How to assess and select the right EQA program for the lab especially in tight economic situation.

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The role of quality management in a medical laboratory

- Every medical laboratory must ensure to have a quality management system in place to meet general requirements for diagnostic performance.
- In this context, there are various standards and guidelines that apply:

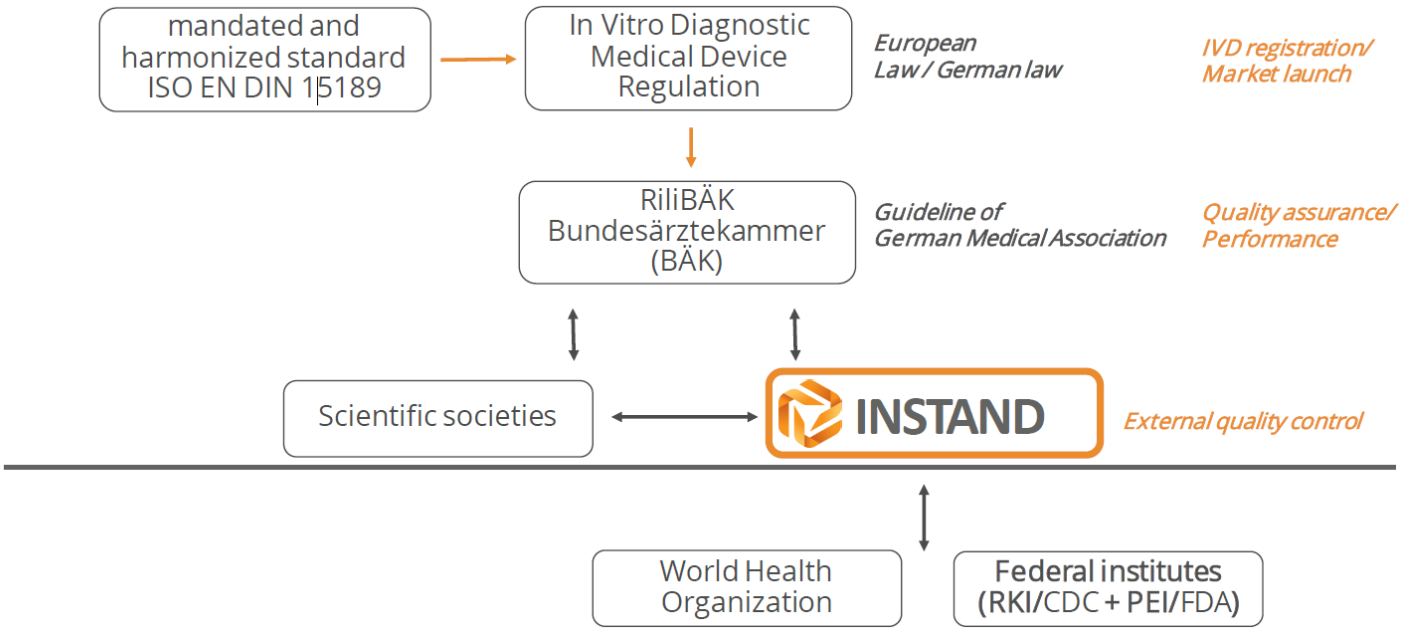
ISO 15189

ISO 17025

ISO 17043

…

Quality Assurance in Diagnostics



INSTAND is a scientific , independent medical society for promoting quality in medical laboratories.

Aim: improving quality in medical labs

Tools: EQA schemes, scientific activities, education

EQA schemes: sending about 160,000 samples per year to around 12,000 laboratories that participate in our EQAs

INSTAND FACTS

1. **WHO WE ARE**
   - Founded in 1966
   - Non profit, interdisciplinary, scientific medical society
   - Accredited according to DIN/ISO 17043 for reference institutions
2. **OUR PARTNERS**
   - Can rely on experienced advisers and ring test leaders for External Quality Assessment schemes
   - (EQA schemes = interlaboratory comparison = proficiency testing = ring trial = round robin test)
3. **OUR NETWORK**
   - Cooperates with national and international network of scientists
4. **OUR MARKET**
   - In all essential fields of laboratory medicine.
   - The certificates are valid for laboratory accreditation processes

INSTANDs international scientific projects 2023

EU Horizon 2020 h01 Project **GenomeMET** an innovative project to improve laboratory diagnostics in the field of innovative diagnostics of ctDNA in tumor diseases.

Collaborating project with the World Health Organization (WHO): WHO/INSTAND External Quality Assessment (EQA): WHO Monkeypox virus detection by molecular methods

Publication of EQA evaluations with scientific background. In contact with manufacturers when discrepancies should occure

INSTAND International GmbH

INSTAND international GmbH is a wholly owned subsidiary of INSTAND e.V. It is tailored to the special needs of our international participants/ costumers.

- Benefit from the unique expert network of INSTAND e.V.
- Personal customer service by our motivated employees
- Easy, accessible online platform for results and evaluation documents

What are External quality controls?

