ESfEQA
European Society for
External Quality Assessment

ESfEQA REPORT INTERPRETATION

EXPLANATION MANUAL FOR SURVEY REPORTS AND STATISTICAL EVALUATIONS

ESfEQA PROGRAMS

BIOCHEMISTERY

Blood Gas and Electrolytes, Cardiac Marker, Cerebrospinal Fluid, Clinical Chemistry, Coagulation, Drugs of Abuse, Ethanol, Fecal Occult Blood, Glycated Hemoglobin, Qualitative Urine Analysis, Therapeutic Drugs, Urine Chemistry, Urine Sediments

IMMUNOLOGY

hCG, Hormones, Procalcitonin, Specific Proteins, Tumor Marker

MICROBIOLOGY

Adenovirus, Aspergillus Fumigatus, Bacteriology (Pathogen Identification and Antimicrobial Susceptibility Testing according to EUCAST and CLSI), Borrelia, Brucella, Chagas, Chlamydophila Pneumoniae, Chlamydophila Trachomatis, Chikungunya Virus, Coxsackie-virus, Dengue Virus, ECHO Virus, Enterovirus, Epstein-Barr Virus, Hepatitis A Virus, Hepatitis B Virus, Hepatitis E Virus, HTLV I/II, Infectious Disease (HIV, HCV, HBV), Influenza A Virus, Influenza B Virus, Leptospira, Malaria Microscopy (Parasite/Stage Identification), Measles, Mosquito Transmitted Diseases (Chikungunya, West-Nile, Zika, Dengue), Parainfluenza Virus, Parvovirus B 19, Respiratory Syncytial Virus, SARS-CoV-2, Syphilis, ToRCH, Varicella Zoster Virus, West-Nile-Fever Virus, Zika Virus

HEMATOLOGY

Blood Grouping, Immunhematology, Erythrocyte Sedimentation Rate, Erythrocyte Sedimentation Rate for Alifax and Alcor devices, Hemogram, Hemogram including 3-part Diff.

EXTERNAL QUALITY ASSESSMENT BY ESfEQA

Quality Standards in Medical Laboratories

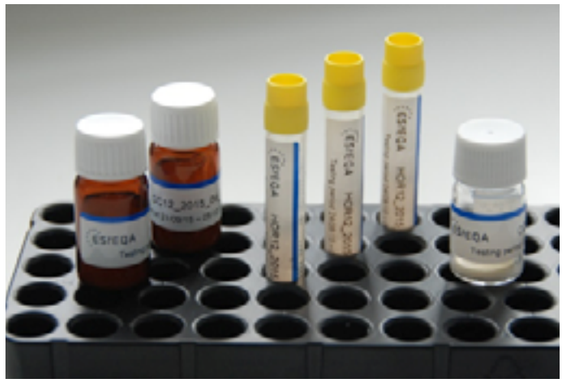
A high quality standard is essential for every medical laboratory since test results are the basis for medical decisions and have an important impact on the well-being and treatment of patients.

There are different approaches to maintain and improve quality in medical laboratories. ESfEQA -European Society for External Quality Assessment – supports laboratories to assess the quality of their analytical results and ultimately improve their performance by providing well-designed external quality assessment programs.

ESfEQA offers a wide range of External Quality Assessment Schemes

ESfEQA was founded in Heidelberg/Germany in 2013 and is accredited according to the international standard ISO 17043:2010 by the German national accreditation body DAkkS. Since its foundation, ESfEQA has expanded its program portfolio and at the same time the number of laboratories participating in ESfEQA's external quality assessment schemes. Currently, ESfEQA offers more than 70 quantitative and qualitative EQA programs worldwide in the areas of biochemistry, immunology, microbiology and hematology.

Participants submit their results to the ESfEQA database via the secured TEQA web application. ESfEQA evaluates the participants' results according to ISO 13528 and provides the reports to the participants via TEQA.



External Quality Assessment Reports

This manual is intended to explain the survey reports and statistical evaluations to the participants. ESfEQA reports are designed to provide participants with detailed information on their laboratory performance in order to assess their level of quality and to show how the the quality of the laboratory performance can be improved if quality standards are not fully met. ESfEQA reports provide a comparison of laboratory results with other laboratories that use the same analytical system, in particular the same analytical device or reagent, but also provide detailed information for comparison to other analytical devices. We consider the comparison to other analytical devices, methods etc. to be very important since the medical interpretation of laboratory results is usually not associated to any particular instrument, method or reagent brand.

In addition to detailed information, ESfEQA reports contain a summary that allows participants to capture the laboratory performance at a glance.

We are looking forward to support you with our enthusiasm for quality in medical laboratories in maintaining and improving the quality standard in your laboratory.

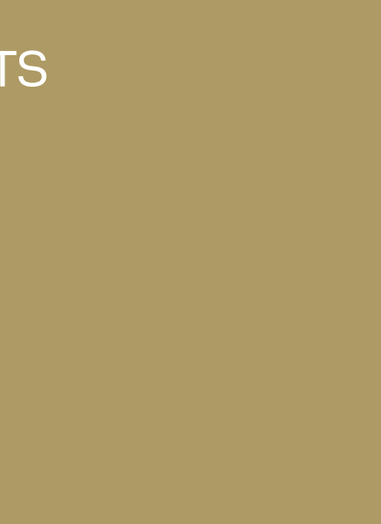
STRUCTURE OF ESfEQA REPORTS

The reports for quantitative analytes (e. g. in Clinical Chemistry, Hormones or Hematology) consist of several sections. The structure of the report is described below – further details on each section of the report are provided on the following pages.

Participants receive the survey reports electronically as PDF-files via the TEQA web application. Reports from previous surveys are stored in the TEQA database so that participants can download them. These electronic reports can be saved on the computer or forwarded electronically. Although reports may be printed in part or in full by the participants, they are not intended to be printed out in full.

1

Cover Page



Final Report for Clinical Chemistry 4
Survey 04, Cycle 2019

1. GENERAL REMARKS

EQA Provider: ESfEQA Heidelberg, Germany
Study Coordinator: Dr. Dieter Grioche, ESfEQA
Scientific Advisor: Prof. Dr. Wolfgang Hermann

Sample 1: CC4_2019_04_a
Sample 2: CC4_2019_04_b
Deadline for data entry: October 28th, 2019

The samples were lyophilized material that needed to be reconstituted according to the procedure described in the instructions for use.

The manufacturing and the homogeneity testing of the controls were subcontracted by ESfEQA. The stability and homogeneity data of the samples were evaluated by ESfEQA. The samples were approved for use as control material by ESfEQA.

Individual EQA data is kept confidential. The report is intended for the external quality assurance of your laboratory. This may not be published, passed on or used for purposes other than quality assurance without the written consent of ESfEQA.

