ESfEQA

European Society for
External Quality Assessment

Quality Assessment Schemes Program

2015/2016

ABOUT ESfEQA

ESfEQA EQA programs
The European Society for External Quality Assessment offers laboratories a wide range of EQA schemes organised in four programs: biochemistry, haematology, immunology and microbiology.
The ESfEQA programs for external quality assessment are intended for those who perform laboratory investigation either in their own lab or who are responsible for the quality in the lab.

About ESfEQA samples and services
ESfEQA samples and services provide quality, reliability, convenience and flexibility.

Quality
The appropriateness of all samples for different technologies is achieved by multidisciplinary approaches to assess the reliability of control materials. All samples of human origin are designed for commutability.

Reliability
All fields of activity necessary to provide EQA samples are streamlined for reliability: production and selection of materials, shipment logistics as well as electronic data and results handling.
Prior to their use in EQA schemes, samples are carefully selected, thus guaranteeing high and constant sample quality. ESfEQA works hand in hand with reliable distributors for timely shipment. And finally, the participant has full and reliable control over his data.

Convenience and flexibility by web-interface data entry
ESfEQA's proficiency testing software features easy-access web interfaces which allow participants to input the results, consult the coding tables and see the statistic reports displayed directly online. Requests for new method, instrument and reagent codes can be made online.
A subscription to the ESfEQA programs allows to submit up to 3 results for evaluation using the same control set.
Reports are provided online as pdf-files. These files can be stored electronically, forwarded and printed.

Sample Ordering
ESfEQA cooperates globally with reliable distributors. They are the direct business partners of the participants, responsible for the ordering process, invoicing and local shipping.

ESfEQA offers programs with 4, 6 or 12 rounds per year, respectively. In general programs should be ordered for an entire calendar year. Please contact your distributor or us for sample ordering for periods of less than a year.

Survey Calendar
The dates for registration, sample shipment, deadline of result entry and availability of reports are published on the ESfEQA website (www.esfeqa.eu).

Heidelberg, September 2015

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EXTERNAL QUALITY ASSESSMENT SCHEMES PROGRAMS

Content

BIOCHEMISTRY PROGRAM

CLINICAL CHEMISTRY CC

2 liquid or lyophilized samples (minimum 3 mL) of human sera with added enzymes and proteins of human origin.
4, 6 or 12 surveys per year. One sample per survey in monthly program.

Analytical parameters:

Acid Phosphatase	Cholesterol	Magnesium
Albumin	CK Creatinkinase	Osmolality
ALP Alkaline phosphatase	Creatinine	pancreatic Amylase
ALT/GPT	Gamma GT	Phosphate
Amylase	Glucose	Potassium
AST/GOT	HDL Cholesterol	Sodium
Bilirubin, direct	Iron	TIBC Total Iron Binding Capacity
Bilirubin, total	Lactate	Total protein
Calcium	LDH Lactate Dehydrogenase	Triglycerides
Calcium (ionized)	LDL Cholesterol	Urea
CHE Cholinesterase	Lipase	Uric acid
Chloride	Lithium	

URINE CHEMISTRY UC

2 liquid or lyophilized samples (minimum 5 mL) of urine of human origin with added preservatives and stabilizers.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

Albumin	Magnesium	Urea
Calcium	Phosphate	Uric acid
Chloride	Potassium	
Creatinine	Total protein	
Glucose	Sodium	

CARDIAC MARKER CM

2 liquid or lyophilized samples (minimum 1 mL) of human sera with added analytes of human origin.
4 surveys per year.

Analytical parameters:

BNP	Homocysteine	NT-proBNP
CK-MB (mass)	Myoglobin	Troponin I
CK-MB (activity)		Troponin T

GLYCATED HEMOGLOBIN — GHB

2 liquid or lyophilized samples (minimum 0.5 mL) of hemolysate of human blood.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

HbA1c (mmol/mol)

ETHANOL — ETH

2 liquid samples (minimum 3 mL) of human serum with added compounds.
4 surveys per year. Available 2016.

Analytical parameters:

Ethanol	Ammonium

THERAPEUTIC DRUGS — TDM

2 liquid or lyophilized samples (minimum 3 mL) of pooled human sera with added sera from patients treated with pharmaceutical drugs and/or with added compounds.
4 surveys per year.

Analytical parameters:

Amikacin	Lidocain	Salicylate
Carbamazepine	NAPA	Theophylline
Chinidine	Paracetamol	Tobramycin
Digoxin	Phenobarbital	Valproic Acid
Disopyramide	Phenytoin	Vancomycin
Ethosuximide	Primidone	
Gentamicin	Procainamide	

DRUGS OF ABUSE — DAT

1 liquid sample (minimum 1 mL) of filtered human urines with added drugs.
4 surveys per year. Available 2016.