- Is the use comparisons of test results or measurements to determine and monitor the performance of individual laboratories
- Proficiency tests assess and demonstrate the reliability of the data laboratories are producing

EQAs – How it Works

1. Participating laboratories are provided with uniform testing objects for analysis under specified cinditions
2. Laboratory analyses the samples, preferably as part of their normal routine, and reports the results to the scheme organizers
3. Laboratory receives a report showing the extent to which its results are in compliance with the accepted values

Benefits of Quality Controlled and Standardized Diagnostics

Diagnostic data have to be solid and comparable irrespective of

- Diagnostic system
- Diagnostic laboratory
- Staff

EQAs Value & Benefits

- Identifying testing or measurement problems
    - May identify potential problems related to imprecision, systematic errors and/or human errors
    - Determining method precision and accuracy
- Comparing methods and procedures
- Educating Staff
- Confirming competent performance

Correct Diagnostic Data is the basis for

- Lead to **quality improvement** of diagnosis
- **Protect the patient** from false positive and false negative diagnostic results and support the decision for the right therapy
- **Save money** for health care system
- Allow **vigilance** of the market
- Helps in the **detection** of epidemiological events (e.g.: detection of re-/emerging infections)

INSTAND AT A GLANCE

Over 390 Different EQA Schemes

Clinical Chemistry 132

Biochemistry 19
Cardiac Marker 2
Fecal Diagnostics 2
Hemostaseology 22
Hormones 13
Cerebrospinal Fluid 8
Pharmaceuticals 31
Plasma Proteins 4
POCT 6
Trace Elements 3
Tumor Markers 3
Urine Analysis 15
Vitamins 4

Virus-Diagnostics 86

Virus Gen. Detection 58
Multiplex tests 4
Virus Gen. Detection 3
Virus Immunology 25

Microbiology 68

Bacterial Gen. Det. 18
Bacteriology 3
Bacterial Inf. Serol. 23
Mycology 6
Parasite Diagnostics 9
Tubercu. Diagnostics 7
Fungal Gen. Detection 2

Genetics 49

Immunogenetics 7
Molecular Genetics 41
Transplan.diagnostics 1

Immunology 30

Autoimmune Diseases 14
Immunohematology 7
Complement Analytics 6
Immunodeficiency 2
Tubercu. diagnostics 1

Hematology 14

Allergy Diagnostics 2

Hand in Hand: INSTAND Calibration Laboratory

- The **main task** of the reference laboratory of INSTAND **is the value assignment for interlaboratory samples** by using reference measurement procedures.
- These **assigned values are used as target values for evaluation of our EQAS** as required by the German Medical Association for 32 analytes.
- The calibration laboratory also provides **services for companies** in the diagnostic field.
- The reference laboratory of INSTAND e.V. is listed in the database of **the Joint Committee for Traceability in Laboratory Medicine (JCTLM)** for measurement services for several analytes.

INSTAND Calibration Laboratory

Accreditation scope:

Enzymes ALT, AST, CK, GGT, LDH

Electrolytes Calcium, Chloride, Sodium, Potassium, Magnesium

Hormones Cortisol, 17 beta Estradiol, Progesterone , Testosterone , Thyroxin

Substrates/Metabolites Triglycerides Cholesterol, Glucose, Urea, Uric acid , Creatinine

Proteins Total Hemoglobin , Total Protein, HbA1c

Drugs Digoxin , Digitoxin, Lithium, Theophyllin

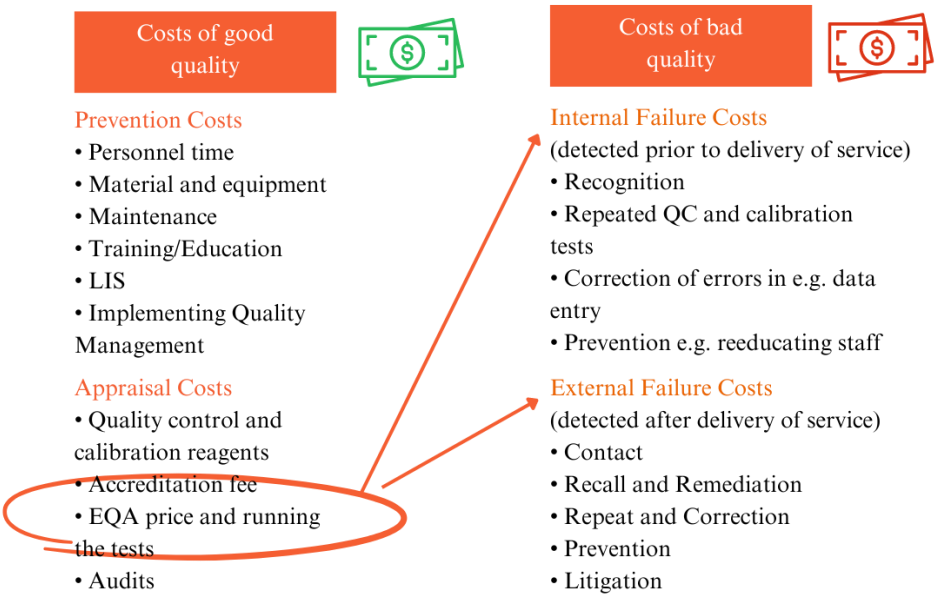
The calibration laboratory of INSTAND e.V. is **accredited** by the German accreditation body DAkkS as calibration laboratory **according to ISO 17025 and ISO 15195**

Face to face Contact with our Experts

- Cooperation with a **unique and large network of scientists** who are also serving as **advisers** and EQA experts for EQA schemes.
- Contact with **our specialists** from various disciplines such as transfusion medicine, clinical chemistry, biochemistry, etc.
    - Feedback from experts with years of practical experience.
    - **Up to date** through its unique network of scientists.
- Constantly **growing** further education programs.
- Scientific Research and Development (Research projects, publications).