2. STATISTICS

For the assessment of the laboratory performance, various results were merged into one group, e.g. instrument, method or reagent group. The minimum number of results for one group must be 5 results. If the minimum number of 5 results was not obtained in these groups, the individual result has to be compared to the robust mean of the next larger group that could be evaluated or the general group containing the results of all participants.

The target values were calculated as the robust mean (Algorithm A) of each group according to ISO 13528.

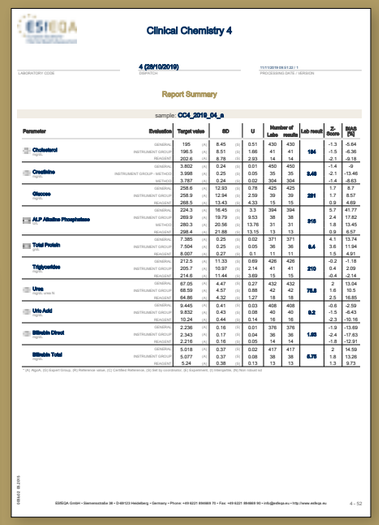
The permissible range for each analyte is derived from its medical relevance as well as the reference interval and is listed below:

Acid Phosphatase	± 0.3 U/l up to 4 U/l, ± 23% > 4 U/l
Albumin	± 6 g/l up to 30 g/l, ± 20% > 30 g/l
ALP/GPT	± 10 U/l up to 40 U/l, ± 25% > 40 U/l
ALT/GPT	± 10 U/l up to 40 U/l, ± 25% > 40 U/l
Amylase	± 25 U/l up to 100 U/l, ± 25% > 100 U/l
Amylase pancreatic	± 8.3 U/l up to 33 U/l, ± 25% > 33 U/l
AST/GOT	± 8 U/l up to 40 U/l, ± 21% > 40 U/l
Bilirubin-direct	± 4.4 µmol/l up to 20 µmol/l, ± 22% > 20 µmol/l
Bilirubin-total	± 4.4 µmol/l up to 20 µmol/l, ± 22% > 20 µmol/l
Calcium	± 0.25 mmol/l up to 2.5 mmol/l, ± 10% > 2.5 mmol/l
Cholesterol (enzymat)	± 0.5 mmol/l up to 5 mmol/l, ± 10% > 5 mmol/l
CPK *	± 1 150 U/l up to 6000 U/l, ± 23% > 6000 U/l
Chloride	± 8 mmol/l up to 100 mmol/l, ± 8 % > 100 mmol/l
Cholesterol	± 0.65 mmol/l up to 3 mmol/l, ± 13% > 5 mmol/l
CK	± 15 U/l up to 100 U/l, ± 15% > 100 U/l
Creatinine	± 13 µmol/l up to 100 µmol/l, ± 19% > 100 µmol/
Copper *	± 30%
γ-GT	± 8.4 U/l up to 40 U/l, ± 21% > 40 U/l
Glycose	± 0.75 mmol/l up to 5 mmol/l, ± 15% > 5 mmol/
HDL	± 0.16 mmol/l up to 0.8 mmol/l, ± 20% > 0.8 mmol/l
Iron	± 5.7 µmol/l up to 40 µmol/l, ± 14% > 40 µmol/l
Lactate	± 0.27 mmol/l up to 1.8 mmol/l, ± 15% > 1.8 mmol/l
LDH	± 49 U/l up to 250 U/l, ± 18 % > 250 U/l
LDL	± 0.4 mmol/l up to 2 mmol/l, ± 20% > 2 mmol/l
Lipase	± 16 U/l up to 80 U/l, ± 27% > 60 U/l
Lithium	± 0.38 mmol/l up to 2 mmol/l, ± 19% > 2 mmol/l
Magnesium	± 0.163 up to 1.25 mmol/l, ± 13% > 1.25 mmol/l
Phosphate	± 0.12 mmol/l up to 0.75 mmol/l, ± 16% > 0.75 mmol/l
Potassium	± 0.32 mmol/l up to 4 mmol/l, ± 8% > 4 mmol/l
Sodium	± 4 mmol/l up to 150 mmol/l, ± 3% > 150 mmol/l
TIBC*	± 4.3 µmol/l up to 23 µmol/l, ± 18% > 23 µmol/l
Total Protein	± 6 g/l up to 60 g/l, ± 10% > 60 g/l
Triglycerides	± 0.28 mmol/l up to 1.8 mmol/l, ± 16% > 1.8 mmol/l

Identifies the EQA program, survey number and sample description. It provides information about the permissible range for each quantitative analyte and the target value for qualitative analytes, the statistical procedure used for data evaluation and survey-specific comments.

2

Summary Page (for quantitative surveys)



Clinical Chemistry 4

4 (28/10/2019)