Analytical parameters (qualitative):

Amphetamines	Cannabinoids	Methadone
Benzodiazepines	Cocaine	Opiates
Buprenorphine	Barbiturates	

QUALITATIVE URINE ANALYSIS (URINE STICK) — US

2 liquid samples (min. 10 mL) of urine preparation of human origin with added preservatives and stabilizers.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

Bilirubin	Ketonic bodies	pH
Glucose	Leucocytes	Specific Gravity
Hemoglobin	Nitrite	Total Protein

BLOOD GAS AND ELECTROLYTES — BG

2 liquid buffered aqueous solution samples (minimum 2.5 mL).
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

pH	Sodium, Na^+	Calcium, Ca^{2+}
pCO_2	Potassium, K^+	Glucose
pO_2	Chloride, Cl^-	Lactate

CARBOHYDRATE-DEFICIENT TRANSFERRIN — CDT

1 sample (1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

CDT

IMMUNOSUPPRESSANTS — IS

2 liquid or lyophilized samples (2 mL) of pooled human sera with added sera from patients treated with pharmaceutical drugs and/or with added compounds.
4 surveys per year. Available 2016.

Analytical parameters:

Cyclosporine	Sirolimus	Tacrolimus
Everolimus		

LIPIDS — LIP

2 samples (1 mL) of human serum.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

Apolipoprotein A1	Cholesterol	Lp (a)
Apolipoprotein B	Triglycerides	
LDL Cholesterol	HDL Cholesterol	

HEMATOLOGY PROGRAM

HEMOGRAM — HEM

2 liquid samples (minimum 2.5 mL) of whole blood. The samples contain stabilized human red blood cells, white blood cells and platelets of human and/or non-human analogs.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

- HGB (haemoglobin)
- HCT (haematocrit)
- MCH (mean corpuscular haemoglobin)
- MCHC (mean cellular haemoglobin concentration)
- MCV (mean corpuscular volume)
- PLT (platelets)
- RBC (red blood cells)
- WBC (white blood cells)

COAGULATION — COA

2 lyophilized samples (1 mL) of human plasma.
4 surveys per year.

Analytical parameters:

- aPTT (activated Partial Thromboplastin Time)
- Antithrombin III
- D-Dimer
- Fibrinogen
- PT (prothrombin time)

IMMUNOHEMATOLOGY — IHM

2 liquid samples with a minimum of 2 mL of erythrocyte suspension and 2 mL of serum or plasma.
4 surveys per year. Available 2016.

Analytical parameters:

- AB0 erythrocytic typing
- RH typing
- RH extended phenotype
- direct Coombs Test
- Kell-Antigen

ERYTHROCYTE SEDIMENTATION RATE — ESR

2 liquid samples (minimum 4.5 mL) of whole blood. The samples contain stabilized human red blood cells in a preservative medium.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

- RBC sedimentation rate

PATHOLOGICAL HEMOGLOBINS PHB

2 lyophilized samples (0.2 mL) of pooled erythrocytes of human origin.
4 surveys per year. Available 2016.

Analytical parameters:

HbA2	HbF	HbS

RETICULOCYTES RET

2 liquid samples (minimum 1.5 mL) of human red cells suspended in a solution with mammal components.
4 surveys per year. Available 2016.

Analytical parameters:

Reticulocyte count

FECAL OCCULT BLOOD FOB

2 liquid samples (minimum 1 mL).
4 surveys per year.

Analytical parameters:

Human hemoglobin in faeces

IMMUNOLOGY PROGRAM

ALLERGOLOGY (IGE) AL

2 liquid or lyophilized samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters (below listed parameters are exemplary):

IgE total		g 12	rye	w 2	ambrosia, perennial ragweed
d 70	acarus siro	i 1	bee venom	w 6	mugwort (Artemisia vulgaris)
e 3	horse epithelia	i 3	wasp venom	w 7	marguerite
e 5	dog epithelia	i 6	cockroach	w 9	buckhorn plantain
f 2	milk	t 2	alder	w 20	nettle
f 13	peanut	t 4	hazel	w 206	camomile pollen
f 17	hazelnut	t 7	oak		
g 6	timothy grass				

AUTOIMMUNITY-I AI1

2 liquid samples (1 mL) prepared from human sera.
4 surveys per year. Available 2016.

Analytical parameters:

Anti-CCP	RF IgA	RF IgM
ASO (Antistreptolysin O)	RF IgG	RF total

AUTOIMMUNITY-II AI2

1 liquid sample (1 mL) prepared from human sera.
4 surveys per year. Available 2016.

Analytical parameters:

Anti-TG	Anti-TPO	Anti-TSH-R

TUMOR MARKER TM

2 liquid or lyophilized samples (minimum 2 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program.

Analytical parameters:

AFP (α1-Fetoprotein)	CA 15-3	PSA, total
CEA (Carcino Embryonic Antigen)	CA 72-4	PSA, free
CA19-9	Cyfra 21-1	PSA, complex
CA 125	Ferritin	

HORMONES — HOR

2 liquid or lyophilized samples (minimum 3 mL) of human sera with added analytes of human origin.
4 or 12 surveys per year. One sample per survey in monthly program.

Analytical parameters:

Aldosterone	Human Growth Hormone	T3, total
Cortisol	Insulin	T4, free
DHEA-S	LH (Luteinizing Hormone)	T4, total
Estriol	Estradiol	Testosterone
Folate	Progesterone	TSH
FSH	Prolactin	Vitamin B12
hCG	T3, free	Vitamin D total

SPECIFIC PROTEINS — SP

2 liquid samples (minimum 1 mL) of human sera with added analytes of human origin.
4 surveys per year.

