Labkvalita 2009

Challenges in External Quality Assurance; laboratory focus and the new accreditation standard (ISO 17043) of providers

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Content

- Role of External Quality Assurance (EQA)
- Laboratory focus
- International standards
- Different kinds of EQA programmes
- Expectations by laboratories

Role of EQA 1(5)

- Show the competence of participating laboratory
  - Fullfill the criteria of accreditation, authorities, clients, marketing aspects etc.
- Objective evaluation of test results and performance of tests
  - Comparative test results
- Continous quality maintenance and improvement

Role of EQA 2(5)

- To show the national or international areas which need to be improved (Guidelines)
- Learning and education
- Improve methodology in cooperation with industry

Role of EQA 3(5)

Benefits for the participating laboratory?

Role of EQA 4(5)

Benefits for the participating laboratory?

- Risk management tool
- Information on accuracy and precision
- Traceability of the test results to SI units (certified reference materials, national reference materials, calibration etc.)

Role of EQA 5(5)

- Help in verification procedures
- Improve laboratory´s performance
  - (reliable patient test results)
- Support IQA

International standards 1(2)

- **ISO/IEC CD 17043** (2008-03-11) Conformity assessment – general requirements for proficiency testing
- **ISO/IEC Guide 43-1**: 1996 Proficiency testing by Interlaboratory Comparisons- Part 1: Development and Operation of Proficiency testing Schemes
- **ILAC-G13:2007 ILAC** Guidelines for the requirements for the Competence of Providers of proficiency testing Schemes
- **ISO 13528** (2005-09-11) Statistical methods for use in proficiency testing by interlaboratory comparisons

International standards 2(2)

- **IUBAC Technical report 1/2006**, The International Harmonized Protocol for the Proficiency testing of Analytical Chemistry Laboratories
- **ISO/TS 20612,** Water Quality – Interlaboartory comparisons for proficiency testing of analytical chemistry laboratories
- **ISO/IEC Guide 99:2007** (E/F) International vocabulary of metrology – basic and general concepts and associated terms (VIM)

- ISO 3534:2006 Statistics – Vocabulary and Symbols –Part 1…
- ISO/IEC 17000:2004 Conformity Assessment - Vocabulary and general principles
- ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

Std ISO/IEC CD 17043 1(3)

Criteria for the provider to organize the EQAs

- 5 main categories
- 3 informative Annex

- **Annex A** Types of proficiency testing schemes
- **Annex B** Statistical Methods for Proficiency Testing
- **Annex C** Selection and Use of Proficiency Testing

Std ISO/IEC CD 17043 2(3)

1. Scope
2. Normative referencies
3. Terms and definitions
4. **Technical Requirements**

   4.1 General
   4.2 Personnel
   4.3 Accomodation and environmnet
   4.4 Design of proficiency testing schemes
   4.5 Choice of method or procedure
   4.6 Conduct of proficiency testing schemes
   4.7 Data analysis and evaluation of proficiency testing scheem results
   4.8 Reports
   4.9 Communication with participants
   4.10 Confidentiality

Std ISO/IEC CD 17043 3(3)

5. Management Requirements

5.1 Organisation
5.2 Management system
5.3 Document control
5.4 Rewiev of requests, tenders and contracts
5.5 Subcontracting services
5.6 Purchasing services and supplies
5.7 Service to the customer
5.8 Complaints
5.9 Control of nonconforming activities
5.10 Improvment
5.11 Corrective action
5.12 Preventive action
5.13 Control of records
5.14 Internal audits
5.15 Management reviews

Annex A
Annex B
Annex C

Main points 1(4)

- Strengthens educational value of PTs
- Need for technical experts to review results and provide experts comments
- Calculating and reporting the uncertainty of assigned value
- Use of VIM terminology

Main points 2(4)

- PT providers are <u>not allowed</u> to subcontract the following key functions:

1. Design and planning of the PT scheme
2. Evaluating performance
3. Authorizing the release of reports

Main points 3(4)

- PT providers are allowed to subcontract the following functions:
  - Manufacturing of PT items
  - Shipping of samples
  - Data processing

Main points 3(4)

Aspects under question:

- Assigned values with metrological traceability are essential for PT scheme in some situations (calibration schemes)
- Certificates of participation
  - for enrolment
  - Successfull (??) participation

Annex A
Types of proficiency testing schemes

- A.2 Sequential participation schemes
- A.3 Simultaneous participation schemes
  - A.3.1 External Quality Assessment (EQA) programs
  - A3.2 Split-level designs
  - A.3.3 Split-sample testing schemes
  - A.3.4 Partial-process schemes

Annex B
Statistical Methods for Proficiency Testing

- B.1 Determination of the assigned value and its uncertainty
- B.2 Calculation of performance statistics
- B.3 Evaluation of performance
- B.4 Demonstration of proficiency test item and stability

Annex C
Selection and Use of Proficiency Testing

- C.1 Introduction
- C.2 Selection of proficiency testing scheme
- C.3 Policies on participation in proficiency testing schemes
- C.4 Use of results by interested parties

Laboratory focus 1(7)

- Laboratory´s own quality criteria
  - Competence of the personnel
  - Central laboratories vs. point of care testing units (POC)
  - Stage in quality improvement culture
  - ”certificate seeker?, value seeker?, improvement seeker?”