Report Summary

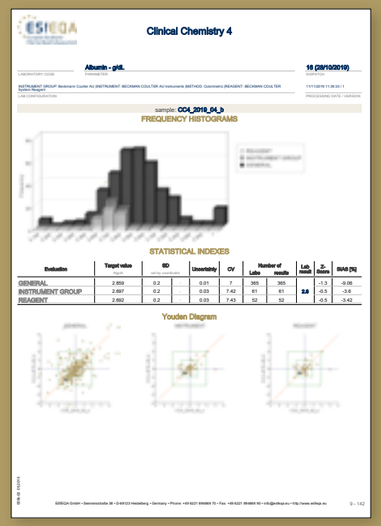
sample: CC4_2019_04_a

Parameter	Evaluation	Target value	SD	U	Number of Labs	Number of results	Lab result	Z-Score	RIAS [%]
Cholesterol	GENERAL	195	8.45	0.51	430	430	184	-1.3	-5.64
	INSTRUMENT GROUP	196.5	8.51	1.66	41	41		-1.5	-6.38
	REAGENT	202.6	8.78	2.93	14	14		-2.1	-8.18
Creatinine	GENERAL	3.802	0.24	0.01	450	450	3.48	-1.4	-6
	INSTRUMENT GROUP - METHOD	3.998	0.25	0.05	35	35		-2.1	-13.46
	METHOD	3.197	0.24	0.02	304	304		-4.4	-8.63
Glucose	GENERAL	258.6	12.93	0.78	425	425	291	1.7	8.7
	INSTRUMENT GROUP	258.9	12.94	2.59	39	39		1.7	8.57
	REAGENT	268.5	13.43	4.33	15	15		0.9	4.69
ALP Alkaline Phosphatase	GENERAL	224.3	16.45	3.3	394	394	215	5.7	41.77
	INSTRUMENT GROUP	269.9	19.79	9.53	36	36		2.4	17.62
	METHOD	280.3	20.56	13.76	31	31		1.8	13.45
	REAGENT	298.4	21.88	13.15	13	13		0.5	6.57
Total Protein	GENERAL	7.385	0.25	0.02	371	371	6.4	4.3	13.74
	INSTRUMENT GROUP	7.504	0.25	0.05	36	36		3.6	11.04
	REAGENT	8.007	0.27	0.1	11	11		1.5	4.81
Triglycerides	GENERAL	212.5	11.33	0.69	426	426	210	-0.2	-1.18
	INSTRUMENT GROUP	205.7	10.97	2.14	41	41		0.4	2.09
	REAGENT	214.6	11.44	3.89	15	15		-0.4	-2.14
Urea	GENERAL	67.05	4.47	0.27	432	432	70.8	2	13.04
	INSTRUMENT GROUP	68.59	4.57	0.88	42	42		1.6	10.5
	REAGENT	64.86	4.32	1.27	18	18		2.5	16.85
Uric Acid	GENERAL	9.445	0.41	0.03	408	408	9.2	-0.6	-2.59
	INSTRUMENT GROUP	9.832	0.43	0.08	40	40		-1.5	-6.43
	REAGENT	10.24	0.44	0.14	16	16		-2.3	-10.16
Bilirubin Direct	GENERAL	2.236	0.16	0.01	376	376	1.68	-1.8	-13.69
	INSTRUMENT GROUP	2.343	0.17	0.04	36	36		-2.4	-17.63
	REAGENT	2.216	0.16	0.05	14	14		-1.8	-12.61
Bilirubin Total	GENERAL	5.018	0.37	0.02	417	417	6.76	2	14.59
	INSTRUMENT GROUP	5.077	0.37	0.08	38	38		1.8	13.26
	REAGENT	5.24	0.38	0.13	13	13		1.3	9.73

Each analyte that was determined by the participant is listed in this table, which displays the participant result, z-score and bias.

3

Analyte-specific Information (for quantitative surveys)



Clinical Chemistry 4

Albumin - g/dL

10 (28/10/2019)

sample: CC4_2019_04_b

FREQUENCY HISTOGRAMS

STATISTICAL INDEXES

Evaluation	Target value	SD	Uncertainty	CV	Number of Labs	Number of results	Lab result	Z-Score	RIAS [%]
GENERAL	2.859	0.2	0.01	7	365	365	2.8	-1.3	-9.06
INSTRUMENT GROUP	2.897	0.2	0.03	7.42	61	61		-0.5	-3.6
REAGENT	2.892	0.2	0.03	7.43	52	52		-0.5	-3.42

Youden Diagram

A Frequency Histogram, Statistical Indices, Youden Diagram (if 2 samples were analyzed in the survey) and Statistical Comparison Data are provided in this part of the report.

4

Analyte-specific Information (for qualitative surveys)

Infectious Disease Combination Control / INF

Anti-HIV I/II

5 (28/10/2019)

sample: INF_2019_04_b

True result: positive

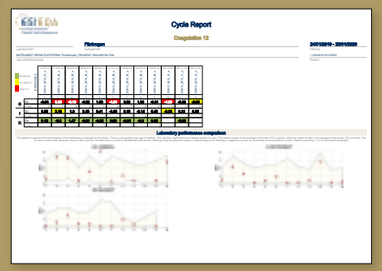
Lab result: positive

Evaluation	positive	borderline	negative
general	66	0	0
INSTRUMENT			
OTHER	0	0	2
BIORAD IMARK	2	0	0
ALERE Determine	2	0	0
ABBOTT Alinity	2	0	0
RAYTO RT Series	2	0	0
FORTRESS DIAGNOSTICS Analyst 2010	1	0	0
AWARENESS TECHNOLOGY Chromate	1	0	0
DIAMEDIX MAGO	1	0	0
ADALTIS Personal Lab	1	0	0
BIORAD Plate reader 680	1	0	0
INSTRUMENT GROUP			
Roche Cobas	9	0	0
SIEMENS ADVIA Group	3	0	0
DIASORIN LIAISON (XL)	5	0	0
DYNEX Technologies DSX/DS2	1	0	1
bioMerieux VIDAS/ mini VIDAS	1	0	0
Manual Testing	6	0	9
AWARENESS TECHNOLOGY	3	0	0
ORTHO Vitros	2	0	0
HITACHI Instrument	1	0	0
ABBOTT Architect	14	0	0
HUMAN Semi-automated ELISA reader	8	0	0

A table of results and a bar chart illustrate the results for each analyte.