Analytical parameters:

Albumin	C4	Kappa Light Chain
Alpha-1-acid glycoprotein	Ceruloplasmin	Lambda Light Chain
Alpha-1-antitrypsin	CRP (C-Reactive Protein)	Prealbumin
Alpha-2-macroglobulin	Haptoglobin	RF
ASO	IgA	Transferrin
Beta-2-microglobulin	IgG	
C3	IgM	

FETAL-MATERNAL SCREENING — FMS

2 lyophilized samples (1 mL) of pooled sera.
4 surveys per year. Available 2016.

Analytical parameters:

AFP (α1-Fetoprotein)	fbhCG (free beta subunit hCG)	Inhibin A
hCG (Chorionic Gonadotropin)	Estriol free	PAPP A

TUMOR MARKER/HORMONES — TM/HOR

1 lyophilized sample (minimum 3 mL) of human sera with added analytes.
12 surveys per year. Available 2016.

Analytical parameters:

AFP	Folate	PTH
Aldosterone	FSH	T3, free
CA125	hCG	T3, total
CA15-3	Human Growth Hormone	T4, free
CA19-9	Insulin	T4, total
CEA	LH (Luteinizing Hormone)	Testosterone
Cortisol	Progesterone	Thyreoglobulin
DHEA-S	Prolactin	TSH
Estradiol	PSA, free	Vitamin B12
Ferritin	PSA, total	Vitamin D

VIROLOGY PROGRAM

CYTOMEGALOVIRUS — CMV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year.

Analytical parameters:

anti-CMV IgG + total	anti-CMV IgM

HEPATITIS A VIRUS — HAV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year.

Analytical parameters:

anti-HAV IgG + total	anti-HAV IgM

HEPATITIS B VIRUS — HBV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

anti-HBs	anti-HBe	HBeAg
anti-HBc	HBsAg (qual. and quant.)	anti-HBc IgM

HEPATITIS C VIRUS — HCV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

anti-HCV

INFECTIOUS DISEASE COMBINATION CONTROL — INF

2 liquid samples (minimum 1 mL) of human plasma.
4 surveys per year.

Analytical parameters:

anti-HIV 1/2	anti-HBc	HBsAg
anti-HCV		

HERPES VIRUS SIMPLEX 1 AND 2 — HSV

2 liquid samples (1 mL) of human serum.
4 surveys per year.

Analytical parameters:

anti-HSV 1 / 2 IgG + total	anti-HSV 1 / 2 IgM

HIV — HIV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

anti-HIV 1/2

TOXOPLASMOSIS — TOX

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

anti-Toxoplasmosis IgG + total	anti-Toxoplasmosis IgM

RUBELLA — RUB

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

anti-Rubella IgG + total	anti-Rubella IgM

VARICELLA ZOSTER VIRUS — VZV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 3rd quarter 2015.

Analytical parameters:

anti-VZV IgG + total	anti-VZV IgM

SYPHILIS — SYP

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

- anti-Treponema pallidum antibodies

EPSTEIN-BARR VIRUS — EBV

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

- anti-EBV VCA IgG + total
- anti-EBV EBNA IgG + total
- anti-EBV VCA IgM

TORCH — TORCH

2 liquid samples (minimum 1 mL) of human serum.
4 surveys per year. Available 2016.

Analytical parameters:

- anti-Toxoplasmosis IgG + total
- anti-Toxoplasmosis IgM
- anti-Rubella IgG + total
- anti-Rubella IgM
- anti-CMV IgG + total
- anti-CMV IgM
- anti-HSV 1/2 IgG + total
- anti-HSV 1/2 IgM

STATISTICAL DATA EVALUATION AND REPORT

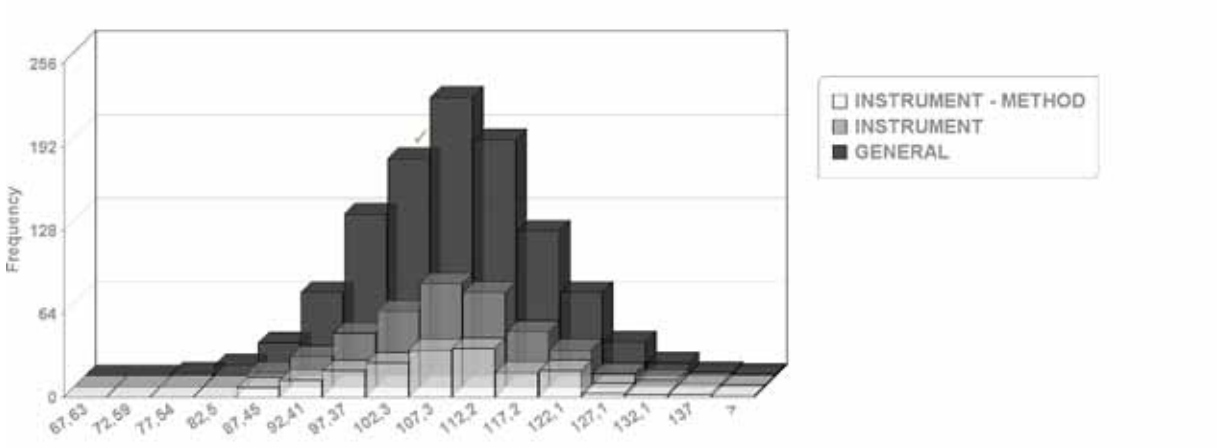
Performance data are provided in a clear and concise format. The reports contain a histogram for method and instrument comparison. Target value, number of participants and statistical data are displayed for various groups, e.g. filtered by method or instrument. A Youden diagram is displayed when two similar samples have been tested in one round. Furthermore a comparison of the methods and instruments that were used by the participants is illustrated.