How EQA schemes can make an economic impact

Cost of Quality Model



What do I need to consider for the perfect EQA scheme for my lab?

Frequency of participation

- In which time periods do I need to participate in EQAs?
    - These time periods are usually fixed by standards and regulations (e.g., German Guideline (RiliBÄK), CLIA, CBAHI.

Find an EQA provider that offers EQA as often as you need to perform it.

Frequency of participation

- In which time periods do I need to participate in EQAs? These time periods are usually fixed by standards and regulations.

(e.g. RiliBÄK Guideline of German Medical Association for quality assurance in medical laboratories) laboratories), CLIA, **CBAHI Standards**

Adenoviruses, genome detection	Half-year
Cytomegalovirus, genome detection	Half-year
Enteroviruses, genome detection	Half-year
Epstein-Barr virus, genome detection	Half-year
Hepatitis A virus, genome detection	Half-year
Hepatitis B virus, genome detection	Half-year
Hepatitis B virus, HBs antigen detection	Half-year
Hepatitis B virus, HBe antigen detection	Half-year
Hepatitis C virus, genome detection	Half-year
Hepatitis C virus genotyping, genome detection	Calendar year
Hepatitis C virus, HCV antigen detection	Half-year
Hepatitis E virus, genome detection	Half-year
Herpes simplex virus type 1 / type 2, genome detection	Half-year

Virus genome detection: most EQAs need to be participated in twice a year (Germany)

Example: German guideline: RiliBÄK (based on ISO15189)

Frequency of participation

Other

- **Clinical chemistry** only 3 shipments/ year
- **CRP** only 3 shipments/ year

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- Clinical chemistry (100)
- 6 shipments/ year
- CRP (222)
- 4 shipments/ year

Validity of certificates

- How long are certificates valid after successful completion of EQAs.
- Do you need a certificate or a certificate of participation?

Make sure to meet all important requirements

Validity of certificates

- How long are certificates valid after successful completion of EQAs?
- Do you need a certificate or a certificate of participation?
- Virus Genome Detection – Adenoviruses (371)

Samples:	4 samples of 1.1 ml
Sample properties:	Lyophilised cell culture lysates
	These prices apply exclusively to orders placed through INSTAND e.V. For orders placed through distributors, prices and services may differ.
Dates:	June (4) Nov. (6)
Registration deadline:	14.04.2023 08.09.2023
Sample shipment:	13.06.2023 07.11.2023
Closing Date:	30.06.2023 24.11.2023
Shipping Information:	Shipping at ambient temperature
Parameters:	Determination of species of adenovirus, Typing of adenovirus, Polymerase chain reaction (PCR) and other nucleic acid amplification techniques (NAT) for adenovirus DNA
Certificate Validity:	12 months

Show your competence : Certificates


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CERTIFICATE OF PARTICIPATION

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Clinical Chemistry - Conventional Analysis (100):

Certificate of participation: for each participation per parameter and per term


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CERTIFICATE

Survey of 24 October 2018

Clinical Chemistry - Conventional Analysis (100):

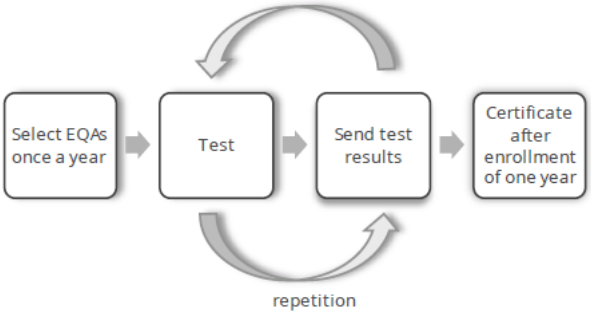
Certificate: for each successful participation per parameter and per term

Validity is dedined by German Medical Association

Validity of certificates

Other

- Certificate only after one enrollment year



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- The certificate validity is based on the German guidelines of the German Medical Association and varies between a few months and one year

Certificate after every successful EQA

Ordering & flexibility

Other

- Often you can only order your EQAs once a year with order deadlines:
  - You have to order early Programs have limited quantities
- **You cannot react quickly to changes (e.g. new instruments or no longer need)**

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- Order your proficiency tests flexibly throughout the year
- Adapt quickly to new circumstances
- Spare sample material available on request for internal quality management
- If desired, you can opt for annual subscription
- Clear and concise deadlines for each available cycle (up to 6 EQAs per year)

