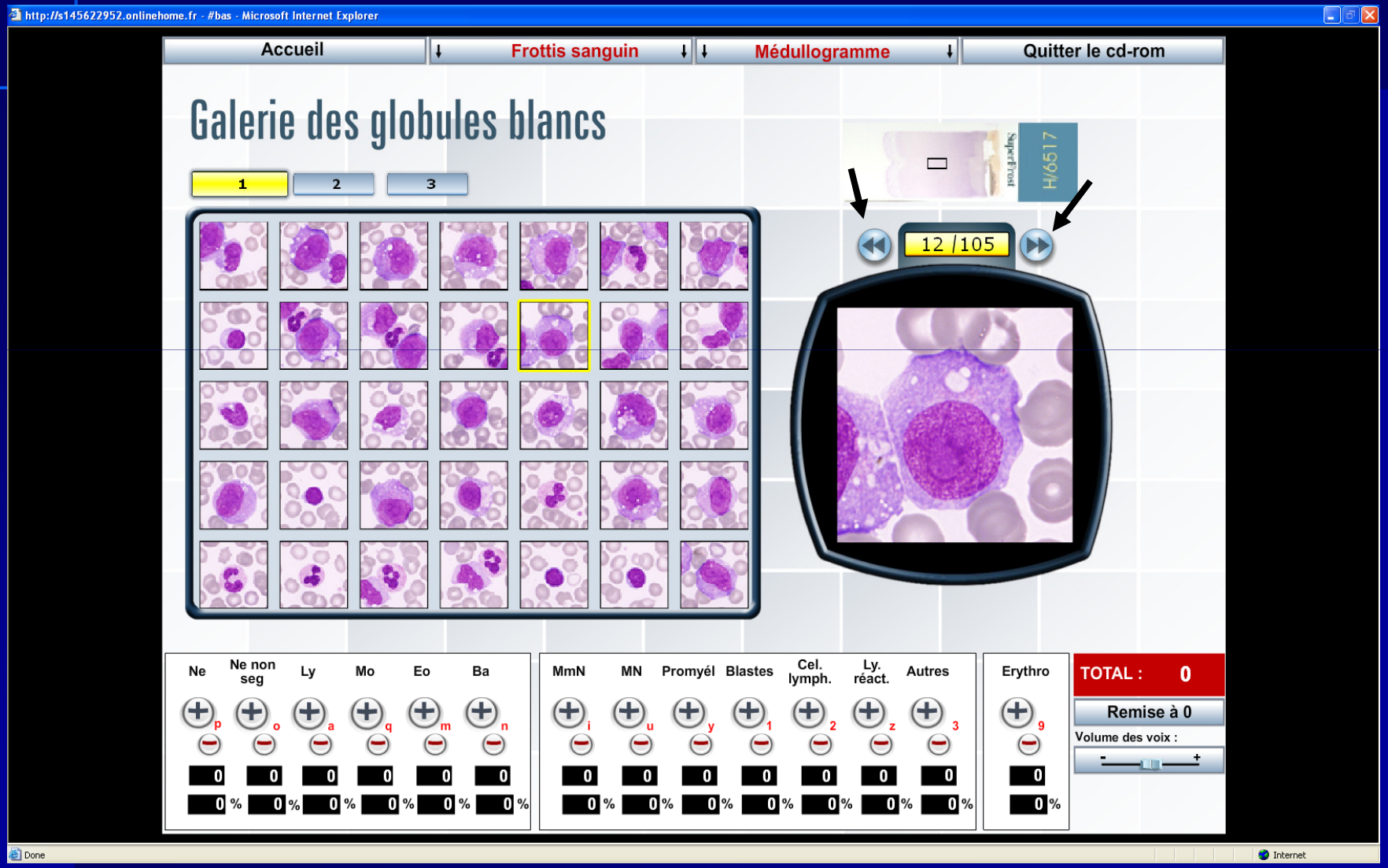
- Flow cytometry: markers of lymphocytosis
  - T-cell markers performed
  - Results

Available data

- Report of the cell counting
  - Select your analyzer
  - View of the report



Virtual peripherical blood smear



WBC differentiation in smear H 3456

Neutrofiele segmentkernigen	55	55 %
Neutrofiele staafkernigen	6	0 %
Eosinofiele segmentkernigen	3	3 %
Basofiele segmentkernigen	2	2 %
Lymfocyten	26	26 %
Reactionele lymfocyten	0	0 %
Monocyten	8	8 %
Promyelocyten	0	0 %
Neutrofiele myelocyten	0	0 %
Neutrofiele metamyelocyten	0	0 %
Blasten	0	0 %
Lymfomateuze cellen	0	0 %
Andere cellen	0	0 %
Erytroblasten	0	0 %
TOTAAL	100	100 %

details

WBC differentiation in smear H 3456

Neutrofiele segmentkernigen	55	55 %
Neutrofiele staafkernigen	6	0 %
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Blasten	0	0 %
Lymfomateuze cellen	0	0 %
Andere cellen	0	0 %
Erytroblasten	0	0 %
TOTAAL	100	100 %

details

Lymphocytes:

A4c, A4d, A7a, B2e, ……;

Monocytes:

A6e, D2f,…

Every cell can be checked by the EQAS organizer

Hidden additional information

Clinical chemistry examinations and results

Bone marrow results or data

You may open one or more drawers and use the information. Only open those that you consider as essential for your final advice

Evaluation externe de la qualité en hématologie : Médullogramme

Externe kwaliteitsevaluatie hematologie : Medullogram

Contrôle

H-7330

Uitstrijkje

Frottis sanguin

- Morphologie des globules rouges et des plaquettes
- Galerie des globules blancs
- Renseignements patient
- Résultats

Bloeduitstrijkje

- Morfologie rode bloedcellen en bloedplaatjes
- Fotogalerij witte bloedcellen
- Gegevens patiënt
- Resultaten

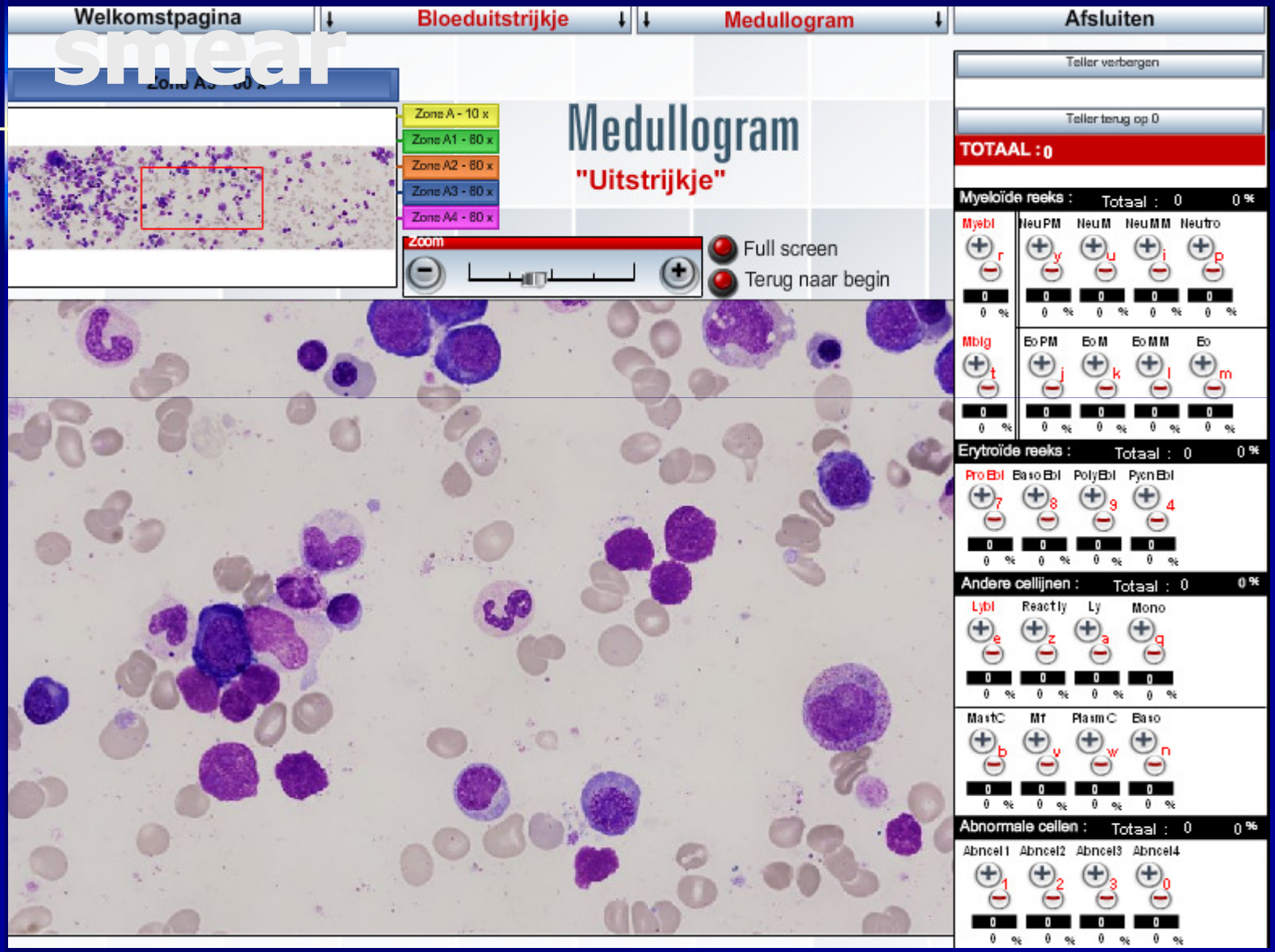