Laboratory focus 2(7)

- Quality status of your laboratory?
- Suitable EQA programme for your needs of competence and/or calibration
- Choose a competent provider
- Needs of different specialities?

Laboratory focus 3(7)

- Independent provider (Is this important?)
- Accredited or certified provider
  - EQA programme fulfills the criteria of ISO 17043 or ISO 9001:2008
- Quality system (audits allowed?)

Laboratory focus 4(7)

- Professional staff and expertise
- Confidential relationship
- Language
- Well designed logistic

Laboratory focus 5(7)

- Sample materials, test items
  (native patient samples, one donor samples, spiking materials, concentration ranges etc.)
- Clear instructions
- Reasonable turn around time

Laboratory focus 6(7)

- Extensive, informative reports, summaries etc.
- Qualified data treatment (Annex B)
  - Determination of the assigned value and its uncertainty
  - Calculation of performance statistics
  - Evaluation of performance
  - Demonstration of proficiency test item and its stability

Laboratory focus 7(7)

- Educational aspects
- Frequency of the surveys
  - Once a year
  - Every other year
  - Once a month
  - Twice a month
  - 1 - 12 - 24 times a year
- Practical interaction
- Ethical considerations
- Competetive pricing

Different types of EQA programmes (Annex A) 1(4)

- National programmes
- International programmes (**reports by countries**)
- Programmes by industry

Different types of EQA programmes (Annex A) 2(4)

- Multianalyte vs one analyte programmes (design of the scheme)
- Only for analytical performance
- Pre- and postanalytical phase included

Different types of EQA programmes (Annex A) 3(4)

- Voluntary programmes (educational aspects)
- Mandatory (control, supervision)
- Acreditated programme
- Open to all participants /Restricted only to certain laboratories

Different types of EQA programmes (Annex A) 4(4)

- Quantitative parameters /Qualitative parameters/Statements etc.
- Amount of results in different method groups
- Up-to-date, qualified methods and instruments

Expectations by laboratories

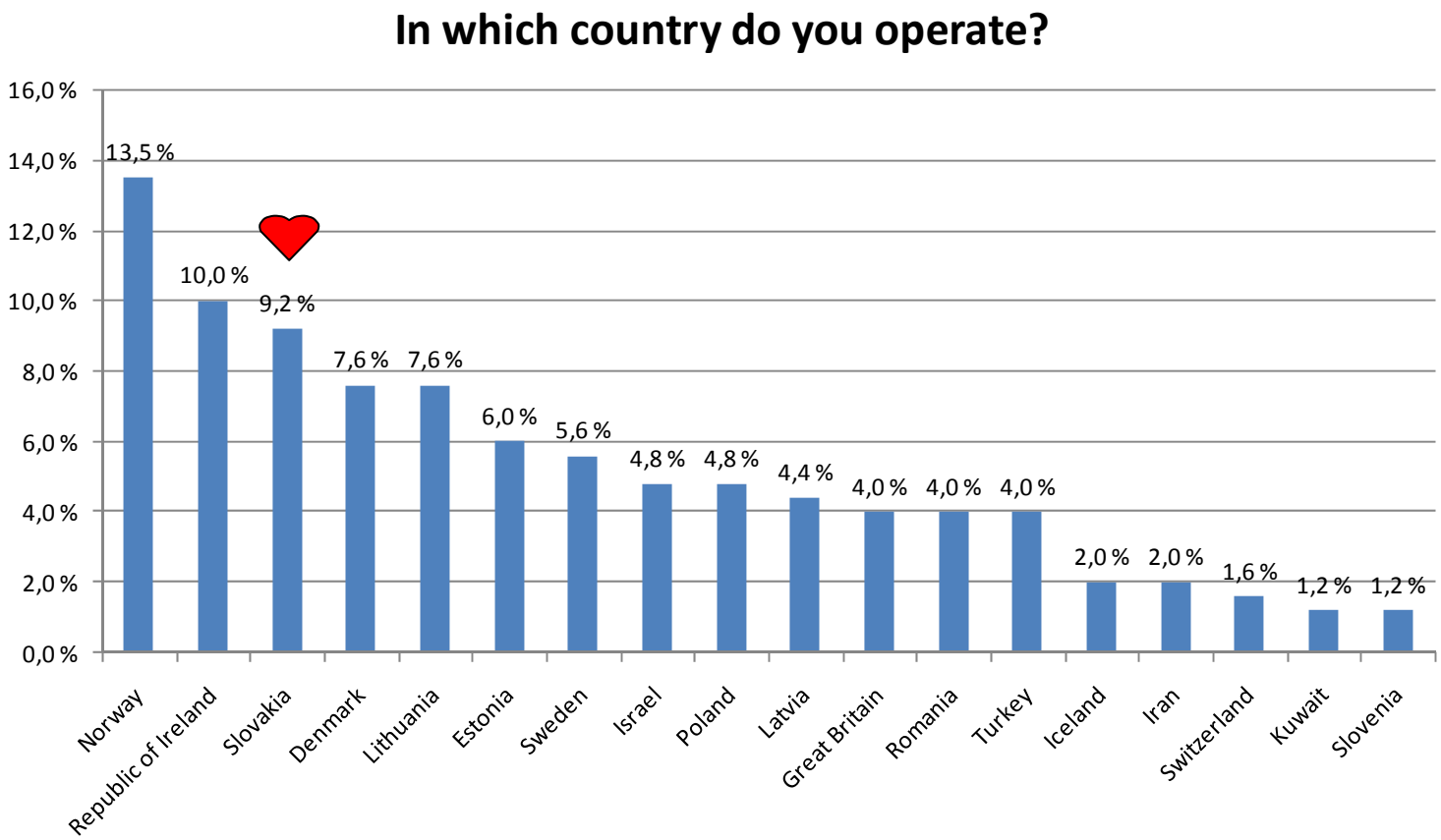
- Labquality´s customer satisfaction survey 2008-2009