Sample Quality

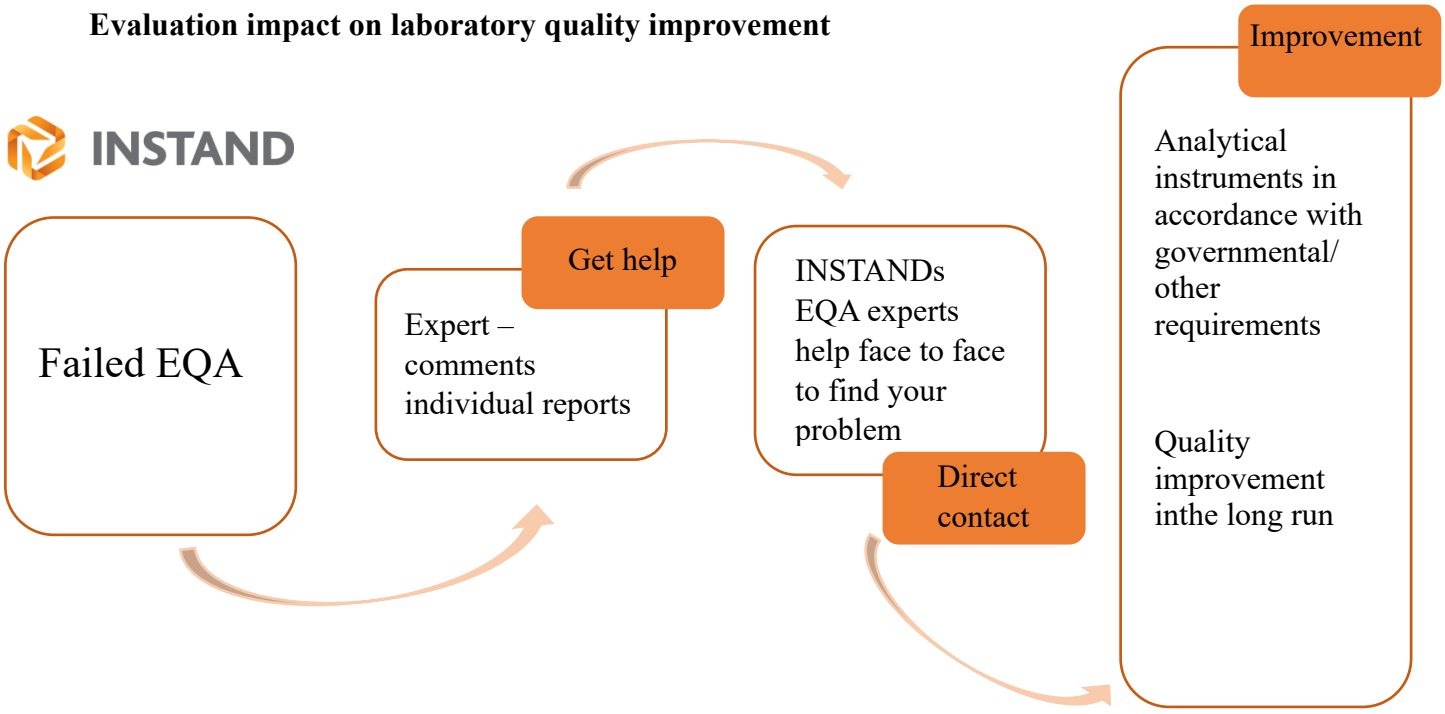
How can I ensure that I get the best sample quality?

- Make sure that the samples are pre tested by selected expert laboratories with many years of experience.
- To ensure the best quality of the samples, inform yourself about the stability of the samples.
- Ask the EQA distributing institution if there is experience in long transportation routes.

How up to date is the Offer and the Sample composition?

- respond to urgent health situations (epidemiological events such mpox) in a timely manner.
- In addition, new variants are added at regular intervals, for example in INSTAND's viral genome detections.

