ESfEQA
European Society for
External Quality Assessment

ESfEQA
REPORT INTERPRETATION

EXPLANATION MANUAL FOR SURVEY REPORTS AND STATISTICAL EVALUATIONS

ESfEQA PROGRAMS

BIOCHEMISTRY

Blood Gas and Electrolytes, Cardiac Marker, Cardiac Marker POCT, Clinical Chemistry, Coagulation, Co-Oximetry, CSF Diagnostics, Drugs of Abuse, Ethanol Ammonia and Bicarbonate, Fecal Occult Blood, Glucose POC - Whole Blood, Glycated Hemoglobin (HbA1c), Lipids, Prothrombin Time (INR-POCT), Qualitative Urine Analysis (Urine stick), Therapeutic Drugs, Urine Chemistry, Urine Sediment for Light Scattering Methods, Urine Sediment for Microscopic Methods.

HEMATOLOGY

Blood Grouping, Erythrocyte Sedimentation Rate, Erythrocyte Sedimentation Rate for Alcor Analysers, Erythrocyte Sedimentation Rate for Alifax Analysers, Erythrocyte Sedimentation Rate for Mindray, Hemogram, Hemogram incl. 3-part Diff., Hemogram incl. 5-part Diff., Immunohematology.

IMMUNOASSAYS

Antinuclear Antibodies, Cyclic Citrullinated Peptide Antibodies, hCG in Serum, Hormones, Procalcitonin, Specific Proteins, Thyroid Antibodies, Tumor Markers, Tumor Markers & Hormones.

MOLECULAR DIAGNOSTICS

HBV Molecular, HCV Molecular HIV Molecular Human Papilloma Virus Molecular Respiratory Pathogens Molecular Sexually Transmitted Infections Molecular

MICROBIOLOGY

Adenovirus & Rotavirus Stool Antigen, Adenovirus Serology, Aspergillus Fumigatus Serology, Aspergillus Galactomannan Antigen, Bacteriology, Bacteriology Blood Culture, Bacteriology Urine Culture, Bordetella Serology, Borrelia IgG Antibody Index, Borrelia IgM Antibody Index, Borrelia Serology, Brucella Serology, Chagas Serology, Chikungunya Virus Serology, Chlamydia Trachomatis Serology, Clostridium difficile Stool Antigen, Coxsackievirus Serology, Dengue Virus Antibodies, Dengue Virus NS1 Antigen, ECHO Virus Serology, Enterovirus Serology, Epstein-Barr Virus Serology, Helicobacter Pylori Antibodies, Helicobacter Pylori Antigen, Hepatitis A Virus Serology, Hepatitis B Virus Serology, Hepatitis E Virus Serology, HIV Antibodies and Antigen, HTLV I/II, Infectious Disease Combination Control (HBV, HCV, HIV) Serology, Influenza A Virus Serology, Influenza B Virus Serology, Legionella Pneumophila Antibodies, Leptospira Serology, Malaria Microscopy, Measles Serology, Mycoplasma Antibodies, Norovirus Stool Antigen, Parainfluenza Virus Serology, Parvovirus B19 Serology, Respiratory Syncytial Virus Serology, Respiratory Viral Antigen Detection, SARS-CoV-2 Antigen, SARS-CoV-2 Serology, Streptococcus A Antigen, Syphilis Serology, TBEV IgG Antibody Index, TBEV IgM Antibody Index, ToRCH Serology, Varicella Zoster Virus Serology, West Nile Virus Serology, Zika Virus Serology.

EXTERNAL QUALITY ASSESSMENT BY ESfEQA

Quality Standards in Medical Laboratories

A high standard of quality is essential for every medical laboratory, as laboratory test results form the basis for medical decisions and have an important impact on patient care and treatment.

There are different approaches to maintaining and improving quality in medical laboratories. **ESfEQA supports laboratories in assessing the quality of their analytical results and continuously improving their performance through well-designed External Quality Assessment (EQA) programs.**

ESfEQA was founded in Heidelberg, Germany, in 2013 and is accredited according to the international standard **ISO 17043:2023** by the German national accreditation body DAkkS. Since its foundation, ESfEQA has continuously expanded its programme portfolio as well as the number of participating laboratories and distributors worldwide. Today, ESfEQA offers more than **130 quantitative, qualitative and educational EQA programs** covering areas such as biochemistry, haematology, immunoassays, microbiology and molecular diagnostics.

