

# What can we learn from Finnish EQA provider

Juha Wahlstedt  
Client relations manager  
Labquality

# Labquality

Has been an organizer of  
External Quality  
Assurance Services  
since 1971

Over 35 years experience

# Labquality

Non-profit impartial organization  
owned by Finnish  
health care organizations



# Labquality

Labquality's  
quality system has  
been certified to  
ISO 9001 standard



# Organization



## Shareholders

- Hospital districts (19)
- Association of Finnish Local Authorities
- Association of Finnish Chemists
- Association of Medical Group Practices
- Association of Clinical Chemistry
- Private Clinical Laboratories
- Finnish Medical Association
- Finnish Red Cross

# Labquality group

- Labquality (EQA services)
- Bioclin (Control materials for internal use)
- Qualisan (Health care certification)



# Office (28)

- Manager 1
- Production (schemes) 10 (+1)
- Logistics (packing, mailing etc) 6
- Client service 2
- IT 1 (+1)
- Economy 3
- Information and education 1
- Bioclin 2
- Qualisan 1

# Activities of Labquality

## 1. EQA Schemes

- 160 schemes, 539 surveys in 2007

## 2. Information and Training

- Bulletin
- Annual Labquality Days

## 3. Research and Development

- Standards
- Specimens
- Working groups for recommendations

# Bioclin

Control materials for:

- Clinical chemistry
- Hematology
- Microbiology
- Immunology
- Immunochemistry
- Virology

**bioclin**

is affiliated  
company  
of Labquality

Calibrators & Controls  
& Reference materials  
for clinical laboratories

# Qualisan

- Quality assessment
- Certification of quality systems
- Education and classification

for social welfare and health care in Finland.



# EQA services



CONTACTS COMPANY FEEDBACK LINKS



Search

Printable version

### PARTICIPANT SERVICES

Unsecured Connection

Client code

Password

- Home
- New Client Info
- External Quality Assessment Services
- Labquality Days
- Instructions and other publications
- Forms
- GHBA1c [ERL] and Allergy [SKML]

**Remark to e-scheme participants:  
Please log in via the secured Client Services Channel.**

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**Welcome to Labquality's website**

Labquality is an impartial and non-profit organization owned by Hospitals and associations.

Labquality is a member of EQALM (External Quality Assessment in Laboratory Medicine) and cooperates with other EQA organizers in Europe.

The aim External Quality Assessment Schemes is to improve quality in clinical laboratories by supplying data to the laboratories on their performance compared with other laboratories.

- Introduction to Virtual microscopy
- Test your equipment and Internet connection speed.
- Mailing dates of deliveries
- Articles and presentations
- FAQ [Frequently asked questions]

**Identification of Parasites in Blood**  
Check your performance by participating in EQA Scheme.

**2007 EQA Services**

**Labquality News**



AGREE  
Association of Quality

**LABQUALITY DAYS**

e-scheme

### News

[Higher security on Participant Services Channel](#)  
In September, the security has been improved on Labquality's website.

[Three posters were presented in EuroMedLab Congress](#)  
The posters dealt with experiences and results from Labquality's surveys.

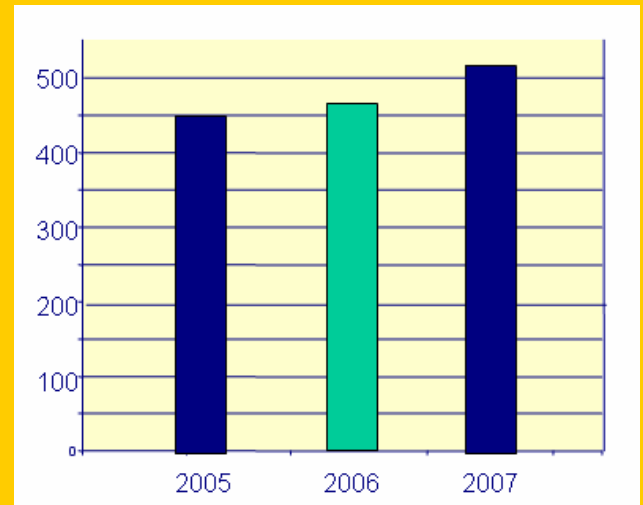
[EUROMEDLAB Amsterdam 3 - 7.6.2007](#)  
We look forward to meeting you at Labquality's booth no. 30 in the Exhibition Hall. Labquality and Bidin have a shared department. We introduce our services for EQA and IQC. Welcome!