5

Cycle Report



Cycle Report

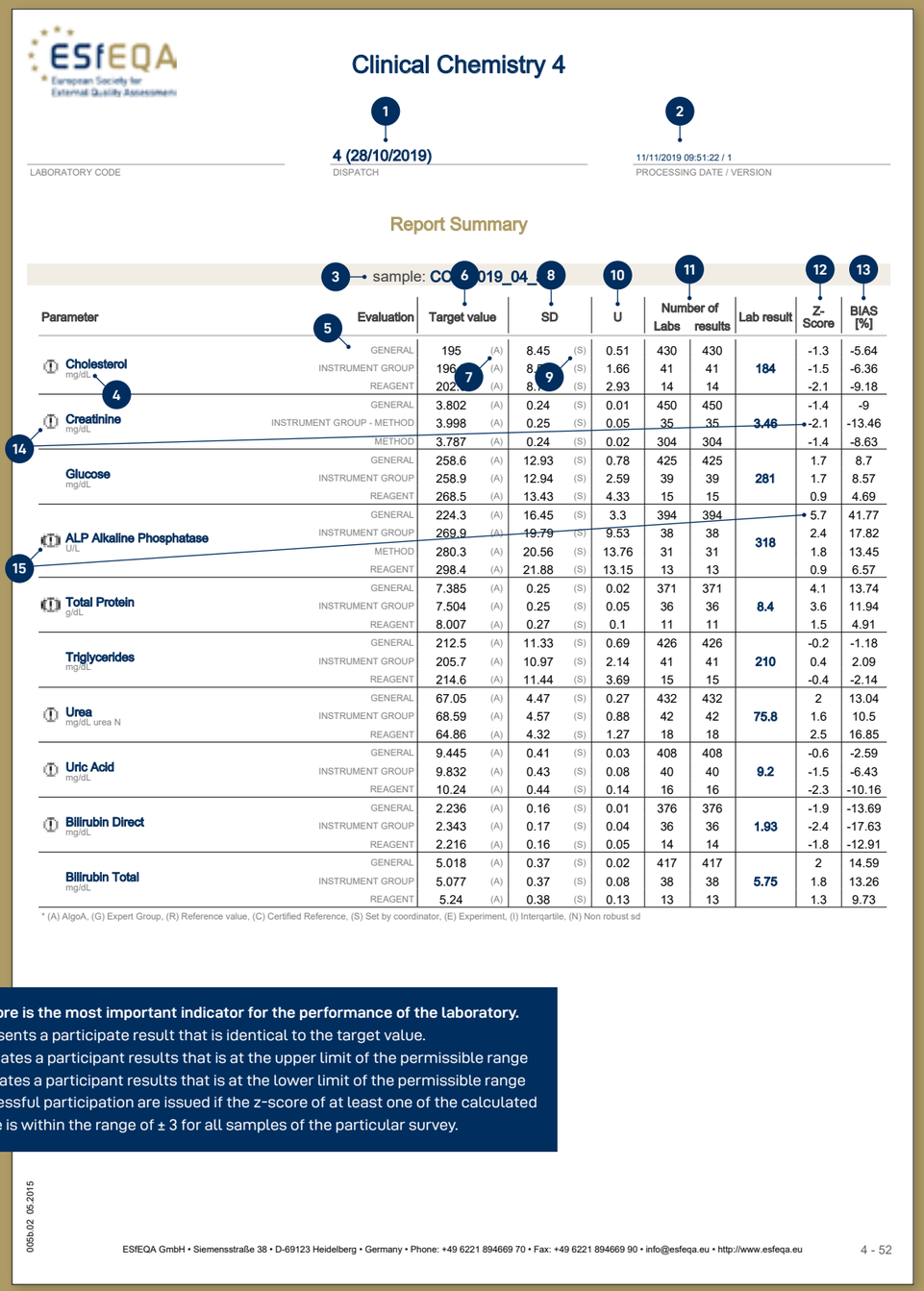
Coagulation 12

Fibrinogen

The Cycle Report allows the monitoring of the z-scores of all analytes over a selected time period. The Cycle Report can be retrieved and downloaded separately.

Summary Page

The summary page lists all analytes that were determined by the participant and that were statistically evaluated. For each analyte, the participant result, z-score and bias are displayed.



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Clinical Chemistry 4

1 — 4 (28/10/2019) — DISPATCH

2 — 11/11/2019 09:51:22 / 1 — PROCESSING DATE / VERSION

LABORATORY CODE

Report Summary

3 — sample: CC[illegible]019_04_[illegible]

Parameter	Evaluation	Target value		SD		U	Number of Labs	Number of results	Lab result	Z-Score	BIAS [%]
Cholesterol mg/dL	GENERAL	195	(A)	8.45	(S)	0.51	430	430		-1.3	-5.64
	INSTRUMENT GROUP	196	(A)	8.[illegible]	(S)	1.66	41	41	184	-1.5	-6.36
	REAGENT	202	(A)	8.[illegible]	(S)	2.93	14	14		-2.1	-9.18
Creatinine mg/dL	GENERAL	3.802	(A)	0.24	(S)	0.01	450	450		-1.4	-9
	INSTRUMENT GROUP - METHOD	3.998	(A)	0.25	(S)	0.05	35	35	3.46	-2.1	-13.46
	METHOD	3.787	(A)	0.24	(S)	0.02	304	304		-1.4	-8.63
Glucose mg/dL	GENERAL	258.6	(A)	12.93	(S)	0.78	425	425		1.7	8.7
	INSTRUMENT GROUP	258.9	(A)	12.94	(S)	2.59	39	39	281	1.7	8.57
	REAGENT	268.5	(A)	13.43	(S)	4.33	15	15		0.9	4.69
ALP Alkaline Phosphatase U/L	GENERAL	224.3	(A)	16.45	(S)	3.3	394	394		5.7	41.77
	INSTRUMENT GROUP	269.9	(A)	19.79	(S)	9.53	38	38	318	2.4	17.82
	METHOD	280.3	(A)	20.56	(S)	13.76	31	31		1.8	13.45
	REAGENT	298.4	(A)	21.88	(S)	13.15	13	13		0.9	6.57
Total Protein g/dL	GENERAL	7.385	(A)	0.25	(S)	0.02	371	371		4.1	13.74
	INSTRUMENT GROUP	7.504	(A)	0.25	(S)	0.05	36	36	8.4	3.6	11.94
	REAGENT	8.007	(A)	0.27	(S)	0.1	11	11		1.5	4.91
Triglycerides mg/dL	GENERAL	212.5	(A)	11.33	(S)	0.69	426	426		-0.2	-1.18
	INSTRUMENT GROUP	205.7	(A)	10.97	(S)	2.14	41	41	210	0.4	2.09
	REAGENT	214.6	(A)	11.44	(S)	3.69	15	15		-0.4	-2.14
Urea mg/dL urea N	GENERAL	67.05	(A)	4.47	(S)	0.27	432	432		2	13.04
	INSTRUMENT GROUP	68.59	(A)	4.57	(S)	0.88	42	42	75.8	1.6	10.5
	REAGENT	64.86	(A)	4.32	(S)	1.27	18	18		2.5	16.85
Uric Acid mg/dL	GENERAL	9.445	(A)	0.41	(S)	0.03	408	408		-0.6	-2.59
	INSTRUMENT GROUP	9.832	(A)	0.43	(S)	0.08	40	40	9.2	-1.5	-6.43
	REAGENT	10.24	(A)	0.44	(S)	0.14	16	16		-2.3	-10.16
Bilirubin Direct mg/dL	GENERAL	2.236	(A)	0.16	(S)	0.01	376	376		-1.9	-13.69
	INSTRUMENT GROUP	2.343	(A)	0.17	(S)	0.04	36	36	1.93	-2.4	-17.63
	REAGENT	2.216	(A)	0.16	(S)	0.05	14	14		-1.8	-12.91
Bilirubin Total mg/dL	GENERAL	5.018	(A)	0.37	(S)	0.02	417	417		2	14.59
	INSTRUMENT GROUP	5.077	(A)	0.37	(S)	0.08	38	38	5.75	1.8	13.26
	REAGENT	5.24	(A)	0.38	(S)	0.13	13	13		1.3	9.73

* (A) AlgoA, (G) Expert Group, (R) Reference value, (C) Certified Reference, (S) Set by coordinator, (E) Experiment, (I) Interqartile, (N) Non robust sd

4 — Cholesterol — 5 — GENERAL — 6 — 195 — 7 — (A) — 8 — 8.45 — 9 — (S) — 10 — 0.51 — 11 — 430 / 430 — 12 — -1.3 — 13 — -5.64

14 — Creatinine — 3.46

15 — ALP Alkaline Phosphatase — 318

IMPORTANT: The z-score is the most important indicator for the performance of the laboratory.

- A z-score of 0 represents a participate result that is identical to the target value.
- A z-score of +3 indicates a participant results that is at the upper limit of the permissible range
- A z-score of -3 indicates a participant results that is at the lower limit of the permissible range
- Certificates of successful participation are issued if the z-score of at least one of the calculated groups of an analyte is within the range of ± 3 for all samples of the particular survey.