Evaluation impact on laboratory quality improvement

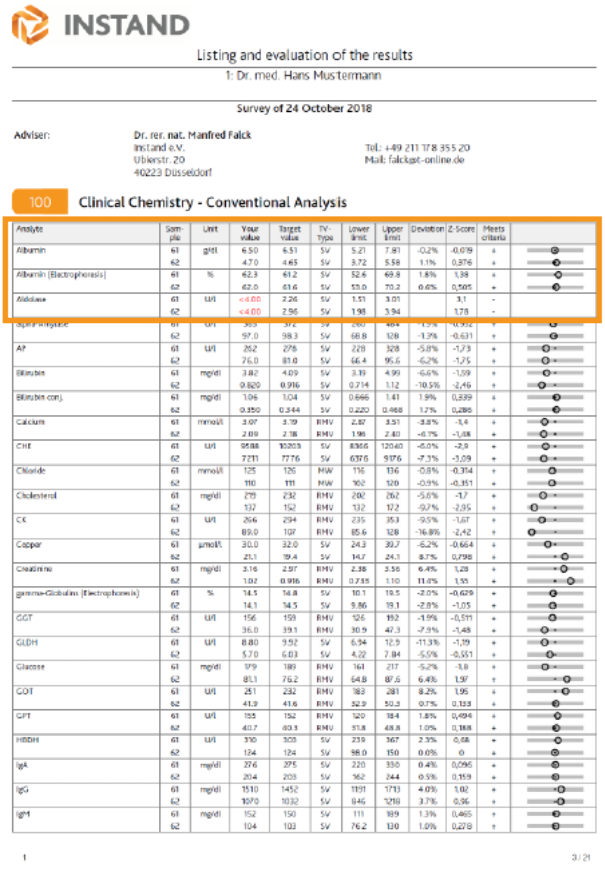


Evaluation impact on laboratory quality improvement

- Individual counselling by in case of not passing the EQA from one of our qualified 170 EQA experts.
- You will not be left alone with your problems. INSTAND's experts can support you where your analytical problem lies and help you to solve it.
- The individual support results in short response times.

Make sure to get the most of your test results

Example of quantitative evaluation documents Individual results



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Listing and evaluation of the results

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Survey of 24 October 2018

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100 Clinical Chemistry - Conventional Analysis

Analyte	Sam-ple	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
Albumin	61	g/dl	6.50	6.51	SV	5.21	7.81	-0.2%	-0,019	+
	62		4.70	4.65	SV	3.72	5.58	1.1%	0,376	+
Albumin (Electrophoresis)	61	%	62.3	61.2	SV	52.6	69.8	1.8%	1,38	+
	62		62.0	61.6	SV	53.0	70.2	0.6%	0,505	+
Aldolase	61	U/l	<4.00	2.26	SV	1.51	3.01		3,1	-
	62		<4.00	2.96	SV	1.98	3.94		1,78	-

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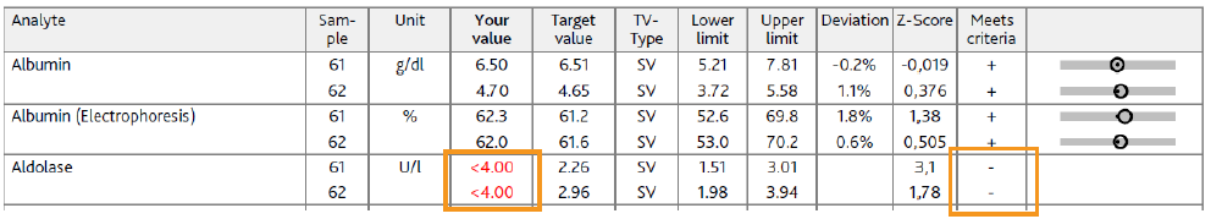


Analyte	Sam-ple	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria	
Albumin	61	g/dl	6.50	6.51	SV	5.21	7.81	-0.2%	-0,019	+	
	62		4.70	4.65	SV	3.72	5.58	1.1%	0,376	+	
Albumin (Electrophoresis)	61	%	62.3	61.2	SV	52.6	69.8	1.8%	1,38	+	
	62		62.0	61.6	SV	53.0	70.2	0.6%	0,505	+	
Aldolase	61	U/l	<4.00	2.26	SV	1.51	3.01		3,1	-	
	62		<4.00	2.96	SV	1.98	3.94		1,78	-	

Red numbers and (criteria = no certificate for the corresponding analyte)

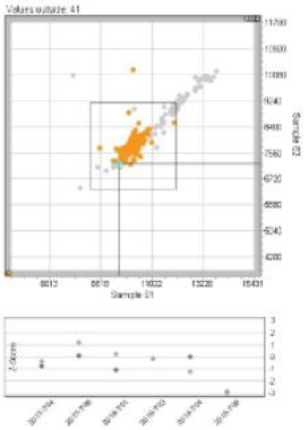
Interpretation of quantitative evaluation documents General overview (Peer Groups)

CHE (U/l, N = 449)

Collective	Sample	Target value	Target range	Participants collective AVG	CV	Num.	Rate (%) Sam.	total
Abbott	61	12079	9905 - 14253	12079	3.52	25	96.0	96.0
	62	9153	7505 - 10801	9153	2.80	25	96.0	
Beckman	61	9897	8116 - 11678	9897	3.42	14	100	100
	62	7552	6193 - 8911	7552	3.24	14	100	
Siemens (Bayer Health)	61	12525	10271 - 14780	12525	7.95	32	100	100
	62	9335	7655 - 11015	9335	8.17	32	100	
Siemens (Dade Behring)	61	16235	13313 - 19157	16235	5.69	40	92.5	92.5
	62	12706	10419 - 14993	12706	3.76	40	97.5	
Olympus	61	9964	8170 - 11758	9964	3.73	58	98.3	98.3
	62	7592	6225 - 8959	7592	4.06	58	98.3	
Roche	61	10203	8366 - 12040	10203	2.08	273	99.6	99.3
	62	7776	6376 - 9176	7776	2.35	273	99.3	
oher provider (1)	61	9527	7812 - 11242	9527	11.2	7		
	62	7277	5967 - 8587	7277	8.22	7		