  January 2008 (Finnish) – 51,4 % (360 laboratories)

  February 2009 (International) – 23% (259 laboratories)

  In cooperation with Perfecto Ltd, Finland

The significance of services and Labquality's performance (general estimate) international



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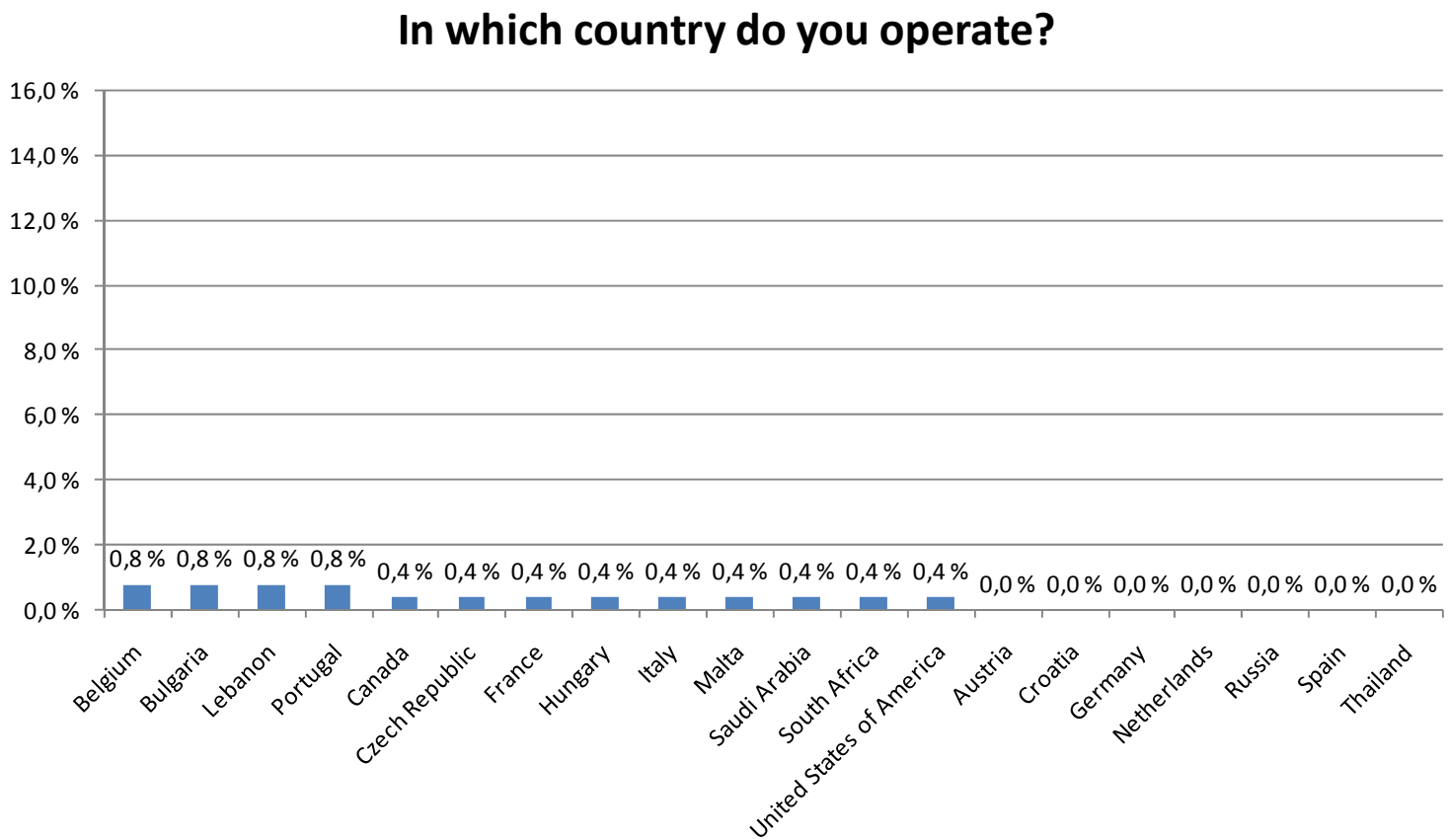