Médullogramme

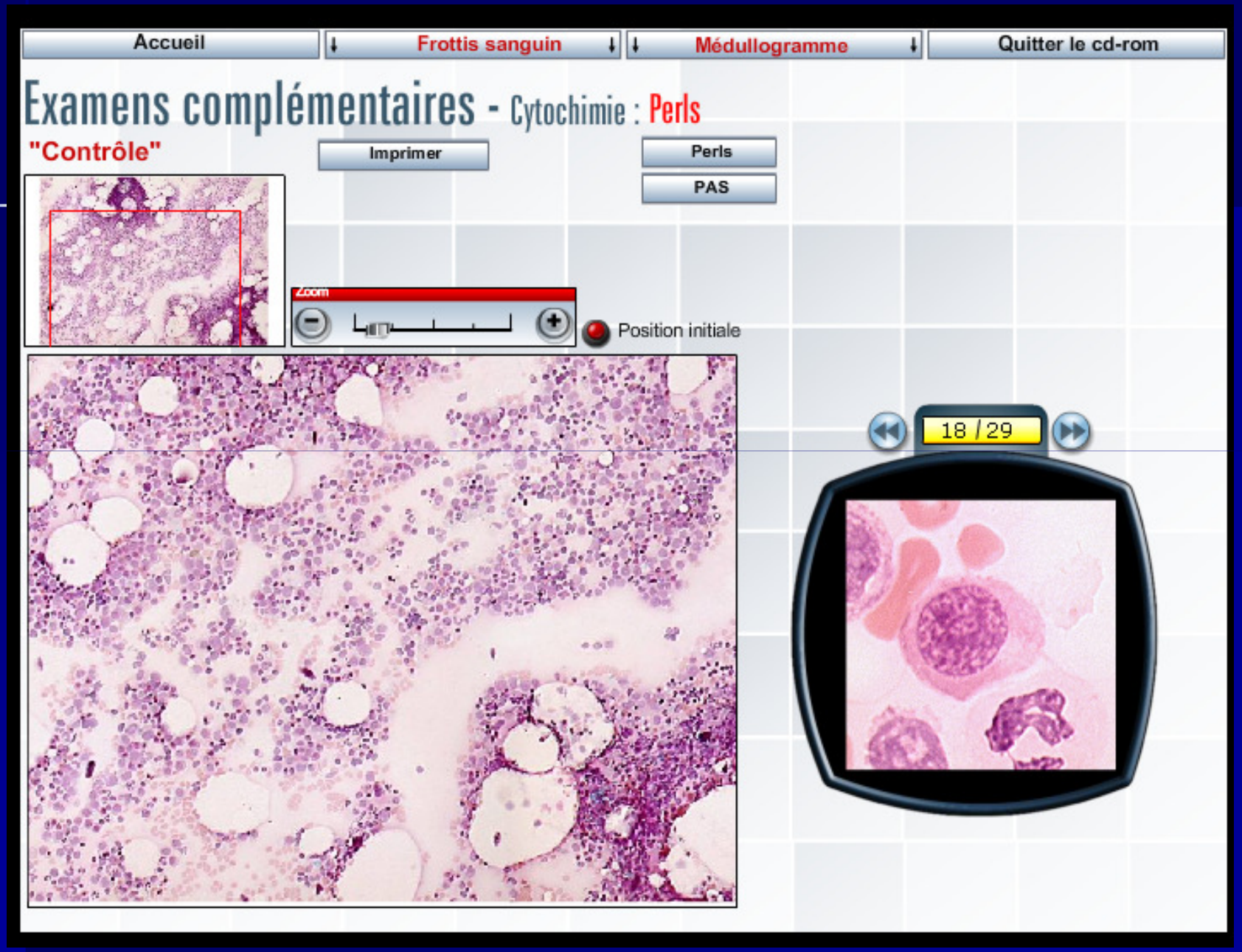
- Coloration May-Grünwald Giemsa
- Examens complémentaires
- Renseignements patient
- Résultats

Medullogram

- May-Grünwald Giemsa kleuring
- Bijkomende onderzoeken
- Gegevens patiënt
- Resultaten

Virtual bone marrow




Accueil
Frottis sanguin
Médullogramme
Quitter le cd-rom
Examens complémentaires - Cytochimie : Perls
"Contrôle"
Imprimer
Perls
PAS
Zoom
Position initiale
18 / 29

Information received by the EQA organizer

- Participant ID
- Information on used technology for the requested analytes performed on the EQA samples
- Results of analysis
- Formulated final advice
- Logging of opened drawer(s)

EQAP is more than PT and traditional EQA!

An important role can be played by


Thank
You!


Goodbye.
I'll miss
you