TEQA 2.0 – A Modernized EQA Platform

The continuous and significant growth in distributors, EQA programs and participating laboratories has created new requirements for the management of EQA activities. TEQA 2.0 has been developed to meet the current needs of distributors, participants and the ESfEQA team, providing a more efficient, intuitive and user-friendly experience. Key improvements include:

- **Improved configuration workflow** – methods can be preselected for each analyte, while instrument selection is streamlined into two steps: manufacturer and model type.
- **Modernized user interface** – a more intuitive environment for managing EQA participation and results.
- **Automated account activation** – access to TEQA 2.0 is automatically activated when EQA surveys are ordered.
- **Multilingual support** – the platform is available in English, Spanish and German. The addition of more language is in progress.
- **Flexible instrument management** – participants can add and manage multiple instruments within a program, as applicable.

Participants submit their results and access the corresponding EQA reports through TEQA 2.0 ESfEQA evaluates participants' results in accordance with **ISO 13528** and provides the corresponding reports electronically through the platform. Reports from previous surveys remain accessible in the TEQA 2.0 database, allowing participants to review and download their historical results when required.

External Quality Assessment Reports

This manual is intended to help participants understand and interpret ESfEQA survey reports and statistical evaluations. The reports are designed to provide detailed information on laboratory performance, helping participants assess their results, identify potential areas for improvement and monitor performance over time.

ESfEQA reports compare laboratory results with those obtained by other laboratories using the same analytical system, including the same instrument or reagent, while also providing information for comparison with other instruments and analytical methods. This broader comparison is important because the medical interpretation of laboratory results is generally independent of a particular instrument, method or reagent brand.

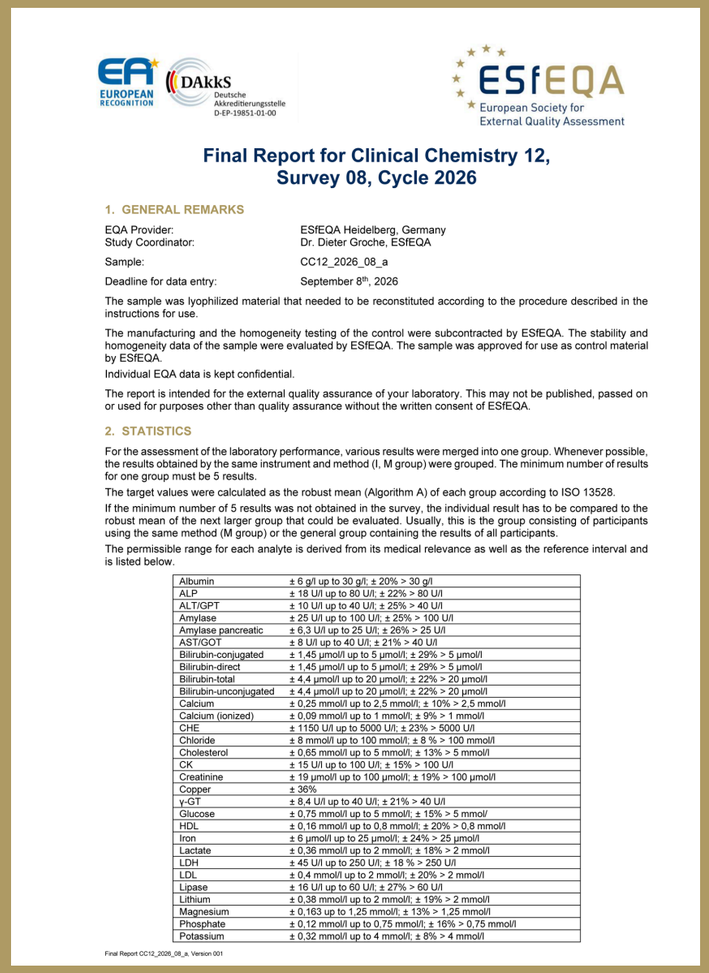
In addition to detailed statistical information, ESfEQA reports include a summary of laboratory performance at a glance, providing a quick overview of the main results and performance indicators.
The reports for quantitative analytes, for example in Clinical Chemistry, Hormones or Haematology, consist of several sections. The structure and interpretation of each section are described in the following chapters of this manual.