CLINICAL CHEMISTRY - Pilot 1

15000 (15000)	Glucose (mg/dL)	3 (01/04/2015)
LABORATORY CODE	PARAMETER	DISPATCH
INSTRUMENT: ROCHE COBAS C6000 METHOD: Esokinase/G6PDH (without deproteinization)		17/04/2015 15:21:30
LAB CONFIGURATION		PROCESSING DATE

sample: **CC2014_03_a**

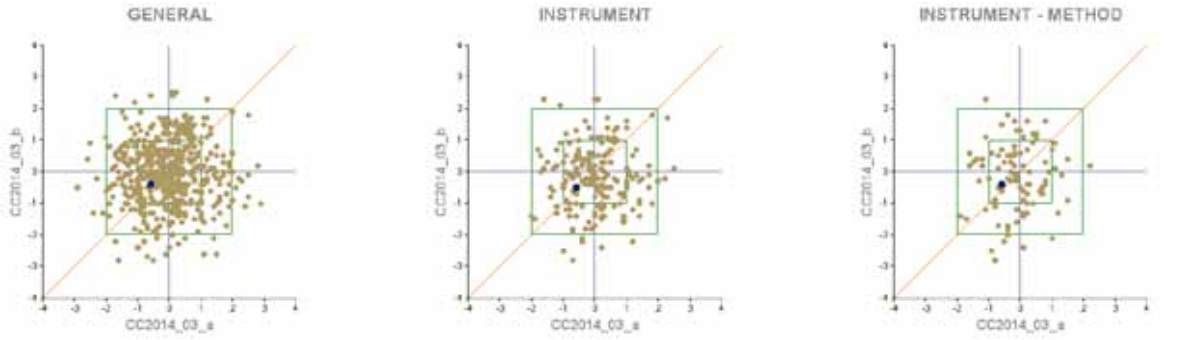
FREQUENCY HISTOGRAMS



STATISTICAL INDEXES

Evaluation	Target value (participants consensus)		SD (participants consensus)	CV	Number of Labs	Number of results	Lab result	ZS	BIAS
GENERAL	104,8	AlgoA	9,912	9,46	500	500	99,2	-0,6	-5,34
INSTRUMENT	105,4	AlgoA	10,68	10,13	186	186		-0,6	-5,88
INSTRUMENT - METHOD	106,4	AlgoA	11,95	11,23	93	93		-0,6	-6,77

YOUDEN DIAGRAM



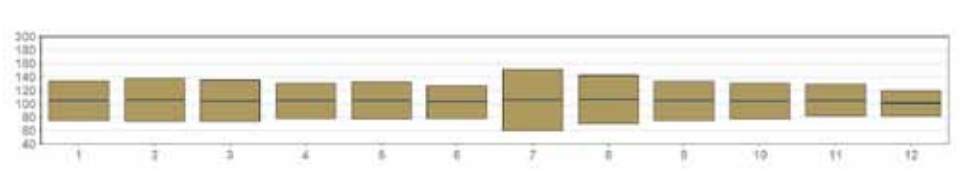
Data for illustration only.

CLINICAL CHEMISTRY - Pilot 1

15000 (15000)	Glucose (mg/dL)	3 (01/04/2015)
LABORATORY CODE	PARAMETER	DISPATCH
INSTRUMENT: ROCHE COBAS C6000 METHOD: Esokinase/G6PDH (without deproteinization)		17/04/2015 15:21:30
LAB CONFIGURATION		PROCESSING DATE