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Header

1 Dispatch number: the dispatches are counted continuously. The deadline for result submission is displayed in brackets.

2 The processing data and version indicate the date when the statistical evaluation for this survey was performed and which version of the statistical evaluation is provided. Usually, there is only a single version (version number "1") of the statistical evaluation.

Report Summary

3 Sample identifier

4 Units: units indicated in the report reflect the units that were used by the participant for result submission.

5 Evaluated groups: in this example for Cholesterol, the evaluation of the general group, the instrument group, and the reagent group is provided. The general group includes results from all participants that submitted results for this analyte. The instrument (reagent) group summarizes results from all laboratories that have used the same instrument (reagent) as the participant of this report. ESfEQA predefines appropriate evaluation groups for each analyte.

6 Target values of the evaluated groups. Target values can be group specific, e.g. the target value for the general group might be different from the instrument group and the target value for different instrument groups might be instrument specific.

7 Statistical basis for the determination of target values:
(A) = calculated as robust mean (Algorithm A) according to ISO 13528
(R) = reference value determined by an expert laboratory
(C) = certified reference value of certified material
(D) = calculated as robust mean of a group of expert laboratories

8 SD = Standard Deviation (Definition of SD see below)

9 Statistical basis how the SD was determined:
(S) = set by coordinator:
SD = (permissible deviation [%] / 100) / 3 · X if the relative deviation applies and
SD = (permissible deviation / 3) if the absolute deviation applies.
(E) = determined by experiment
(I) = determined as interquartile range
(N) = determined as non-robust SD
In most cases of ESfEQA surveys, the permissible deviation for each analyte is derived from its medical relevance and the reference interval for the analyte. For most quantitative analytes ESfEQA, in collaboration with its scientific advisors, has defined a relative permissible deviation (in %) and below a defined concentration threshold an absolute permissible deviation (expressed in the unit of the analyte, e.g. U/l, mmol/l).

10 U = Uncertainty of the assigned value, calculated as:
$U = 1{,}25 \cdot s^*/\sqrt{p}$ (s^* as robust standard deviation calculated by the Algorithm A and p as number of results)
An uncertainty above 0,3 · SD is not negligible and might result in an inappropriate calculation of the z-score.

11 Number of laboratories that submitted results for this analyte and total number of results submitted by these laboratories

12 Z-score, calculated as:
ZS = (x-X)/SD (x as participant value, X as target value)
For results that were included in several groups (e.g. I, M group and general group) there are several target values X and thus several z-scores.

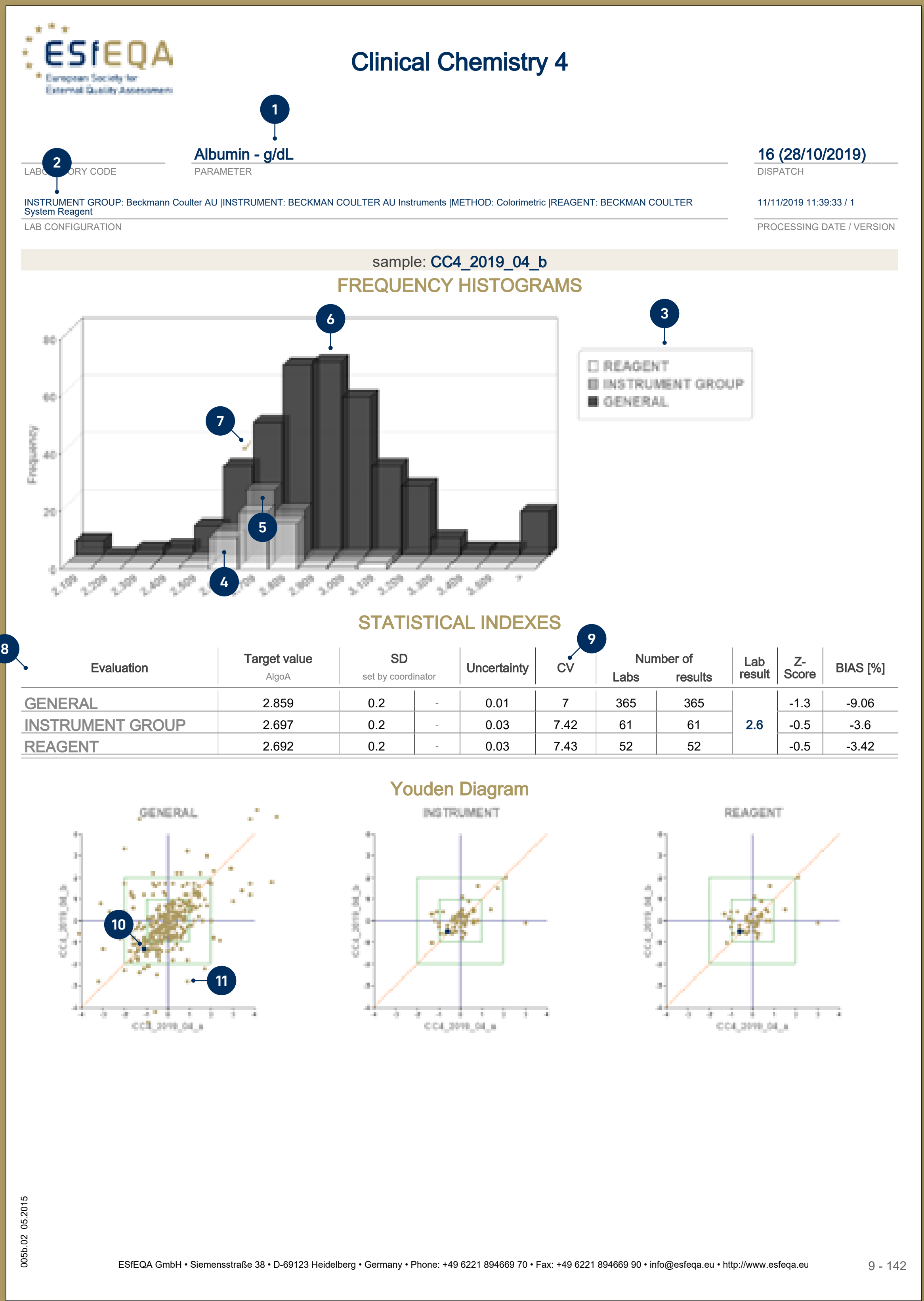
13 BIAS [%] = Deviation of the participants result from the target value in [%]

14 (!) this symbol indicates a z-score above 2,0 or below -2,0 (in this case -2,1 in the instrument-method group) and shall be considered as a warning signal. It is displayed in the line of an analyte if any of the z-cores of the evaluated groups is outside of this range.

15 (!!) this symbol indicates a z-score above 3,0 or below -3,0 (in this case 5,7 in the general group) and shall be considered as an action signal. It alerts the participant about instrument-, method and reagent-specific target values. It is displayed in the line for an analyte if any of the z-cores of the evaluated groups is outside of this range.