Participants receive their survey reports electronically as PDF files through TEQA 2.0. Reports can be downloaded, saved electronically or shared as required. Although individual pages or sections may be printed, the reports are primarily designed for digital use within the TEQA 2.0 platform.

STRUCTURE OF ESfEQA REPORTS

1

Cover Page



EUROPEAN RECOGNITION · DAkkS Deutsche Akkreditierungsstelle D-EP-19851-01-00

ESfEQA European Society for External Quality Assessment

Final Report for Clinical Chemistry 12, Survey 08, Cycle 2026

1. GENERAL REMARKS

EQA Provider: ESfEQA Heidelberg, Germany
Study Coordinator: Dr. Dieter Groche, ESfEQA

Sample: CC12_2026_08_a

Deadline for data entry: September 8th, 2026

The sample was 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 control were subcontracted by ESfEQA. The stability and homogeneity data of the sample were evaluated by ESfEQA. The sample was 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. Whenever possible, the results obtained by the same instrument and method (I, M group) were grouped. The minimum number of results for one group must be 5 results.

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

If the minimum number of 5 results was not obtained in the survey, the individual result has to be compared to the robust mean of the next larger group that could be evaluated. Usually, this is the group consisting of participants using the same method (M group) or the general group containing the results of all participants.

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

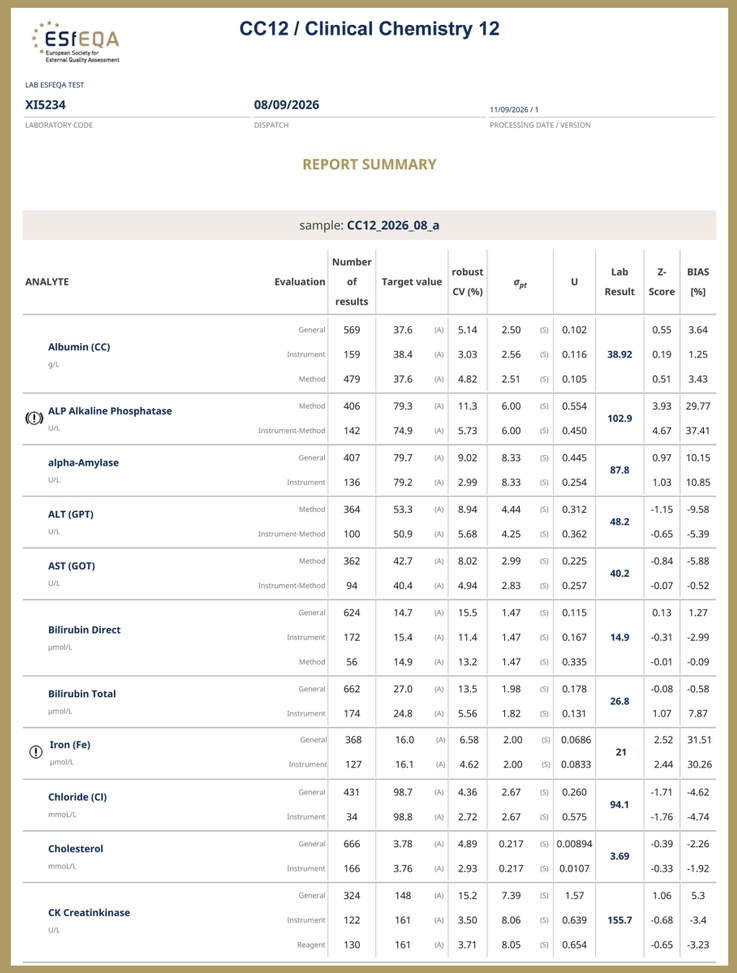
Albumin	± 6 g/l up to 30 g/l; ± 20% > 30 g/l
ALP	± 18 U/l up to 80 U/l; ± 22% > 80 U/l
ALT/GPT	± 10 U/l up to 40 U/l; ± 25% > 40 U/l
Amylase	± 25 U/l up to 100 U/l; ± 25% > 100 U/l
Amylase pancreatic	± 6,3 U/l up to 25 U/l; ± 26% > 25 U/l
AST/GOT	± 8 U/l up to 40 U/l; ± 21% > 40 U/l
Bilirubin-conjugated	± 1,45 µmol/l up to 5 µmol/l; ± 29% > 5 µmol/l
Bilirubin-direct	± 1,45 µmol/l up to 5 µmol/l; ± 29% > 5 µmol/l
Bilirubin-total	± 4,4 µmol/l up to 20 µmol/l; ± 22% > 20 µmol/l
Bilirubin-unconjugated	± 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
Calcium (ionized)	± 0,09 mmol/l up to 1 mmol/l; ± 9% > 1 mmol/l
CHE	± 1150 U/l up to 5000 U/l; ± 23% > 5000 U/l
Chloride	± 8 mmol/l up to 100 mmol/l; ± 8 % > 100 mmol/l
Cholesterol	± 0,65 mmol/l up to 5 mmol/l; ± 13% > 5 mmol/l
CK	± 15 U/l up to 100 U/l; ± 15% > 100 U/l
Creatinine	± 19 µmol/l up to 100 µmol/l; ± 19% > 100 µmol/l
Copper	± 36%
γ-GT	± 8,4 U/l up to 40 U/l; ± 21% > 40 U/l
Glucose	± 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	± 6 µmol/l up to 25 µmol/l; ± 24% > 25 µmol/l
Lactate	± 0,36 mmol/l up to 2 mmol/l; ± 18% > 2 mmol/l
LDH	± 45 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 60 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