sample: **CC2014_03_a**

STATISTIC COMPARISON



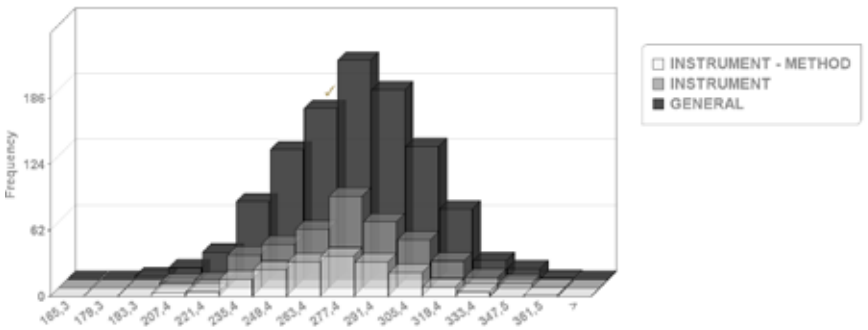
	Evaluation	Target value participants consensus		SD participants consensus	CV	Number of Labs	Number of results
1	general	104,8	AlgoA	9,912	9,46	500	500
	INSTRUMENT						
2	ROCHE COBAS C6000	105,4	AlgoA	10,68	10,13	186	186
3	Roche Cobas 8000	104,4	AlgoA	10,15	9,72	135	135
4	ABBOTT ARCHITECT c8000	104,5	AlgoA	8,696	8,32	85	85
5	SIEMENS Dimension	105,1	AlgoA	9,17	8,73	74	74
6	ROCHE INTEGRA (AT3/D-DIMERO)	103	AlgoA	8,199	7,96	13	13
7	BECKMAN Unicel DxC 600	105,5	AlgoA	15,29	14,49	7	7
	INSTRUMENT - METHOD						
8	ROCHE COBAS C6000 Esokinase/G6PDH (without deproteinization)	106,4	AlgoA	11,95	11,23	93	93
9	Roche Cobas 8000 Esokinase/G6PDH (without deproteinization)	104,5	AlgoA	9,702	9,28	68	68
10	ABBOTT ARCHITECT c8000 Esokinase/G6PDH (without deproteinization)	104	AlgoA	8,792	8,45	42	42
11	SIEMENS Dimension Esokinase/G6PDH (without deproteinization)	105	AlgoA	7,804	7,43	37	37
12	ROCHE INTEGRA (AT3/D-DIMERO) Esokinase/G6PDH (without deproteinization)	100,9	AlgoA	6,39	6,33	7	7

CLINICAL CHEMISTRY - Pilot 1

15000 (15000)	Glucose (mg/dL)	3 (01/04/2015)
LABORATORY CODE	PARAMETER	DISPATCH
INSTRUMENT: ROCHE COBAS C6000 METHOD: Esokinase/G6PDH (without deproteinization)		17/04/2015 15:21:30
LAB CONFIGURATION		PROCESSING DATE

sample: **CC2014_03_b**

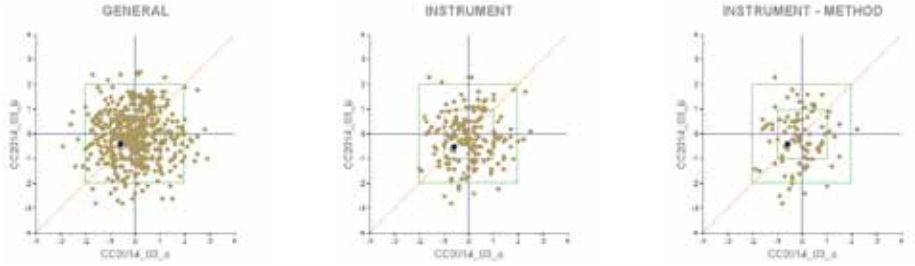
FREQUENCY HISTOGRAMS



STATISTICAL INDEXES

Evaluation	Target value participants consensus		SD participants consensus	CV	Number of Labs	Number of results	Lab result	ZS	BIAS
GENERAL	270,4	AlgoA	28,02	10,36	500	500	258,1	-0,4	-4,55
INSTRUMENT	273,2	AlgoA	28,05	10,27	186	186		-0,5	-5,53
INSTRUMENT - METHOD	269,4	AlgoA	26,86	9,97	93	93		-0,4	-4,19

YOUDEN DIAGRAM



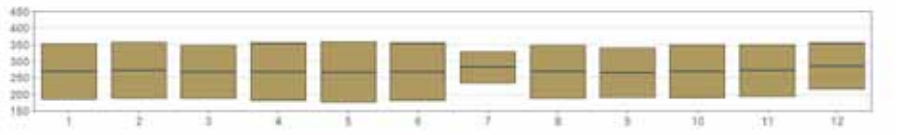
CLINICAL CHEMISTRY - Pilot 1

15000 (15000) — LABORATORY CODE
Glucose (mg/dL) — PARAMETER
3 (01/04/2015) — DISPATCH

INSTRUMENT: ROCHE COBAS C6000 METHOD: Esokinase/G6PDH (without deproteinization) — LAB CONFIGURATION
17/04/2015 15:21:30 — PROCESSING DATE

sample: **CC2014_03_b**

STATISTIC COMPARISON



	Evaluation	Target value (participants consensus)		SD (participants consensus)	CV	Number of Labs	Number of results
1	general	270,4	AlgoA	28,02	10,36	500	500
	INSTRUMENT						
2	ROCHE COBAS C6000	273,2	AlgoA	28,05	10,27	186	186
3	Roche Cobas 8000	268,9	AlgoA	26,7	9,93	135	135
4	ABBOTT ARCHITECT c8000	268,4	AlgoA	29,06	10,83	85	85
5	SIEMENS Dimension	267,4	AlgoA	30,35	11,35	74	74
6	ROCHE INTEGRA (AT3/D-DIMERO)	268,8	AlgoA	28,86	10,74	13	13
7	BECKMAN Unicel DxC 600	281,9	AlgoA	15,47	5,49	7	7
	INSTRUMENT - METHOD						
8	ROCHE COBAS C6000 Esokinase/G6PDH (without deproteinization)	269,4	AlgoA	26,86	9,97	93	93
9	Roche Cobas 8000 Esokinase/G6PDH (without deproteinization)	266,1	AlgoA	24,86	9,34	68	68
10	ABBOTT ARCHITECT c8000 Esokinase/G6PDH (without deproteinization)	270,7	AlgoA	26,68	9,86	42	42
11	SIEMENS Dimension Esokinase/G6PDH (without deproteinization)	272,5	AlgoA	26,01	9,54	37	37
12	ROCHE INTEGRA (AT3/D-DIMERO) Esokinase/G6PDH (without deproteinization)	285,1	AlgoA	23,24	8,15	7	7