[More news >](#)

# EQA schemes 2007

■ Andrology	1
■ Cardiac physiology	1
■ Clinical chemistry	59
■ Genetics	5
■ Hematology	16
■ Instruments	9
■ Microbiology	42
■ Pathology	6
■ Point-of-care	21

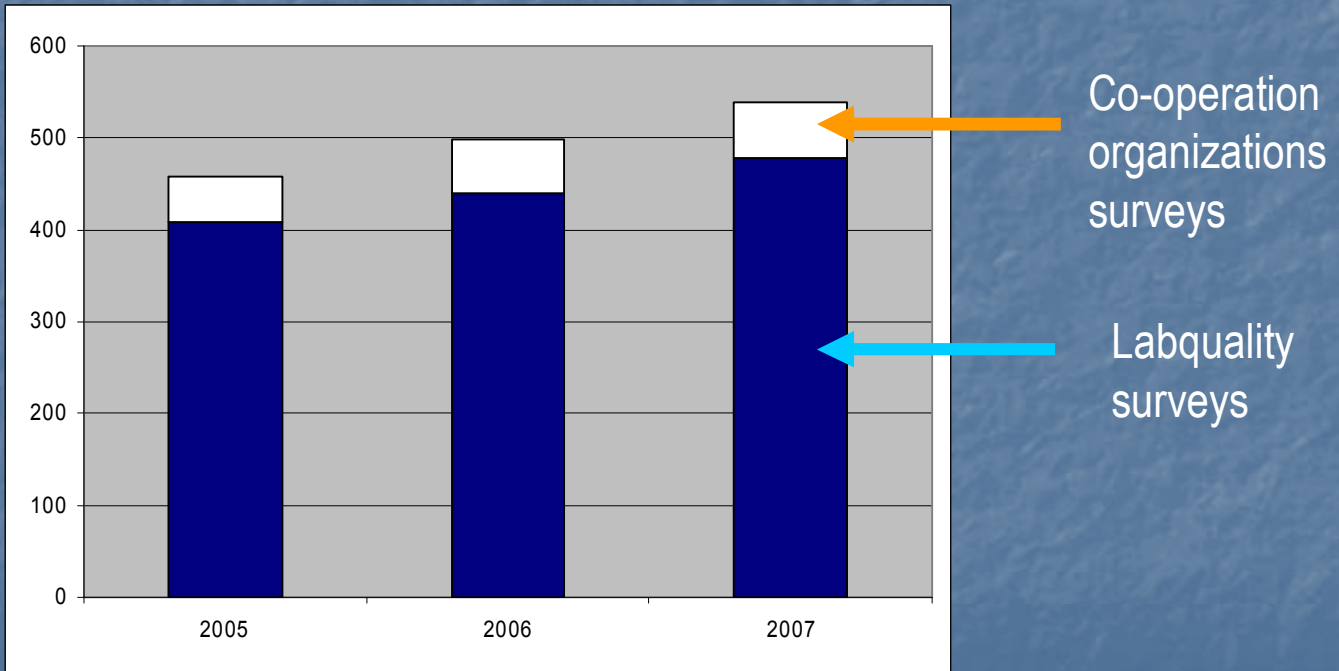
**NUMBERS OF SURVEYS**



# EQA Scheme cooperation 2007

- **UKNEQAS**: United Kingdom National External Quality Assessment Service
- **SKML**: Dutch Foundation for Quality Assessment in Clinical Laboratories (SKML)
- **DEKS**: Danish Institution for Quality Assessment
- **EQUALIS**: External Quality Assurance in Laboratory Medicine in Sweden