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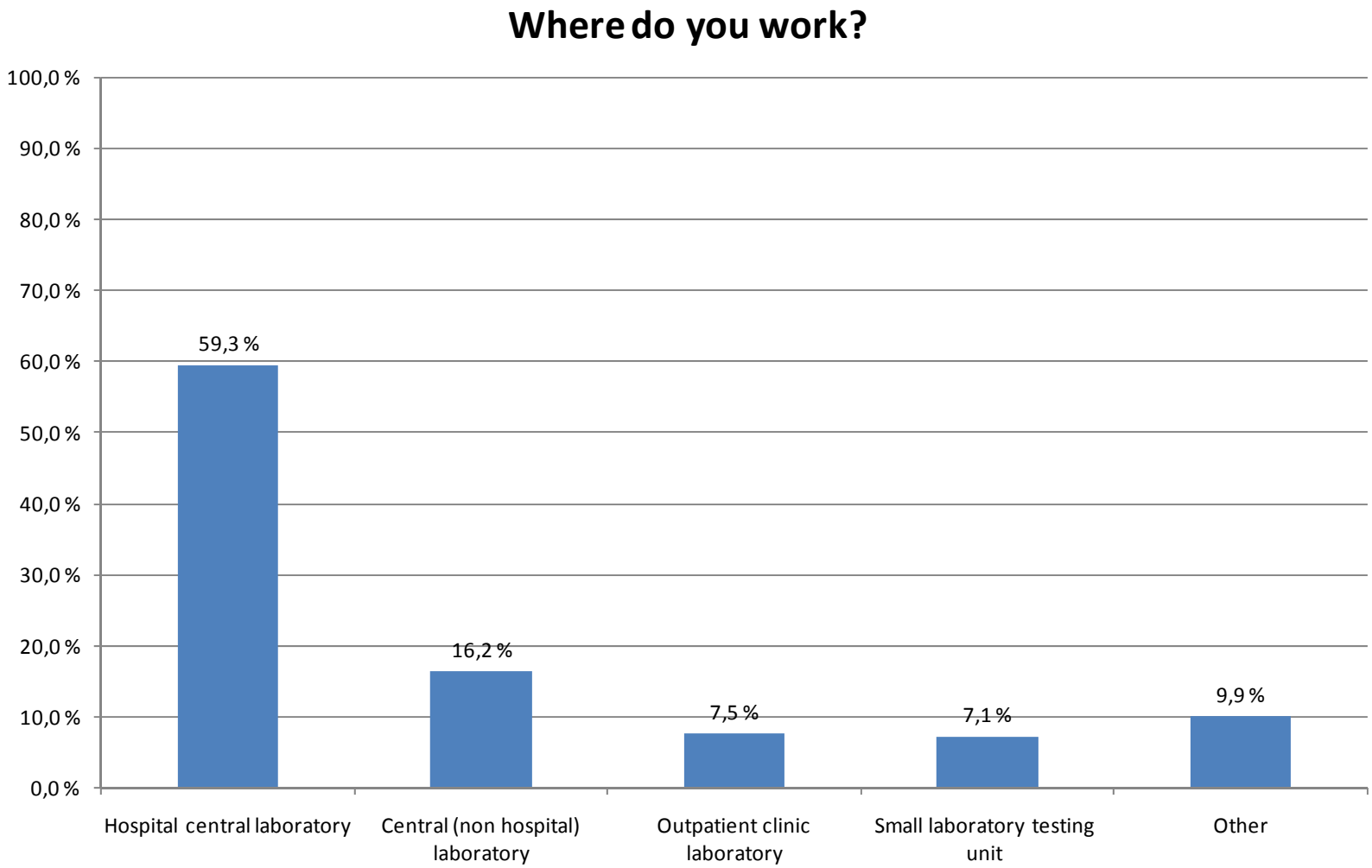