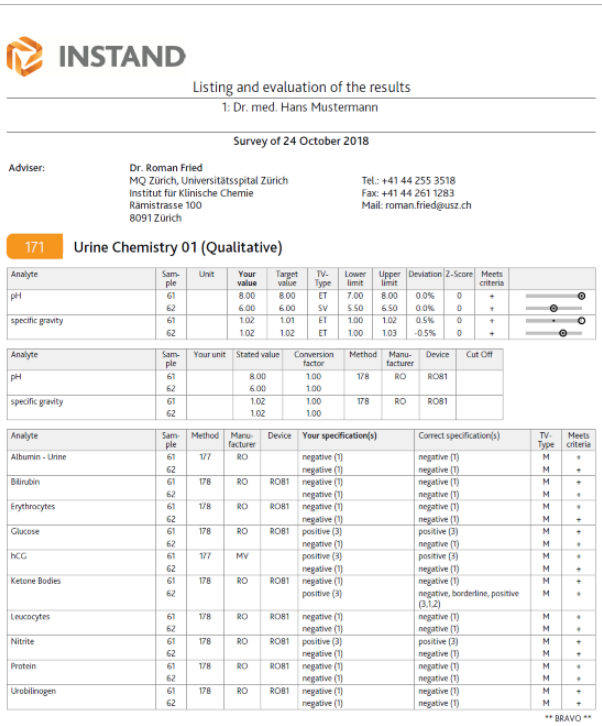
(1) In individual cases is a statistically valid valuation with consensus value not given, because size of the collective < 8 values.

Rate of success: 98,4%



- Participant's collective is marked with an orange bar on the left side of the collective's name.
- In corresponding Youden plot, laboratory's collective is coloured orange.
- Participant's value is marked in blue.
- The evaluation area is marked with a cube.
- Z- scores from your last EQAs are tracked for both samples

Interpretation of qualitative evaluation documents Individual results



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Listing and evaluation of the results

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Survey of 24 October 2018

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171 Urine Chemistry 01 (Qualitative)

Analyte	Sample	Unit	Your value	Target value	TV-Type	Lower limit	Upper limit	Deviation	Z-Score	Meets criteria
pH	61		8.00	8.00	ET	7.00	8.00	0.0%	0	+
	62		6.00	6.00	SV	5.50	6.50	0.0%	0	+
specific gravity	61		1.02	1.01	ET	1.00	1.02	0.5%	0	+
	62		1.02	1.02	ET	1.00	1.03	-0.5%	0	+

Analyte	Sample	Your unit	Stated value	Conversion factor	Method	Manufacturer	Device	Cut Off
pH	61		8.00	1.00	178	RO	RO81	
	62		6.00	1.00				
specific gravity	61		1.02	1.00	178	RO	RO81	
	62		1.02	1.00				

Analyte	Sample	Method	Manufacturer	Device	Your specification(s)	Correct specification(s)	TV-Type	Meets criteria
Albumin - Urine	61	177	RO		negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Bilirubin	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Erythrocytes	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Glucose	61	178	RO	RO81	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
hCG	61	177	MV		positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
Ketone Bodies	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				positive (3)	negative, borderline, positive (3,1,2)	M	+
Leucocytes	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Nitrite	61	178	RO	RO81	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
Protein	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Urobilinogen	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+

** BRAVO **

- Qualitative evaluations only show participant's specification(s), as well as the correct specification(s).
- Target value type can be either "ET"- Expert Decision" or "M - Modal Value".
- If parameter is not passed, the specification is red and "Meets criteria" shows (-)

Analyte	Sam-ple	Method	Manu-facturer	Device	**Your specification(s)**	Correct specification(s)	TV-Type	Meets criteria
Albumin - Urine	61	177	RO		negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Bilirubin	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Erythrocytes	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				negative (1)	negative (1)	M	+
Glucose	61	178	RO	RO81	positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
hCG	61	177	MV		positive (3)	positive (3)	M	+
	62				negative (1)	negative (1)	M	+
Ketone Bodies	61	178	RO	RO81	negative (1)	negative (1)	M	+
	62				positive (3)	negative, borderline, positive (3,1,2)	M	+

Interpretation of qualitative evaluation documents General overview (Peer Groups)

171 Urine Chemistry 01 (Qualitative)

Albumin - Urine (N = 81, Rate of success: 75,3%)

Sample 61

Collective	negative (1)	borderline (2)	positive (3)	total
Siemens	13 •	0	4	17
Roche	20 •	4	2	26
others	33 •	3	2	38

Sample 62

Collective	negative (1)	borderline (2)	positive (3)	total
Siemens	16 •	0	0	16
Roche	22 •	4	0	26
others	32 •	2	4	38

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

Bilirubin (N = 557, Rate of success: 99,5%)

Sample 61

Collective	negative (1)	positive (3)	total
Analyticon	9 •	0	9
Siemens	132 •	0	132
IRIS International	24 •	0	24
AxonLab, Menarini	18 •	0	18
Macherey-Nagel	16 •	0	16
Roche	230 •	0	230
others	127 •	1	128

Sample 62

Collective	negative (1)	positive (3)	total
Analyticon	9 •	0	9
Siemens	132 •	0	132
IRIS International	24 •	0	24
AxonLab, Menarini	18 •	0	18
Macherey-Nagel	16 •	0	16
Roche	230 •	0	230
others	126 •	1	127

The point corresponds to the correct result, the horizontal bar corresponds to your specification, the vertical bar corresponds to your collective

In Microbiology and in Virology , more than one Result per Term can be Reported

Interpretation of virology evaluation documents Individual resultsl

344 Virus Immunology - Hepatitis B Virus Program 1 (HBsAg, Anti-HBs, Anti-HBc)

All entered test systems will be displayed on the evaluation documents.