Analyte Specific Information (quantitative surveys)

In this section of the report, a Frequency Histogram, Statistical Indices, Youden Diagram and Statistical Comparison Data are provided.



Clinical Chemistry 4

Albumin - g/dL — PARAMETER

LABORATORY CODE

16 (28/10/2019) — DISPATCH

INSTRUMENT GROUP: Beckmann Coulter AU |INSTRUMENT: BECKMAN COULTER AU Instruments |METHOD: Colorimetric |REAGENT: BECKMAN COULTER System Reagent — LAB CONFIGURATION

11/11/2019 11:39:33 / 1 — PROCESSING DATE / VERSION

sample: CC4_2019_04_b

FREQUENCY HISTOGRAMS

STATISTICAL INDEXES

Evaluation	Target value AlgoA	SD set by coordinator		Uncertainty	CV	Number of Labs	Number of results	Lab result	Z-Score	BIAS [%]
GENERAL	2.859	0.2	-	0.01	7	365	365		-1.3	-9.06
INSTRUMENT GROUP	2.697	0.2	-	0.03	7.42	61	61	2.6	-0.5	-3.6
REAGENT	2.692	0.2	-	0.03	7.43	52	52		-0.5	-3.42

Youden Diagram

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Header

The HEADER contains the laboratory code and laboratory name, the name of the analyte, the default unit, the dispatch of the EQA survey, the laboratory configuration, the date of the statistical evaluation and the version of data processing.

1. Unit used by the participant for result submission.
2. Lab configuration: Analyte-specific configuration of the participating laboratory. The evaluated participant groups that are displayed in the charts for this analyte are those defined by the participant's configuration. In this case, these groups are:
   - General (including the results of all instrument and reagent groups)
   - Instrument group: Beckmann Coulter AU
     Several comparable instruments can be combined into one group. In this case, the `Beckmann Coulter AU instrument´ was evaluated in the broad instrument group `Beckmann Coulter AU´.
   - Reagent: Beckmann Coulter System-Reagent

Frequency Histograms

The FREQUENCY HISTOGRAMS indicate the result distributions of the various groups (e.g. general and instrument/ method) that were evaluated.

3. Groups in which the result of the participant was evaluated, in this case:
   - General
   - Instrument group: Beckmann Coulter AU
   - Reagent: Beckmann Coulter System-Reagent
4. Number of results submitted for the selected analyte (in this example, 'Albumin')in the reagent group "Beckmann Coulter System-Reagent" that are between 2,509 g/dL and 2,609 g/dL.
5. Number of results submitted for the selected analyte (in this example, 'Albumin')in the instrument group "Beckmann Coulter AU" that are between 2,609 g/dL and 2,709 g/dL.
6. Number of results submitted for the selected analyte (in this example, 'Albumin') in the general group that are between 2,809 g/dL and 2,909 g/dL
7. The check mark indicates the location of the value submitted by the participant.

Statistical Indices

The STATISTICAL INDICES provide information about the target value and how it was calculated (e.g. as participant consensus calculated by the Algorithm A), the SD (Standard deviation), the uncertainty of the assigned value, the number of labs and results that were considered for the statistical evaluation. The last three columns display the lab result, the z-score (ZS) and the BIAS (deviation of the lab result to the target value in percent).

8. Groups in which the result of the participant was evaluated, in this case:
   - General
   - Instrument group: Beckmann Coulter AU
   - Reagent: Beckmann Coulter System-Reagent
9. CV = Coefficient of Variation, calculated as:
   CV = SD/X · 100

Youden Diagram
(only displayed for EQAs with two samples per survey)

10. Blue dot: Display of the participant's z-score for the selected analyte (in this example, 'Albumin') determined in sample CC4_2019_04_a compared to the z-score for the selected analyte determined in sample CC4_2019_04_b.
11. Yellow dots represent the z-scores of all other participants (of the evaluated group) for the selected analyte (in this example, 'Albumin') determined in sample CC4_2019_04_a compared to the z-score for the selected analyte determined in sample CC4_2019_04_b.

Analyte Specific Information (quantitative surveys)