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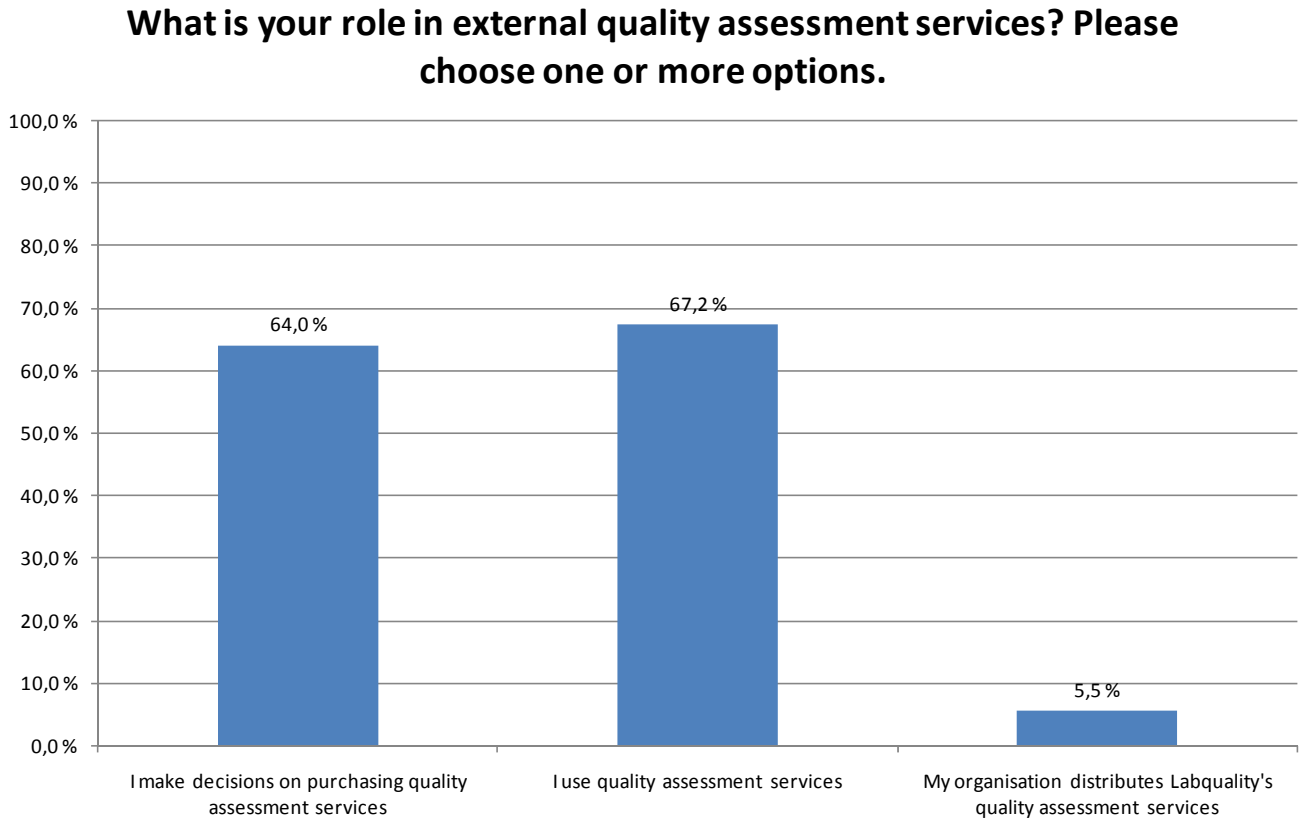