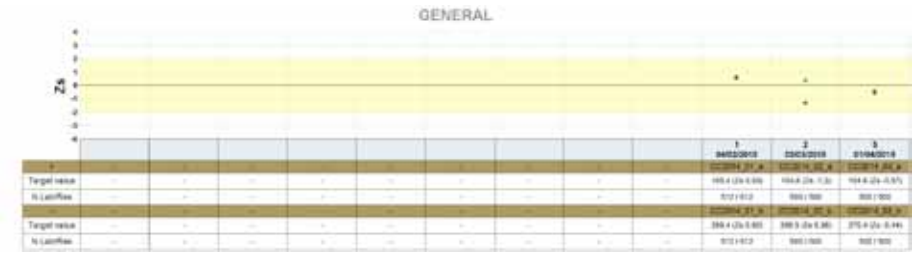
CLINICAL CHEMISTRY - Pilot 1

15000 (15000) — LABORATORY CODE
Glucose (mg/dL) — PARAMETER
3 (01/04/2015) — DISPATCH

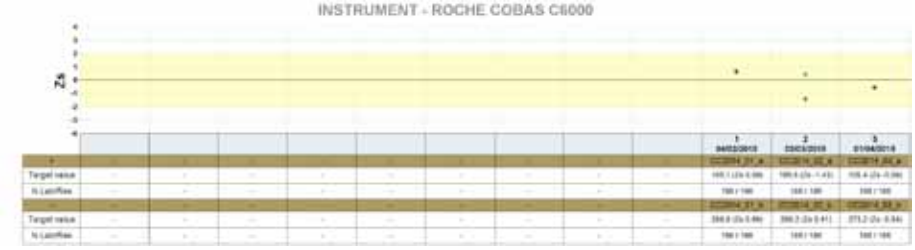
INSTRUMENT: ROCHE COBAS C6000 METHOD: Esokinase/G6PDH (without deproteinization) — LAB CONFIGURATION
17/04/2015 15:21:30 — PROCESSING DATE

SHEWHART

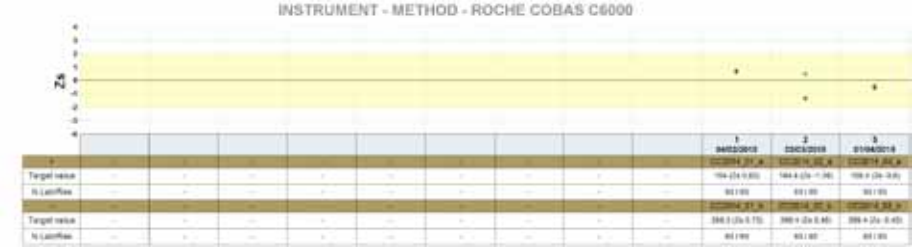
GENERAL



INSTRUMENT - ROCHE COBAS C6000



INSTRUMENT - METHOD - ROCHE COBAS C6000



ESfEQA Calender 2015

Version 07072015

Date			Biochemistry	Hematology	Immunology	Microbiology		Date
Apr 15	27	Deadline for Ordering	CM 1; CC12 1,2,3,4	COA 1	TM12 1,2,3,4; HOR12 1,2,3,4; SP 1	CMV 1; HSV 1; HAV 1; INF 1	Deadline for Ordering	27
Mai 15	15	Deadline for Registration	CM 1; CC12 1,2,3,4	COA 1	TM12 1,2,3,4; HOR12 1,2,3,4; SP 1	CMV 1; HSV 1; HAV 1; INF 1	Deadline for Registration	15
Jun 15	22	Shipment to Participants	CM 1; CC12 1,2,3,4	COA 1	TM12 1,2,3,4; HOR12 1,2,3,4; SP 1	CMV 1; HSV 1; HAV 1; INF 1	Shipment to participants	22
Jul 15	6	Deadline for Result Entry	CM 1; CC12 1	COA 1	TM12 1; HOR12 1; SP 1	CMV 1; HSV 1; HAV 1; INF 1	Deadline for Result Entry	6
Aug 15	5	Deadline for Result Entry	CC12,2		TM12 2; HOR12 2		Deadline for Result Entry	5
	5	Report	CM 1; CC12 1	COA 1	TM12 1; HOR12 1; SP 1	CMV 1; HSV 1; HAV 1; INF 1	Report	5
	18	Deadline for Ordering	CM 2; TDM 1; CC12, 5,6; LIP 1; UC 1	COA 2	TM12 5,6; HOR12 5,6; SP 2	CMV 2; HSV 2; HAV 2; INF 2	Deadline for Ordering	18
Sep 15	7	Deadline for Result Entry	CC12 3		TM12 3; HOR12 3		Deadline for Result Entry	7
	7	Report	CC12 2		TM12 2; HOR 12 2		Report	7
	18	Deadline for Registration	CM 2; TDM 1; CC12, 5,6; LIP 1; UC 1	COA 2; FOB 1	TM12 5,6; HOR12 5,6; SP 2	CMV 2; HSV 2; HAV 2; INF 2	Deadline for Registration	18
Oct 15	5	Deadline for Result Entry	CC12 4		TM12 4; HOR12 4		Deadline for Result Entry	5
	5	Report	CC12 3		TM12 3; HOR12 3		Report	5
	26	Shipment to Participants	CM 2; TDM 1; CC12, 5,6; LIP 1; UC 1	COA 2; FOB 1	TM12 5,6; HOR12 5,6; SP 2	CMV 2; HSV 2; HAV 2; INF 2	Shipment to Participants	26
Nov 15	4	Report	CC12 4		TM12 4; HOR12 4			4
	9	Deadline for Result Entry	CM 2; TDM 1; CC12 5; LIP 1; UC 1	COA 2; FOB 1	TM12 5; HOR12 5 SP 2	CMV 2; HSV 2; HAV 2; INF 2	Deadline for Result Entry	9
Dez 15	4	Deadline for Result Entry	CC12 6		TM12 6; HOR12 6		Deadline for Result Entry	4
	4	Report	CM 2; TDM 1; CC12 5; LIP 1; UC 1	COA 2; FOB 1	TM12 5; HOR12 5 SP 2	CMV 2; HSV 2; HAV 2; INF 2	Report	4
Jan16	5	Report	CC 12 6		TM12 6; HOR12 6		Report	5