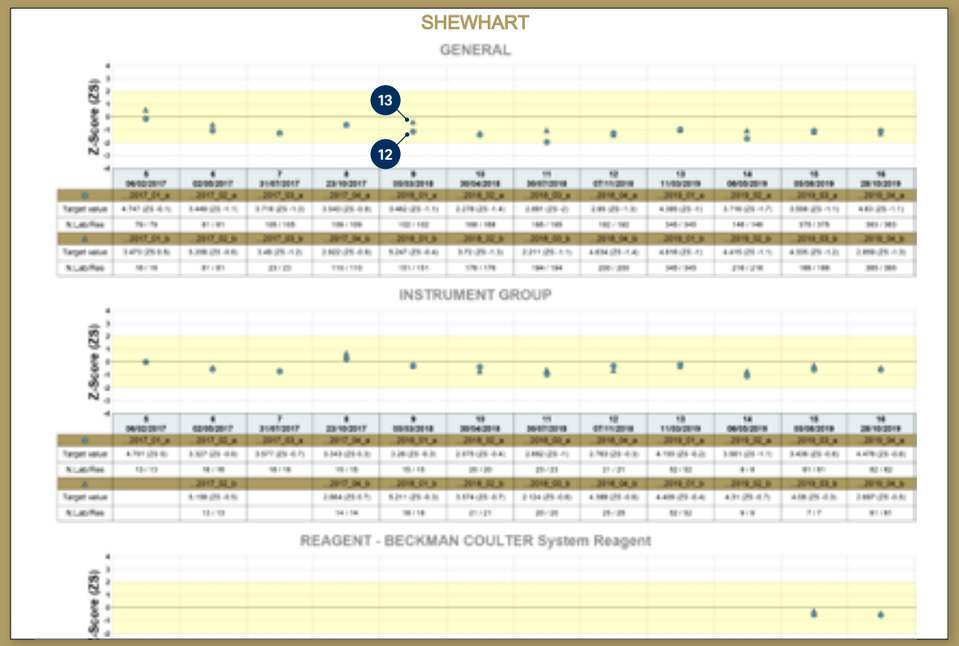
Statistical Comparison

Statistical Comparison

Evaluation	Target value (AlgoA)	SD (set by coordinator)		Uncertainty *	CV	Number of Labs	Number of results
1 general	2.859	0.2	-	0.01	7	365	365
INSTRUMENT GROUP							
2 Roche Cobas	2.894	0.2	-	0.03	6.91	95	95
3 Beckmann Coulter AU	2.697	0.2	-	0.03	7.42	61	61
4 Mindray BS Series	2.939	0.2	-	0.04	6.81	31	31
5 ORTHO Vitros	9.886	0.66	-	0.24	6.67	12	12
6 BIOSYSTEMS	2.822	0.2	-	0.08	7.09	9	9
7 ABBOTT Architect	2.823	0.2	-	0.05	7.08	25	25
8 HUMAN HumaLyzer Photometer	2.883	0.2	-	0.06	6.94	19	19
9 HUMAN HumaStar Analyzers	2.795	0.2	-	0.05	7.16	24	24
10 ELITECHGroup Selectra Pro	3.122	0.21	-	0.12	6.67	5	5
11 ERBA Mannheim	2.993	0.2	-	0.09	6.68	8	8
12 Roche Cobas c111	3.042	0.2	-	0.09	6.67	8	8
REAGENT							
13 ROCHE System-Reagent	2.906	0.2	-	0.03	6.88	96	96
14 BECKMAN COULTER System Reagent	2.692	0.2	-	0.03	7.43	52	52
15 HUMAN Reagent	2.794	0.2	-	0.04	7.16	47	47
16 ABBOTT System-Reagent	2.826	0.2	-	0.05	7.08	21	21
17 ORTHO System-Reagent/Slide	9.886	0.66	-	0.24	6.67	12	12
18 SPINREACT Clinical Chemistry	3.119	0.21	-	0.08	6.67	10	10
19 MINDRAY System-Reagent	2.912	0.2	-	0.08	6.87	9	9
20 ELITECH Group Reagents	3.104	0.21	-	0.12	6.67	5	5
21 DIASYS System Reagent	2.69	0.2	-	0.11	7.43	5	5
22 BIOSYSTEMS System Reagent	2.836	0.2	-	0.11	7.05	5	5
23 ERBA MANNHEIM System-Reagent	3.106	0.21	-	0.12	6.67	5	5
24 SIEMENS System-Reagent	2.75	0.2	-	0.11	7.27	5	5

* Uncertainty of the assigned value

Shewhart Chart



Statistical Comparison

The table STATISTICAL COMPARISON indicates the target value, the SD, the uncertainty (of the calculated target value), the CV and the number of participating laboratories and results for each evaluated group.

Shewhart Chart

For each laboratory, the SHEWHART CHART displays the z-scores of up to 12 previous surveys for the selected analyte of the EQA scheme. The sample number, the deadline of result entry, the sample identifier, the target value, the z-scores and the number of labs/results are displayed in the table. Numbers are provided for all groups (e.g. general, instrument/ method) that were evaluated.

12 Blue dots: Each blue dot in the SHEWHART Chart indicates the z-score of the participant for the selected analyte (in this example, 'Albumin') and the specific comparison group (in this example, the general group) that was determined in the corresponding survey sample:
- Dispatch 9
- Sample CC4_2018_01_a
- Target value of the general group: 3,462 g/dL
- Z-score: -1,1
- Number of labs: 102/number of results: 102

13 Blue triangles: Each blue triangle indicates the z-score of the participant for the selected analyte (in this example, 'Amylase') obtained in the second sample of a survey (only displayed for EQAs with two samples per survey):
- Dispatch 9
- Sample CC4_2018_01_b
- Target value of the general group: 5,247 g/dL
- Z-score: -0,4
- Number of labs: 151/number of results: 151

Analyte Specific Information (qualitative surveys)

A table of results and a bar diagram illustrate the results for each analyte.

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Infectious Disease Combination Control / INF

LABORATORY CODE	PARAMETER	DISPATCH
	Anti-HIV I/II	5 (28/10/2019)

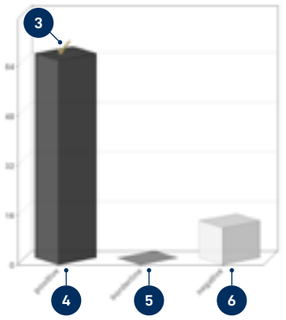
LAB CONFIGURATION	PROCESSING DATE / VERSION
INSTRUMENT GROUP: Roche Cobas |INSTRUMENT: ROCHE Cobas e411 |METHOD: Electrochemiluminescence |REAGENT: ROCHE System-Reagent	14/11/2019 12:37:14 / 1

sample: **INF_2019_04_b**

1 True result: **positive**

2 Lab result: **positive**

Evaluation	positive	borderline	negative
general	66	0	12
INSTRUMENT			
OTHER	0	0	2
BIORAD IMARK	2	0	0
ALERE Determine	2	0	0
ABBOTT Alinity	2	0	0
RAYTO RT Series	2	0	0
FORTRESS DIAGNOSTICS Analyst 2010	1	0	0
AWARENESS TECHNOLOGY Chromate	1	0	0
DIAMEDIX MAGO	1	0	0
ADALTIS Personal Lab	1	0	0
BIORAD Plate reader 680	1	0	0
INSTRUMENT GROUP			
Roche Cobas	9	0	0
SIEMENS ADVIA Group	3	0	0
DIASORIN LIAISON (XL)	5	0	0
DYNEX Technologies DSX/DS2	1	0	1
bioMérieux VIDAS/ mini VIDAS	1	0	0
Manual Testing	6	0	9
AWARENESS TECHNOLOGY	3	0	0
ORTHO Vitros	2	0	0
HITACHI Instrument	1	0	0
ABBOTT Architect	14	0	0
HUMAN Semi-automated ELISA reader	8	0	0



IMPORTANT: A certificate of successful participation for each individual analyte is issued if the lab results for all samples of this survey are identical to the expected result (true result)