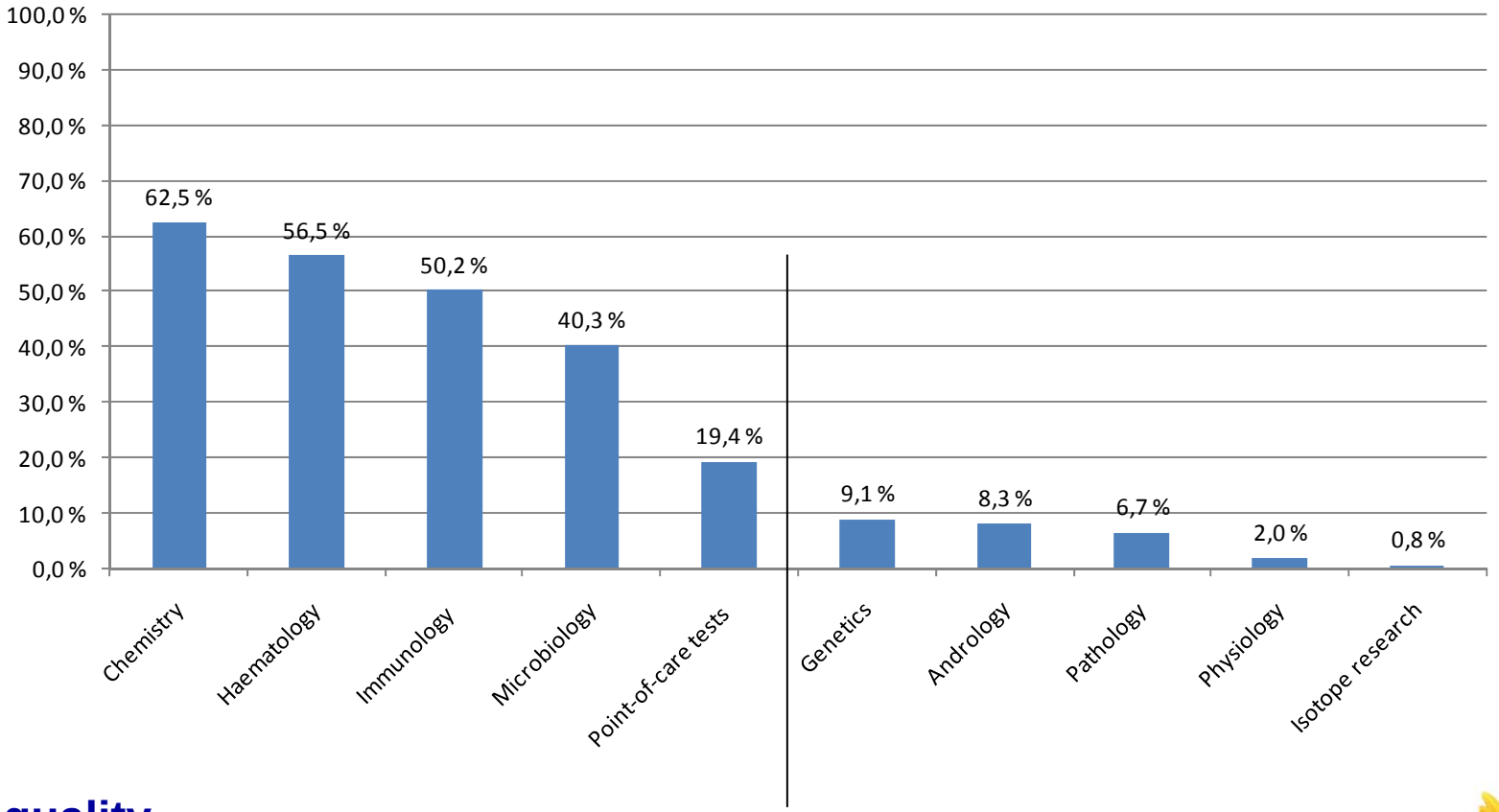
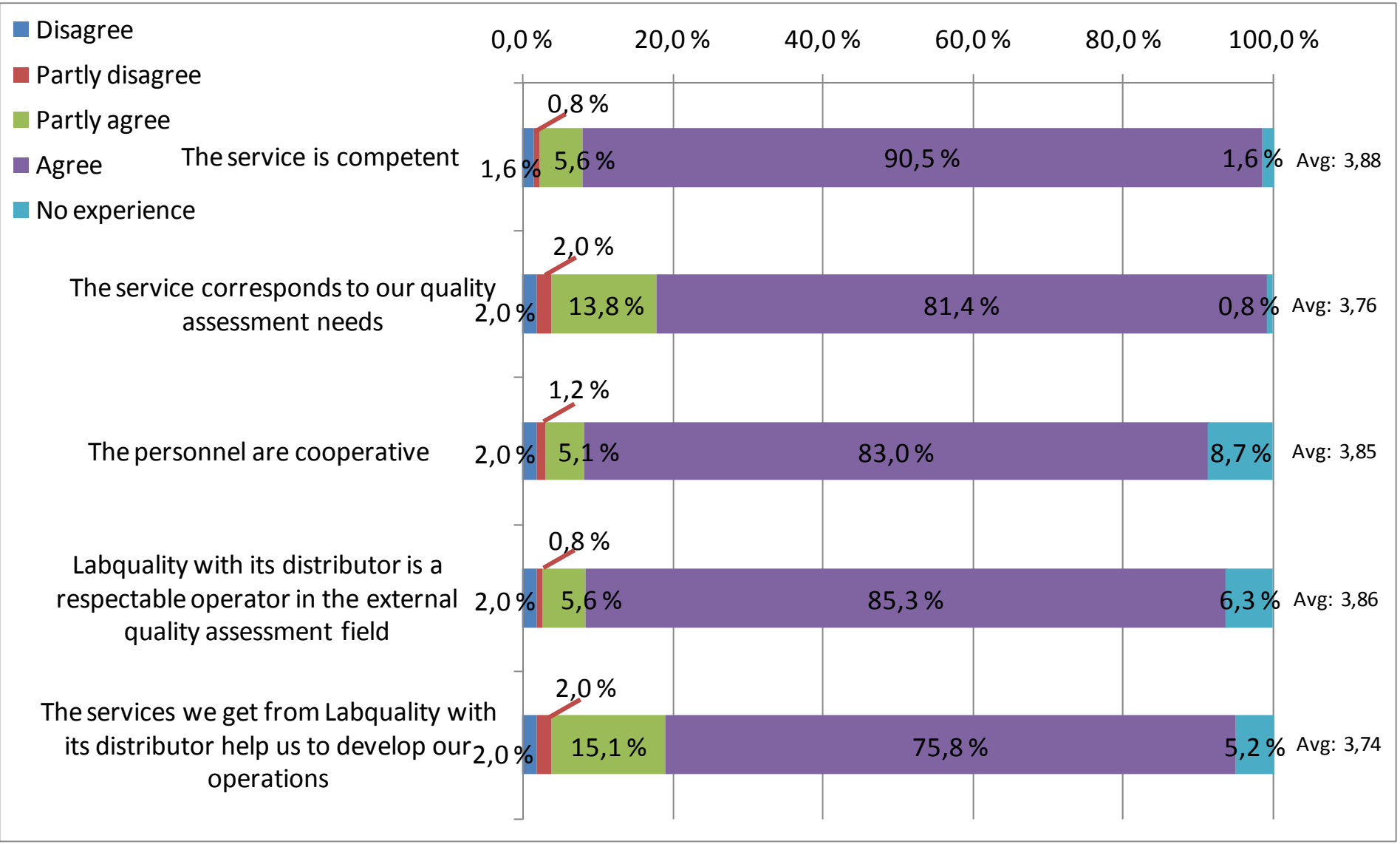