# EQA scheme cooperation

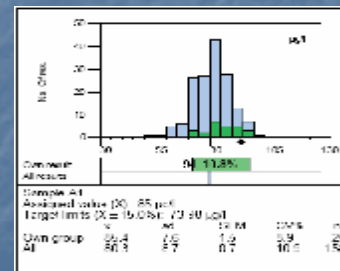
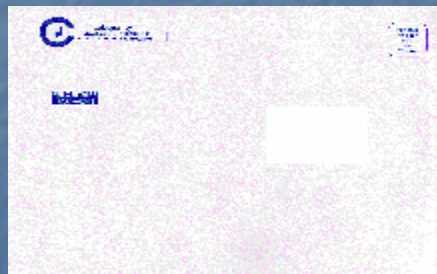


# Scheme statistics 1

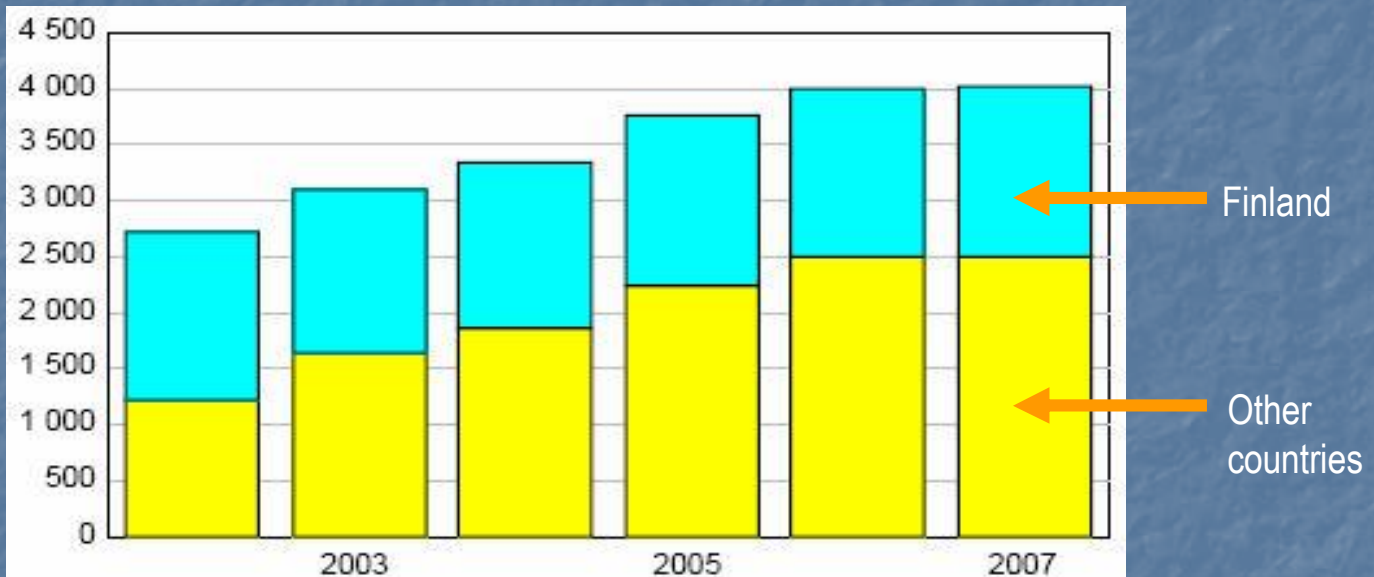
	2006	2007
Andrology	1	1
Physiology	2	2
Genetics	7	6
<b>Hematology</b>	<b>48</b>	<b>48</b>
Immunology	15	16
Radiology	-	1
<b>Clinical chemistry</b>	<b>217</b>	<b>272</b>
Instruments	10	10
<b>Microbiology</b>	<b>168</b>	<b>176</b>
Pathology	8	7
<b>All</b>	<b>457</b>	<b>539</b>

# Scheme statistics 2

- No. of specimen mailings 103 500
- No. of specimens mailed 224 600
- No. of results analysed 1 430 000
- No. of results reported per lab 380



# Clients



2002	2003	2004	2005	2006	2007
1 222	1 631	1 848	2 230	2 493	2 493
1 491	1 469	1 490	1 513	1 499	1 518