The general overview has to be downloaded separately, due to the huge size of the documents.

HBsAg (qualitative)

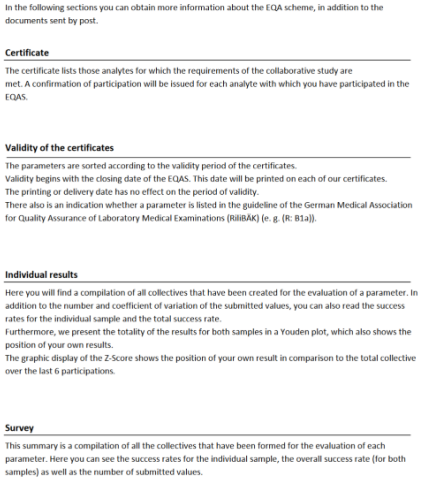
Name of test	Unit	Method	Manufacturer			
ARCHITECT HBsAg II Qualitativ		Immunological test (CMIA) (241)	ABBOTT (AB)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	344409	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344410	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344411	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344412	reactive/ positive (3)	reactive/ positive (3)	SV		+
Name of test	Unit	Method	Manufacturer			
Elecsys HBsAg II		Immunological test (ECLIA) (189)	ROCHE DIAGNOSTICS (RO)			
Result (qual)	Sample	Your specification(s)	Correct specification(s)	TV-Type		Meets criteria
	344409	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344410	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344411	reactive/ positive (3)	reactive/ positive (3)	SV		+
	344412	reactive/ positive (3)	reactive/ positive (3)	SV		+

Combined qualitative and quantitative results for this parameter.

HBsAg (qualitative and results in IU/ml)

Name of test	Unit	Method	Manufacturer				
ARCHITECT HBsAg Quantitativ	IU/ml	Immunological test (CMIA) (241)	ABBOTT (AB)				
Result (quant)	Sample	Your value	Lower limit	Upper limit	TV-Type	Target value	Meets criteria
	344409	2.31	1.10	4.60	ET	2.32	+
	344410	1.16	0.550	2.30	ET	1.14	+
	344411	7.65	4.40	18.4	ET	8.66	+
	344412	4.32	2.20	9.20	ET	4.44	+
Result (qual)	Sample	Your specification(s)	Correct specification(s)		TV-Type		Meets criteria
	344409	reactive/ positive (3)	reactive/ positive (3)		ET		+
	344410	reactive/ positive (3)	reactive/ positive (3)		ET		+
	344411	reactive/ positive (3)	reactive/ positive (3)		ET		+
	344412	reactive/ positive (3)	reactive/ positive (3)		ET		+

EQA Expert‘s comments



In the following sections you can obtain more information about the EQA scheme, in addition to the documents sent by post.

Certificate

The certificate lists those analytes for which the requirements of the collaborative study are met. A confirmation of participation will be issued for each analyte with which you have participated in the EQAS.

Validity of the certificates

The parameters are sorted according to the validity period of the certificates.
Validity begins with the closing date of the EQAS. This date will be printed on each of our certificates.
The printing or delivery date has no effect on the period of validity.
There also is an indication whether a parameter is listed in the guideline of the German Medical Association for Quality Assurance of Laboratory Medical Examinations (RiliBÄK) (e. g. (R: B1a)).

Individual results

Here you will find a compilation of all collectives that have been created for the evaluation of a parameter. In addition to the number and coefficient of variation of the submitted values, you can also read the success rates for the individual sample and the total success rate.
Furthermore, we present the totality of the results for both samples in a Youden plot, which also shows the position of your own results.
The graphic display of the Z-Score shows the position of your own result in comparison to the total collective over the last 6 participations.

Survey

This summary is a compilation of all the collectives that have been formed for the evaluation of each parameter. Here you can see the success rates for the individual sample, the overall success rate (for both samples) as well as the number of submitted values.