The significance of services and Labquality's performance (general estimate) international

- **I am a decision maker or I use quality assessment services in the following special fields**




Disagree
Partly disagree
Partly agree
Agree
No experience
0,0 %
20,0 %
40,0 %
60,0 %
80,0 %
100,0 %
The service is competent
0,8 %
1,6 %
5,6 %
90,5 %
1,6 %
Avg: 3,88
The service corresponds to our quality assessment needs
2,0 %
2,0 %
13,8 %
81,4 %
0,8 %
Avg: 3,76
The personnel are cooperative
1,2 %
2,0 %
5,1 %
83,0 %
8,7 %
Avg: 3,85
Labquality with its distributor is a respectable operator in the external quality assessment field
0,8 %
2,0 %
5,6 %
85,3 %
6,3 %
Avg: 3,86
The services we get from Labquality with its distributor help us to develop our operations
2,0 %
2,0 %
15,1 %
75,8 %
5,2 %
Avg: 3,74

The significance of services and Labquality's performance (general estimate) international

- **Professional personnel** was estimated the most significant area (average 4,31)

- **Active contacting** was estimated the least significant (average 3,57).

Scale:

1= No significance, 2= Low significance,
3= Some significance, 4= High significance,
5= Very high significance, 6= No experience

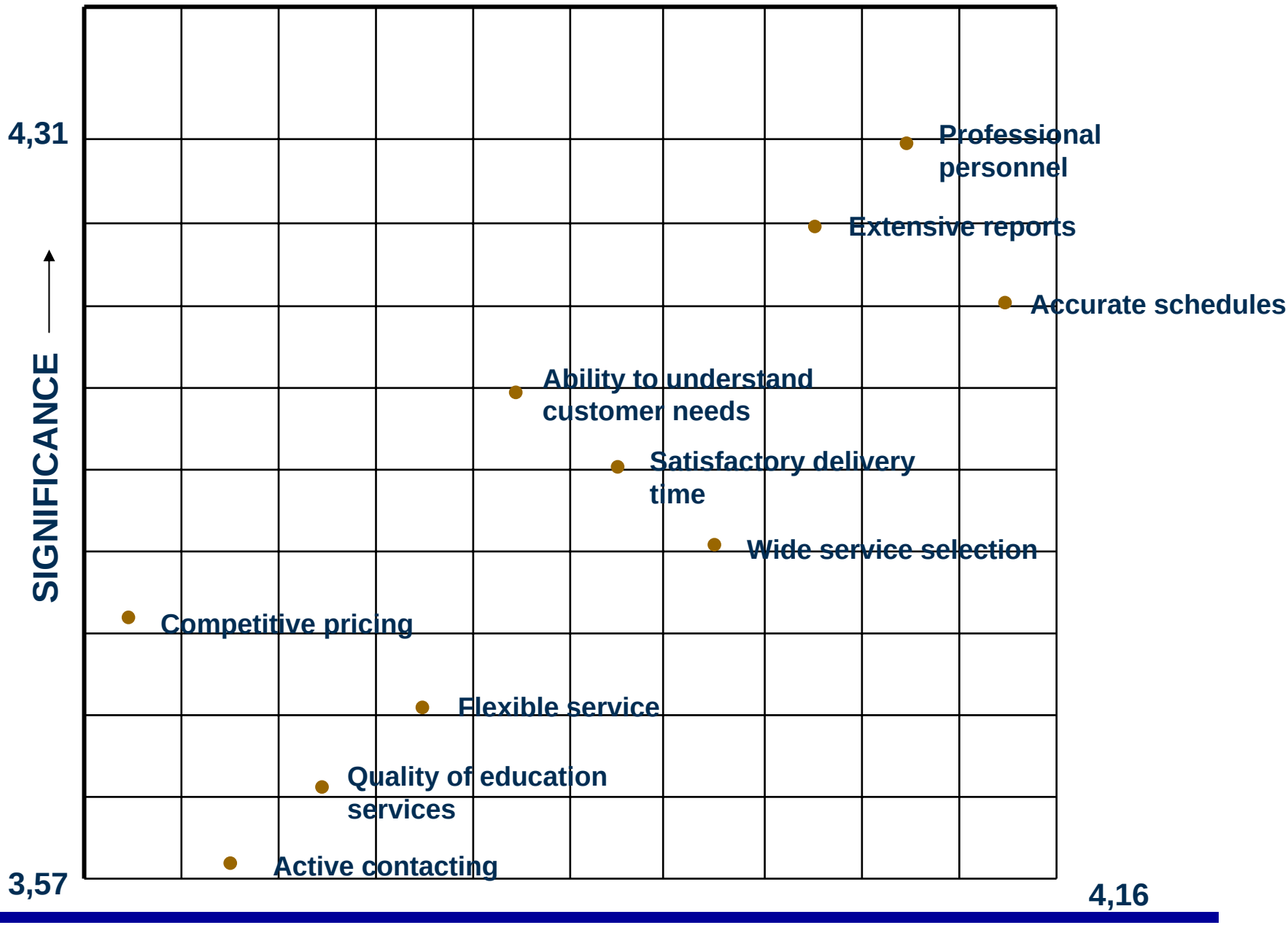
The significance of services and Labquality's performance (general estimate) international

- Labquality had the best performance in **accurate schedules** (average 4,16).

- The worst performance was in **competitive pricing** (average 3,48).

Scale:

1= No significance, 2= Low significance,
3= Some significance, 4= High significance,
5= Very high significance, 6= No experience


4,31
3,57
SIGNIFICANCE
Professional personnel
Extensive reports
Accurate schedules
Ability to understand customer needs
Satisfactory delivery time
Wide service selection
Competitive pricing
Flexible service
Quality of education services
Active contacting
3,48
4,16
PERFORMANCE

The significance of services and Labquality's performance (general estimate) international

- **Understandable reports** were estimated the most significant area (average 4,57).

- **Suitable sample packages** were estimated the least significant (average 4,14).

Scale:
1= No significance, 2= Low significance,
3= Some significance, 4= High significance,
5= Very high significance, 6= No experience

The significance of services and Labquality's performance (general estimate) international