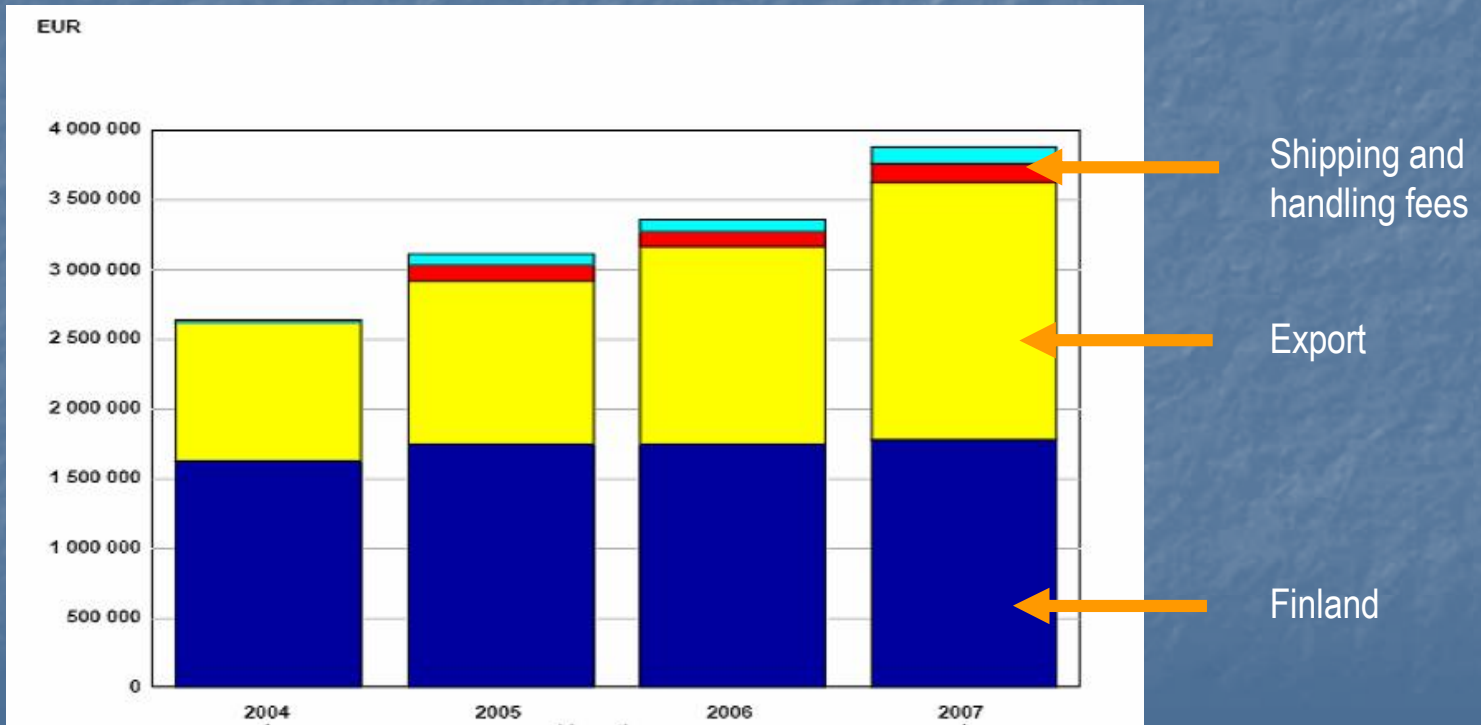
# Export countries 2007

Country	Country	Country	Country
Romania	Ireland	Saudi Arabia	Malta
Norway	Slovakia	Slovenia	Czech republic
Poland	Island	Italy	Spain
Denmark	Turkey	Hungary	Canada
Portugal	Italy	Kuwait	USA
Lithuania	Switzerland	Germany	Thailand
Latvia	Iran	Bulgaria	Costa Rica
Estonia	Lebanon	Russia	Australia
Sweden	United kingdom	Greenland	Senegal
Greece	France	Croatia	Netherlands