Abbreviations CC12=Clinical Chemistry (12 cycles), CM=Cardiac Marker; TDM=Therapeutical Drugs; COA= Coagulation; TM12=Tumor Marker (12 cycles); HOR12=Hormone (12 cycles); SP= Spezifische Proteine; CMV=Cytomegalovirus; HSV=Hepatitis Simplex Virus; HAV=Hepatitis A; INF=Infectious Disease Combination Control

GENERAL TERMS FOR THE PARTICIPATION IN EXTERNAL QUALITY ASSESMENT SURVEYS OF ESFEQA

1. Participation
The participation in the external quality assessment (EQA) surveys of ESfEQA is possible for everyone who performs laboratory tests in their own practice or in a managed medical laboratory. The following conditions for participation apply.

2. Consent to conditions for participation
With the registration by ESfEQA GmbH, the participant is in agreement with these general terms for participation.

3. Assignment of services
Individual parts for EQA (e.g. pretesting of values, packaging and shipping) can be assigned to subcontractors. ESfEQA is responsible for the work of the subcontractors.

4. ESfEQA catalog
The portfolio of the EQA services offered by ESfEQA and the analytes contained in the individual programs are described in the ESfEQA catalog. According to the sample availability and the number of participants, ESfEQA reserves the right to not offer the complete analyte list for each EQA test sample.

5. Schedule
The schedule is published in the catalog and on the homepage of ESfEQA. It contains the binding deadlines for ordering, registration, testing period, deadline for result submission and latest point of time for the creation of the record. After the deadline for ordering and registration there is no claim for the acceptance of late orders and registrations. After the deadline for result submission, no further test results are accepted. The calendar date refers to the time zone at the place of business of ESfEQA in Heidelberg, Germany (GMT +1).

6. Cancelation of EQA surveys
ESfEQA reserves the right to cancel EQA surveys or to defer. This is being told to the participants before the originally planned shipping date of the samples. In this case, ESfEQA tries to offer an appropriate alternative date.

7. Registration
For the participation at the ESfEQA EQA surveys a registration is required. This can be completed online or the required information can be conveyed to ESfEQA in written form. The following information is required: laboratory name, name of the organization/hospital, name of participant, address, phone and fax number, and e-mail address.

8. Ordering of samples
Sales for ESfEQA EQA surveys normally take place through international distributors. If there is no distributor at hand in the country of the participant, the distribution may take place directly through ESfEQA. The order transaction between participant and distributor is the responsibility of both parties. As a rule, an EQA program is ordered for an entire calendar year.

9. Homogeneity and stability of the EQA samples
The EQA test samples chosen by ESfEQA were tested and evaluated in regard to homogeneity and stability. The homogeneity of the samples is specified as $ss \leq 0{,}3\ \sigma^*$ with ss as inter-sample standard deviation and σ^* as the value of the maximum allowable deviation.

10. Labeling of the EQA samples
The EQA samples are identifiable by their labeling. It consists of the short name of the program, the year of transmission, the run and a marker, when several samples are being used for a program and run. Thus, the sample with the labeling CM2015_01_a belongs to the program Cardiac Marker (CM) in the year 2015 and is sample “a” of the first transmission.

11. Shipping of EQA samples
Shipping of the EQA samples takes place by postal or parcel service on the dates published in the catalog. Due to governmental restriction, or because of insufficient stability, the shipping of individual EQA programs in specific countries can be excluded.

12. Instructions for Use
Instructions for Use are provided to the participants for each EQA program on the ESfEQA homepage. Amongst others they contain instructions for the preparatory treatment of the samples, the stability of the sample and the deadline for result submission.