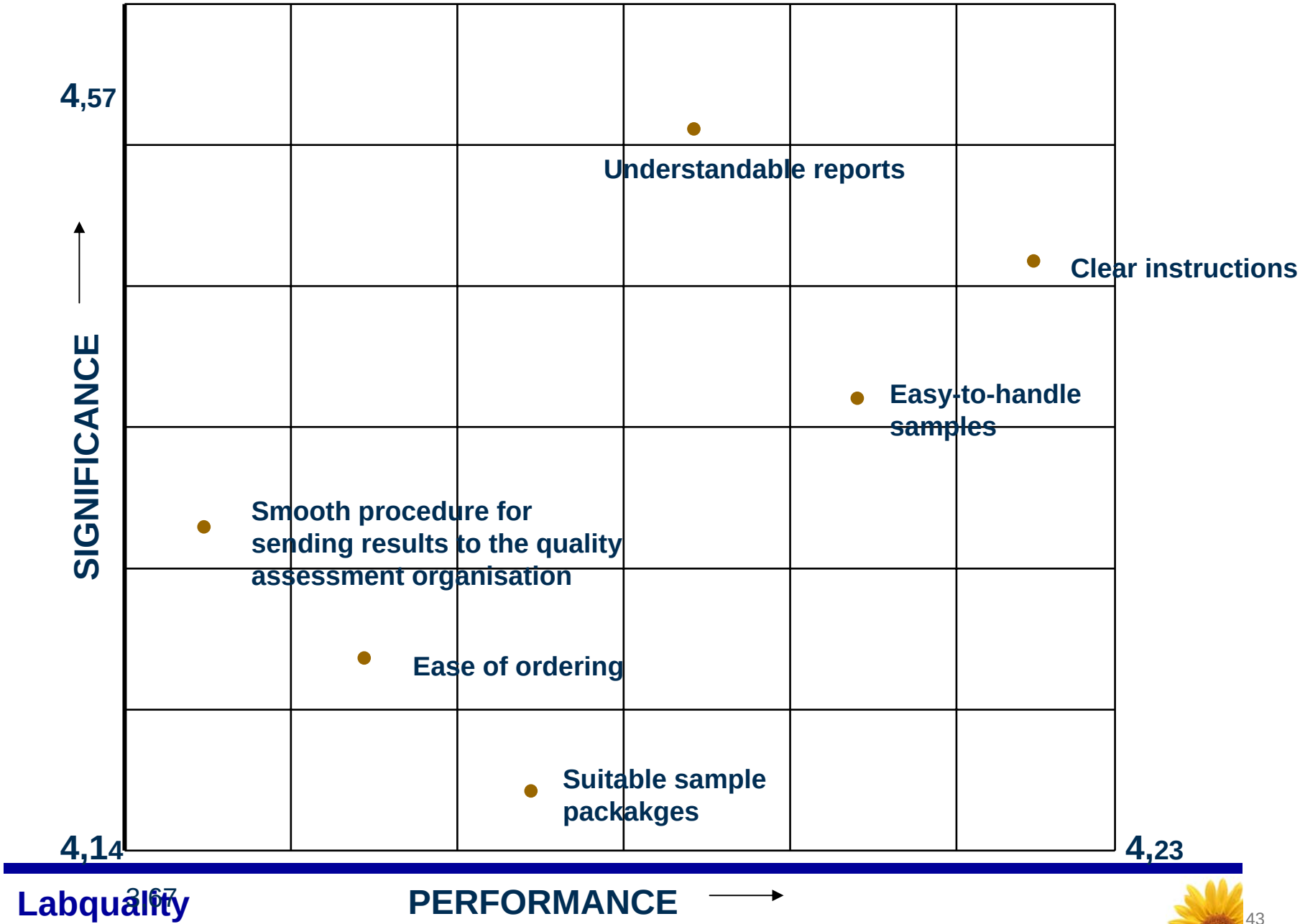
- Labquality had the best performance in **clear instructions** (average 4,23)

- The worst performance was **smooth procedure for sending results** to the quality assessment organisation (average 3,67).

Scale

1= Poor, 2= Adequate, 3= Satisfactory,

4=Good, 5=Excellent, 6= No Experience


4,57
Understandable reports
Clear instructions
Easy-to-handle samples
Smooth procedure for sending results to the quality assessment organisation
Ease of ordering
Suitable sample packakges
4,14
4,23
SIGNIFICANCE
PERFORMANCE
3,67

Which area of Labquality's services are you especially satisfied with (national)?

Top 10, individual comments (n 360):

Reliability	**42**
Customer service	**39**
Reporting	**28**
Service selection	**20**
Electrical communic	**20**
Quality of services	**18**
Speed in services	**17**
Professional touch	**15**
Flexibility	**11**
Information services	**7**
Easy contacts	6
Labquality-Days	5
Education	4

Are there any areas in Labquality's operations that you are dissatisfied with (national)?

Top 10, individual comments (n 360):

E-Schemes	**53**
Turnaraound time	**10**
Prices	**8**
Uncomplete service package	**8**
Time schedule of surveys	**6**
Scoring principles	**6**
Too complicated reports	**6**
Report forms	**5**
Home page	4
Quality of the samples	4
Language problems	3
Instructions	3
Wrong client data	3
Results missing conclusions	2
Delayed surveys	2

The significance of services and Labquality's performance

SUMMARY

The number of participants in the survey was about 600.
Figures were form users
– nonusers comments might be more informative

- **E-scheme** development seems to need more work and focus
- **Reporting** is another clear development area
- **Prices** of the services are not considered cheap, but it is not the most significant issue for the customers.

The significance of services and Labquality's performance

- Why wide service selection of is not seen very significant?

- Individual, open comments and recommendations give a good source of information how EQA provider can improve its services better meet the needs of different client expectations.

- Continuos communication and follow up is needed.

SUMMARY

The standard 17043 will clarify the supplies and harmonise the variety of EQA programmes offered by different providers.

It also will open discussion about the future needs of EQA between providers and participating laboratories to fulfil the expectations of the laboratories in their quality work.

Thank you for your attention

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