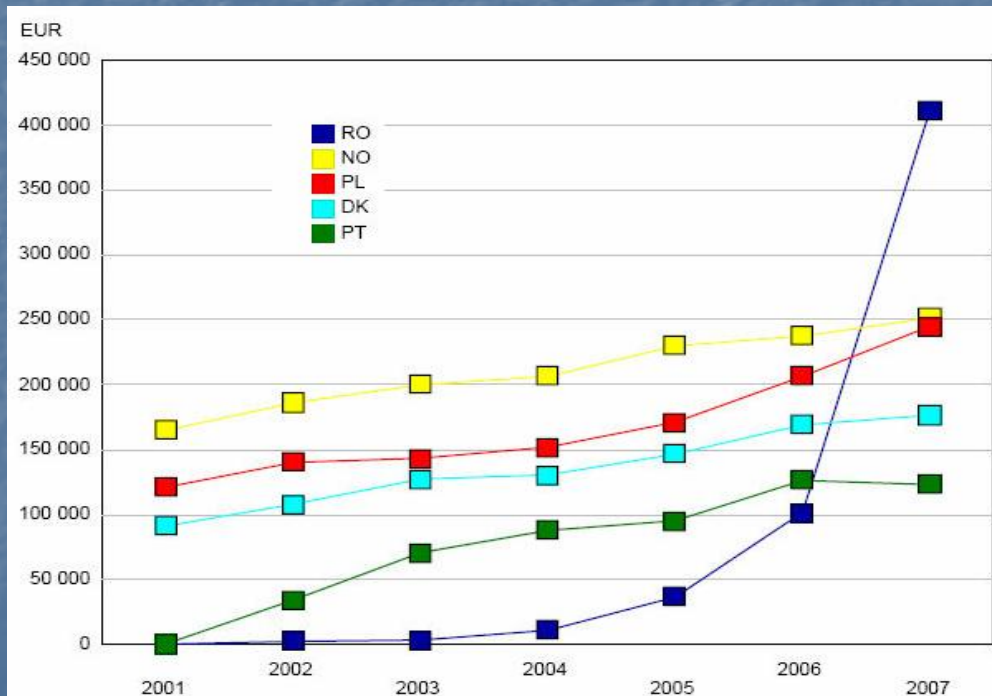
# Distributors and co-operators

<b>Denmark:</b> DEKS	<b>Norway:</b> NKK
<b>France:</b> S.F.T.A.	<b>Poland:</b> Kolegium Medycyny..
<b>Greece:</b> Alpha Medical /Menarini	<b>Portugal:</b> Instituto National de..
<b>Hungary:</b> QualiCont	<b>Sweden:</b> EQALIS
<b>Ireland:</b> IEQAS	<b>Malta:</b> Cherubino Ltd
<b>Iran:</b> Pishro Tashkis	<b>Romania:</b> Tody Laboratories
<b>Israel:</b> Biotest Ltd	<b>Turkey:</b> Teknomed
<b>Italy:</b> Pantec	<b>Slovakia:</b> Manacon
<b>Kuwait:</b> AlBisher & AlKatzemi..	<b>Saudi Arabia:</b> Habib Medical Center
<b>Lithuania:</b> UAB Laboratorine Med..	<b>Estonia:</b> Delivery cooperation
<b>Lebanon:</b> M.E.A.T.O	<b>Latvia:</b> Delivery cooperation

# Sale



# Top five export countries



# Ireland

- Co-operation with IEQAS over 10 years
- Few direct clients

	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Direct clients					3
Clients	46	59	64	84	94
Sale (EUR)	13918	23756	43863	45675	62061
Schemes					37

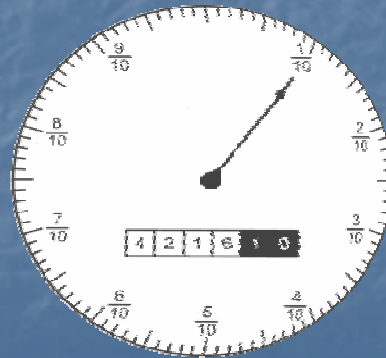
# What is EQA – External Quality Assessment?

- ...a system of objectively checking laboratory results by means of an external agency.
- ...main objective of traditional EQA is not to bring about day to day consistency but to establish between-laboratory comparability.