13. Use of EQA samples
EQA samples are to be handled like patient samples and to be measured similarly as routine samples according to the test instructions of the reagent manufacturer. They may be used only for the purpose of participation at an EQA survey and not for purposes other than intended. Generally, the usual precautions in the laboratory for potential hazardous samples apply for the EQA samples.

14. Input of test results
Input of the measured values by the participant includes, when necessary, not only the actual measuring value but also the method used, the instrument used and the reagent used. The input mask of ESfEQA predetermines the required information for each EQA program. A list for methods, instruments and reagents is provided on the result entry form.
If the method, instrument or reagent used for the measurement by the participant is not contained in the list, participants convey this to ESfEQA through the input mask. He can use his selected method, instrument and reagent information immediately for the input of his test results.
The choice of method, instrument and reagent and the input of the measuring values are conveyed through the

web portal of ESfEQA. The participant receives the login-information required for the input from ESfEQA. The password consists of at least 8 characters, thereof at least 2 special characters. User name and password are to be kept in confidence by the participant.
Alternatively to the online input, the data can be put in by a form, that is sent to ESfEQA either by E-Mail (info@esfeqa.eu) or Fax (+49 6221 894669-90). The EQA program specific form is provided on the ESfEQA homepage.
All test results of the EQA participants conveyed in due time are assessed by ESfEQA. For the loss or the late arrival of his/her data the participant bears the risk. There is no claim for data assessment of test results arrived late.
Quantitative measuring values are generally specified with a value and a unit. The choice of the amount of specified digits is incumbent on the participant. Input of results as "< measurement range" or "< 100" are not allowed. If the analysis system shows such values, they are to be interpreted by the participant, e.g. as 0 or as specification of the value of the lower measurement range.
For the input of quantitative results, several units are normally available. The units are converted into the standard unit used by ESfEQA. This standard unit is also used for the creation of the records.

15. Number of results per participant
For each EQA sample and analyte, up to 3 values per participant can be entered. The values have to be determined by different, independent from each other, analytic systems.

16. Correction of transmitted results
After the input of the results into the web-input mask, a correction or change by the participant is no longer possible. If inaccurate values are recognized by the participant, (s)he can convey this to ESfEQA in written form specifying the reason up until the deadline for submission of the EQA survey. After verification and acceptance of the correction request, the result can be changed by ESfEQA. The same procedure applies for results submitted by e-mail and fax.

17. Evaluation of EQA results
For each analyte measured in the EQA program the kind of determination of target value and the acceptance criteria are predetermined. For quantitative parameters the target value normally is the consensus value. This value is calculated according to ISO/IEC 13528:2005 ‚Statistical methods for use in proficiency testing by interlaboratory comparisons' by robust statistics.
Qualitative samples are being tested thoroughly with differing systems before the usage as EQA samples. Thereby the target value is determined.
As far as reasonable and possible, system specific differences are being considered. The differentiation to the greatest possible extent takes place according to the method used, instrument, and reagent (M,I,R group). The minimum amount of results of an evaluation group is 5 values. If this amount is undercut, an evaluation in the superior group, e.g. all values, which have been measured with the same method (M group) takes place. The determination of the evaluation group is documented in the record.
The maximum allowable deviation from the target value of quantitative specified analytes is predetermined and can be found on the ESfEQA homepage. The interval was derived from the medical relevance and the reference interval. In the presentation of the report, the upper limit of the allowed range corresponds with a z-value of 3 and the lower limit with a z-value of -3.

18. Creation of reports
After the evaluation of the EQA survey, the participants receive reports, which are provided electronically. The reports contain the results submitted by the participant in comparison to the results of his peer group, a display and comparison of all peer groups, a graphic illustration of the data as histogram, a Shewhart-chart with the participant's previous results in the EQA surveys and in the case of quantitative surveys, which consist out of 2 samples, a Youden plot for the illustration of the z-values of both samples in comparison to other participants.

19. Loss and damage of EQA test material
In case of loss or damage of sample material, damages are compensated by ESfEQA GmbH when possible, without acknowledgement of any claims, by sending substitute test specimens when possible, if an immediate notification took place. However, the contract counts as fulfiled already at the posting date of the first shipping.

20. Complaints
After receipt of the EQA reports, complaints are possible within a period of 4 weeks. After the end of this period, the participant's claims on the basis of complaints are excluded. In case of justified complaints, a claim on performance of a substitute EQA survey exists. The eventual incidental costs for reagents, expenditure of time, etc. are not being compensated by ESfEQA, as long as ESfEQA is not liable according to cipher 21 of this conditions of participation.

21. Guarantee
For any type of loss, ESfEQA is liable only in the case of intention and gross negligence and in the case of presentation of the other eligibility requirements for claims.

22. Confidentiality
Individual EQA data are being kept confidentially.
ESfEQA collects, processes and uses personal data of the participant only as far as this is required for the performance of the EQA surveys, the creation of the records and for the purpose of quality assurance. This includes the forwarding of participant and device number identifiable data for the quality assurance measures to the individual manufacturer of the test system (device and reagent).

COMPANY INFORMATION

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