Advice for failed participation

EQA Expert‘s comments

340 SARS-CoV-2 Genome EQAS April 2020 Report 20200502j_updated 20200603c.doc

2.2 Sample properties

For the Extra EQA scheme (340) "Virus Genome Detection – SARS-CoV-2" April 2020 7 samples were provided:

Table 2: Sample properties

Sample No.	Sample source	Dilution	Sample considered for issuing a certificate of successful participation
340059*,§	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 1 000*,§	nein§
340060§	**SARS-CoV-2 negative**, lysate of HCoV OC43 infected cells as specificity control	1 : 2 500§	nein§
340061*	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 1 000 000*	ja
340062	**SARS-CoV-2 negative**, lysate of non-infected cells (MRC-5 cells) as specificity control	----	ja
340063*	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 10 000*	ja
340064*,§	**SARS-CoV-2 positive**, lysate of SARS-CoV-2** infected cells (SARS-CoV-2 inactivated)	1 : 100 000*,§	nein§
340065	**SARS-CoV-2 negative**, lysate of HCoV 229E infected cells as specificity control	1 : 2 500	ja

* The positive samples 340059, 304061, 340063 and 340064 represent different dilution steps of a dilution series of al lysate of cells infected with SARS-CoV-2.

§ In the interim evaluation of 17 April 2020, all participants in the Extra INSTAND EQA scheme (340) virus genome detection of SARS-CoV-2 April 2020 were informed of the sample properties of samples 340059, 340060 and 340064. The results of these 3 samples are not taken into account when issuing a certificate of successful participation.

However, the results submitted for samples 340061, 340062, 340063 and 340065 are considered for the evaluation when issuing a certificate of successful participation.

** Strain: BetaCoV/Munich/ChVir984/2020

Extra INSTAND EQA Scheme (340) Virus Genome Detection SARS-CoV-2
Term April 2020 - Qualitative Tables

340 **70: PCR-34070 - SARS-CoV-2 (RNA) – qualitative**

Sample 340059 (Result (qual)) - SARS-CoV-2 positive (inactivated), 1 : 1 000 diluted

Reagent	Testkit	Total (N=983)	below detection limit/negative (N=2)	intermediate (N=1)	positive (N=980)	Sample not evaluated	Ct/Cp/Ct/CN Median	Ct/Cp/Cq/CN Min	Ct/Cp/Cq/CN Max
ORF1ab									
ANATOLIA GENEWORKS	Bosphore Novel Coronavirus Detection Kit v2	5	0	0	5		22.3	19.7	27.5
OTHER MANUFACTURERS		9	0	0	9		23.1	10.9	29.1
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	4	0	0	4		20.0	19.5	20.9
APPLIED BIOSYSTEMS	TaqPath COVID-19 RT-PCR Kit	2	0	0	2		18.8	16.8	20.8
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	4	0	0	4				
CERTEST BIOTEC	VIASURE SARS-CoV-2	7	0	0	7		21.5	18.8	26.2
DIASORIN	Simplexa COVID-19 Direct Kit	4	0	0	4		19.3	19.1	19.8
IN HOUSE		6	0	0	6		25.2	21.4	28.4
LIFERIVER	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	3	0	0	3		23.0	18.0	23.0
LUMINEX	NxTAG CoV	1	0	0	1				
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	1	0	0	1		21.8	21.8	21.8
VITASSAY	Vitassay qPCR SARSCoV-2	2	0	0	2		22.7	22.4	23.0
		48	0	0	48		21.8	10.9	29.1
RdRP-Gene									
ABACUS DIAGNOSTICA	GenomEra Coronavirus SARS-CoV-2	1	0	0	1				
ABBOTT	RealTime SARS-CoV-2	6	0	0	6		10.6	10.0	14.5
OTHER MANUFACTURERS		10	0	0	10		23.6	21.8	32.1
IN HOUSE (dPCR)		1	0	0	1				
IN HOUSE		42	0	0	42		25.1	19.6	34.5

Comments may also include detailed sample information and a more detailed overall evaluation.

How up to date is the evaluation?

Other

- Other EQA providers offer extra accuracy based programs with additional fees
- Mostly, the peer group mean is designated as the target value for evaluation
- The peer group must consist of greater than nine results after outlier exclusion and the variability of the peer group data must not be too great

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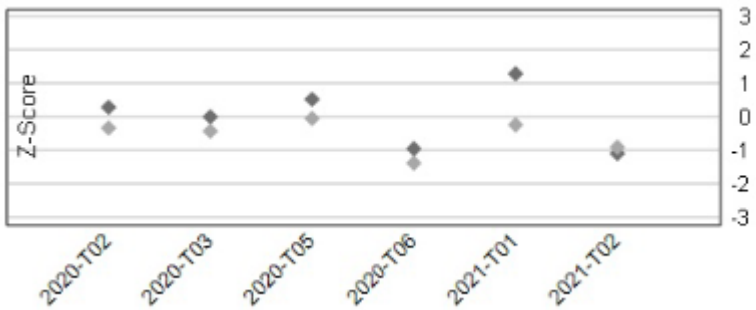
- According to the guidelines of the German Medical Association , the evaluation is always carried out with the value of the reference method , if such is available
- Peer group must consist of greater than three results



Education

- Seminars at regular intervals in order to support the participants in continuously improving their diagnostic performance, for example in the field of CSF diagnostics.
- Promote quality in medical laboratories with innovative, practice oriented, and diverse training by our specialized experts by:
    - Online training courses
    - Seminars
    - Self study courses
- **English courses such as Online Training urine sediment , Online Training Preanalyticsl**

LaboZertGmbH

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