**The definition of EQA was described in *WHO External Assessment of Health Laboratories (1981)***

# General idea behind EQA, comparison measurements, benchmarking

- What gets measured, gets done
- Without measurements, you can not improve



# Different EQA Programs, Different Aims

**There are different kind of EQA providers with slightly different views and aims**

- National EQA programs
- International EQA programs
- Manufacturers with EQA service
- EQA programs focused to specific (new) laboratory medicine disciplines or tests

# Different EQA Programs, Different Aims

## **EQA programs can be:**

- Measuring only analytical performance (narrow meaning)
- Taking also preanalytical and postanalytical issues under the scope (extended meaning)



# Different EQA Programs, Different Aims

## **EQA programs can be:**

- Mandatory (Big brother is watching you)
- Voluntary (Cooperation with EQA provider and other laboratories)



# Different EQA Programs, Different Aims

## **EQA Programs can be:**

- Directed for all Laboratory Medicine disciplines (comprehensive service)
- Directed for some specific laboratory medicine discipline or measurement (focused service)



# Different EQA Programs, Different Aims

## **EQA Programs can be:**

- Directed for all kind of laboratories, manufacturers and POC sites
- Directed for specific user group (according to laboratory size, location, etc.)
  - Hospital laboratories
  - Primary health care laboratories
  - POCT units



# Different EQA Programs, Different Aims

## EQA Programs can be:

- Automated with pre-programmed feedback reports
- Feedback reports and summaries made by Laboratory Medicine experts

**Labquality**  
External Quality Assessment Schemes

**Hormones A**  
**Basic analytes of hormone and immunochemistry 3/2007**

Thank you for participating in the survey of June. There were 205 laboratories, which participated in this survey.

The laboratory-specific histograms, numerical summaries and report letters of Hormone scheme are available through Labquality homepage ([www.labquality.fi](http://www.labquality.fi)). Please choose EQA services and fill in your laboratory's username and password. Then please choose Reports from the column on the left.

**Samples**

Sample A1 was human-based lyophilised serum, coded Har and has been used before in the surveys 2/2006, 3/2006, 6/2006 and 1/2007.

Sample A2 was human-based lyophilised serum, coded Har and has been used before in the surveys 2/2006, 4/2006 and 1/2007.

**Method groups**

The results are divided into groups according to the method. The histogram printout compares your own result directly to your method group, not with the mean value of all results. If the laboratory has not stated its method, the results are grouped under Unknown. Variation in this group is usually larger than in the well-characterised method groups. Please note that the results marked with "4" or "5" cannot be processed.

In order to have method groups with greater number of participants we have reorganised some methods as follows. This grouping applies to all other analytes but folate and vitamin-B12.

Abbott Architect & Architect  
Abbott AxSym & iXc  
Beckman Coulter Access & UniCel  
Bayer Advia Centaur & ACS  
DPC Immulite & Immulite 2000 & Immulite 2500  
Roche Modular E & cobas 6000

In regard to some analytes marked differences were observed in the

**RESULT REPORT**

Basic analytes of hormone and immunochemistry 3/2007

Product no. 2300  
434-8001 LT

The report contains individual histograms (if results have been returned) Numerical summary

Inquiries about the survey, including questions of possible errors in result processing, should be at Labquality's office within a month from the date of this letter

Inquiries  
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ulla.tikkanen@labquality.fi

Pirjo Tansser (PT) of the Helsinki University Central Hospital is the expert for the Hormone Scheme A.

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# Different EQA Programs, Different Aims