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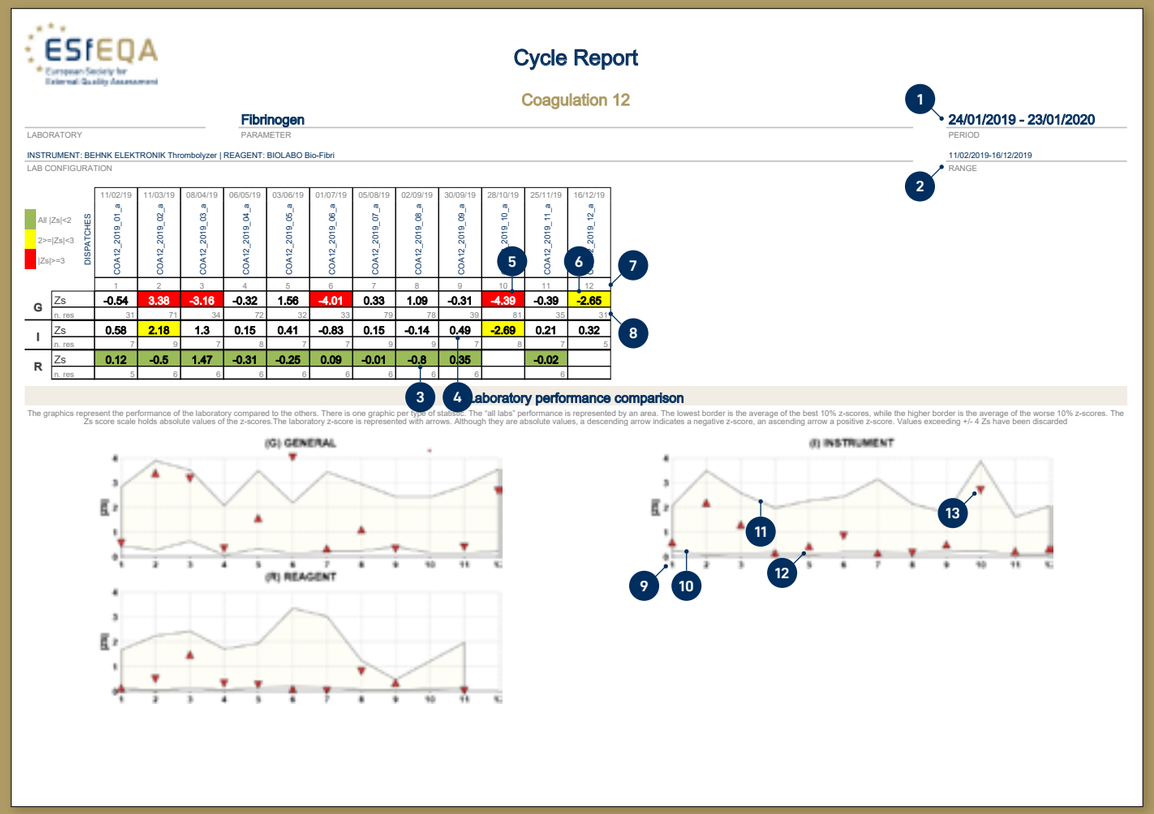
Analyte Specific Information
(qualitative surveys)

The TABLE indicates the results of all participants for each evaluated group (e.g. general and instrument/reagent)

1. True result = Expected result defined by ESfEQA, usually derived from the results of predistribution testings of the sample
2. Lab result = participants result
3. The tick indicates the participant's result
4. Total number of results submitted as "positive"
5. Total number of results submitted as "borderline"
6. Total number or results submitted as "negative"

Cycle Report



ESfEQA
European Society for External Quality Assessment

Cycle Report

Coagulation 12

LABORATORY

Fibrinogen
PARAMETER

1 24/01/2019 - 23/01/2020
PERIOD

INSTRUMENT: BEHNK ELEKTRONIK Thrombolyzer | REAGENT: BIOLABO Bio-Fibri
LAB CONFIGURATION

11/02/19 – 16/12/19
RANGE 2

All |Zs|<2
2>=|Zs|<3
|Zs|>=3

	DISPATCHES	11/02/19 COA12_2019_01_a	11/03/19 COA12_2019_02_a	08/04/19 COA12_2019_03_a	06/05/19 COA12_2019_04_a	03/06/19 COA12_2019_05_a	01/07/19 COA12_2019_06_a	05/08/19 COA12_2019_07_a	02/09/19 COA12_2019_08_a	30/09/19 COA12_2019_09_a	28/10/19 COA12_2019_10_a	25/11/19 COA12_2019_11_a	16/12/19 COA12_2019_12_a
		1	2	3	4	5	6	7	8	9	10	11	12
G	Zs	-0.54	3.38	-3.16	-0.32	1.56	-4.01	0.33	1.09	-0.31	-4.39	-0.39	-2.65
	n. res	31	71	34	72	32	33	79	78	39	81	35	37
I	Zs	0.58	2.18	1.3	0.15	0.41	-0.83	0.15	-0.14	0.49	-2.69	0.21	0.32
	n. res	7	8	7	8	7	7	9	9	7	8	7	8
R	Zs	0.12	-0.5	1.47	-0.31	-0.25	0.09	-0.01	-0.8	0.35		-0.02	
	n. res	6	6	6	6	6	6	6	6	6		6	

3 4 Laboratory performance comparison

The graphics represent the performance of the laboratory compared to the others. There is one graphic per type of statistic. The "all labs" performance is represented by an area. The lowest border is the average of the best 10% z-scores, while the higher border is the average of the worse 10% z-scores. The Zs score scale holds absolute values of the z-scores.The laboratory z-score is represented with arrows. Although they are absolute values, a descending arrow indicates a negative z-score, an ascending arrow a positive z-score. Values exceeding +/- 4 Zs have been discarded

(G) GENERAL

(I) INSTRUMENT

(R) REAGENT

9 10 11 12 13

A table of results and a bar diagram illustrate the results for each analyte.

Header

The HEADER indicates the laboratory code and laboratory name, the analyte, the lab configuration, the selected period of time for evaluation and dates of the first and the last dispatch that were selected for the cycle report (range).

1. Evaluation period of the cycle report that has been selected by the participant in TEQA.
2. The range of dispatches indicates the date of the first and the last dispatch thas included in the cycle evaluation.

Table

The TABLE in the cycle report displays the z-scores of all dispatches for an analyte in the evaluated groups over the selected time period in a color-coded manner.

3. Z-score for Fibrinogen, sample COA12_2019_08_a, deadline 02.09.2019, for the reagent group. The green color indicates that the absolute values of all z-scores in this evaluated group (reagent group) are below 2 (all|Zs| < 2).
4. The line with the instrument group is not highlighted in any color-code since the Z-score for Fibrinogen is not consistently within the +/-2 range.
5. Red color indicates absolute z-scores above 3 (|Zs| ≥ 3).
6. Yellow color indicates absolute z-scores between 2 and 3 (2 ≥|Zs| < 3).
7. Twelve dispatches were evaluated in this cycle report. This number is also used for the graph `Laboratory performance comparison´ below.
8. This number indicates the total number of results in the evaluated group.

Laboratory performance comparison

The LABORATORY PERFORMANCE COMPARISON charts reflect the performance of the laboratory compared to all other participants for each evaluated group over the dispatches of the selected time period. The z-score scale contains absolute values. Values exceeding ± 4 have been discarded.

9. First dispatch evaluated in this cycle report, sample COA12_2019_01, deadline 11.02.2019 (data indicated in the table above).
10. Lower border: average of the best 10 % z-scores
11. Higher border: average of the worst 10 % z-scores
12. Ascending arrow: indicates the absolute value of the z-score of the participant in the instrument group for the 5th evaluated dispatch (deadline 03.06.19, sample name COA12_2019_05_a), ascending arrow indicating a positive z-score.
13. Descending arrow: indicates the absolute value of the z-score of the participant in the instrument group for the 10th evaluated dispatch (deadline 28.10.19, sample name COA12_2019_10_a), descending arrow indicating a negative z-score.

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