## **EQA Programs can be:**

- National, Regional or International



# General aim of EQA Programs

## Use of EQA services as a tool in laboratory quality management

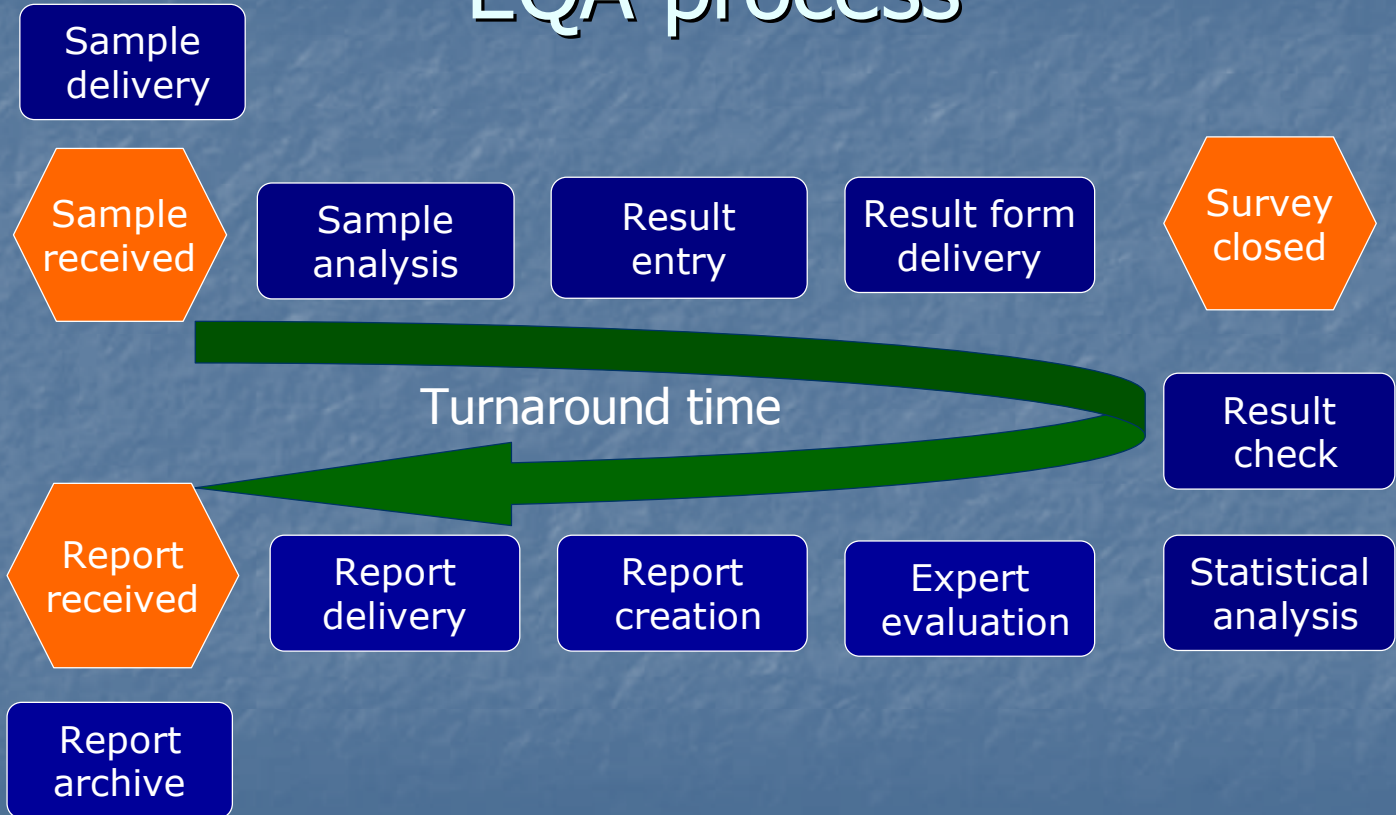
1. Laboratory performance evaluation (*laboratories, regulatory authorities?*)
2. Evaluation of method performance (*laboratories, manufacturers*)
3. Monitoring In Vitro Diagnostic Procedures and Medical Devices (IVD MDs) (*vigilance authorities*)
4. Accreditation purposes (*accreditation authorities*)
5. Training, help and education (*laboratories*)

# Requirements for the competence of providers of EQA schemes

## **All areas of conduct of EQA schemes, including:**

- Planning of EQA schemes
- Selection and preparation of materials
- Assessment of homogeneity and stability
- Identification, labelling, packaging and distribution of materials
- Statistical and technical evaluation of participants' performance
- Content of EQA scheme reports

# EQA process



# Challenges for Labquality – What can be expected?

## Sample materials

- Procurement of good quality sample materials is a priority in any documentation of laboratory performance
- Homogeneity and stability

# Challenges for Labquality – What can be expected?

## Assignment of target values

- Reference method target values
- Values assigned with “best method”
- Consensus method mean

# Challenges for Labquality – What can be expected?

## Performance goals

- Values assigned with “best method”
- Performance goals should be based on clinical outcome, biological variations and state of the art

# Challenges for Labquality – What can be expected?

## Frequency of surveys

- The frequency of the surveys should be fit for the purpose and evaluated critically
- A number of 6 rounds a year has been recommended for the monitoring of IVD-devices but this is not of direct relevance to the laboratories

# Challenges for Labquality – What can be expected?

## Turn around time

- Shorter turn around times should be a realistic goal and a priority

# Challenges for Labquality – What can be expected?

## Reporting

- The conclusions should be presented clearly:
  - Is the performance acceptable for this round?
  - What is the current estimate of bias of the laboratory?
  - And of the reproducibility of the laboratory?
- The graphic design should be of quality and compatible with current style.
- The possibilities using internet reporting should be used

# General aspects from Labquality

- Independent and impartial handling of laboratory data
- Educational approaches in the surveys
- Laboratory medicine professionals involved in the surveys, reports and development of new services
- Quality management system and certification or accreditation
- Global view – local touch

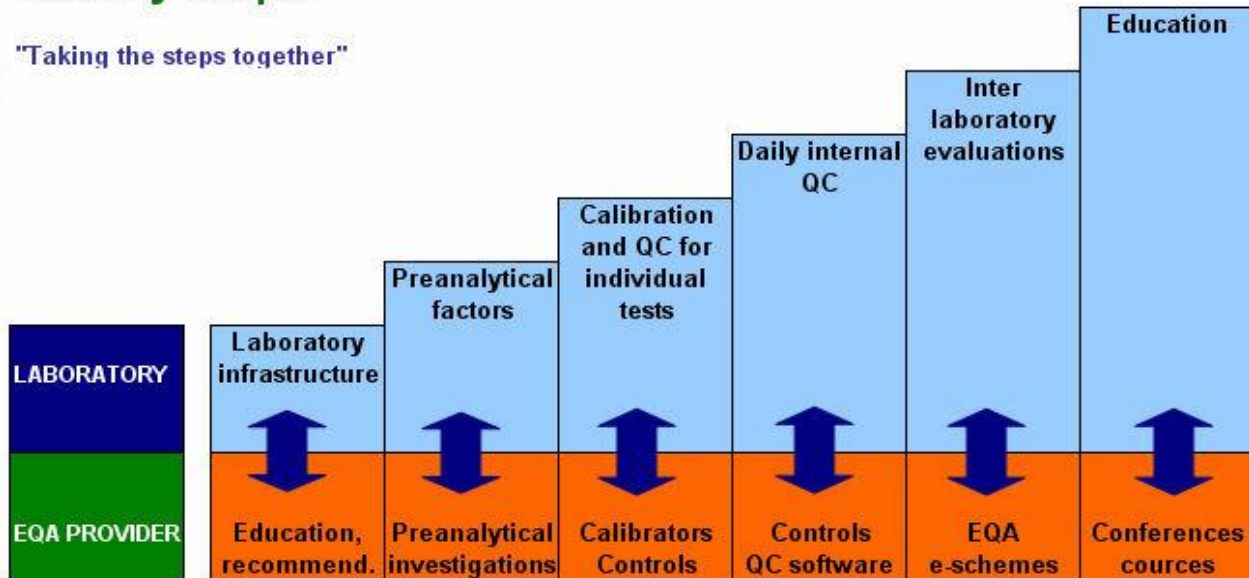
# Quality building blocks



# Taking "Quality Steps" together

## Quality steps

"Taking the steps together"



# Conclusions

- Quality can not be outsourced, it must be build in the processes inside the laboratories
- EQA is a good tool for quality improvement, when used with other tools in laboratory quality management
- EQA schemes and programs can be focused for evaluation of only analytical performance, but many EQA providers are doing more
- Laboratories can expect EQA providers to be their partners in quality improvement work

# Thank you



Dublin 2007-10-04