Final Report CC12_2026_08_a, Version 001

- **EQA Program Name**
- **Survey and Sample Description**
- **Medical Relevance Ranges**
- **Target Values for Qualitative Tests - Statistical Procedure**
- **Survey-Specific Comments**

2

Summary Page (for quantitative surveys)



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CC12 / Clinical Chemistry 12

LAB ESFEQA TEST: XI5234 (LABORATORY CODE) · 08/09/2026 (DISPATCH) · 11/09/2026 / 1 (PROCESSING DATE / VERSION)

REPORT SUMMARY

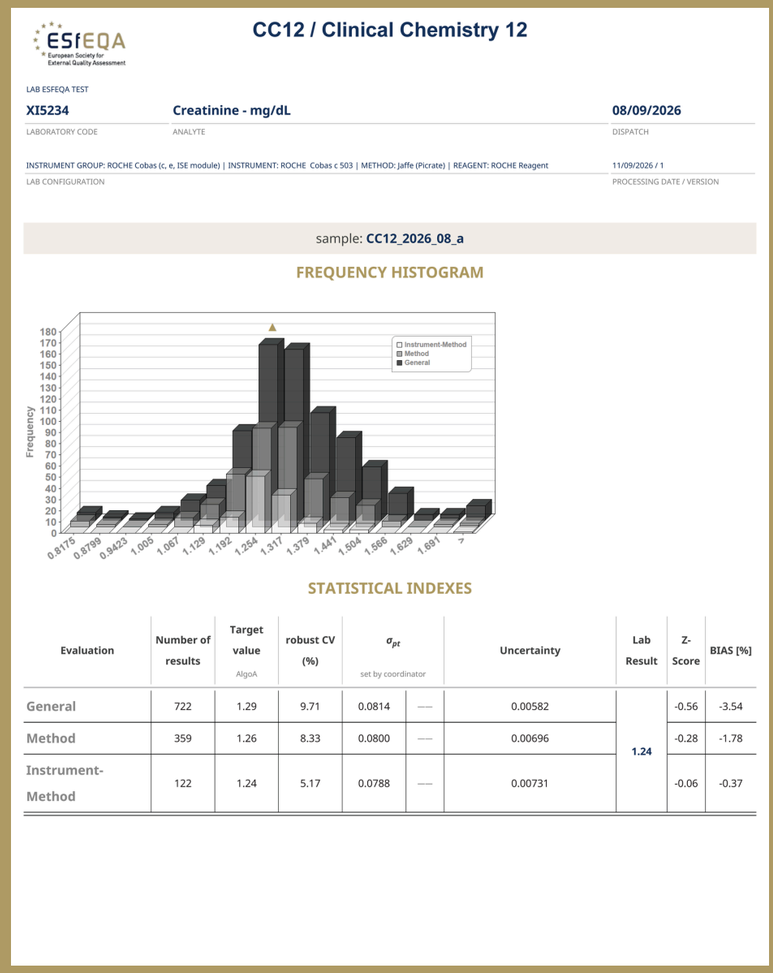
sample: **CC12_2026_08_a**

ANALYTE	Evaluation	Number of results	Target value	robust CV (%)	σ_{pt}	U	Lab Result	Z-Score	BIAS [%]
Albumin (CC) g/L	General	569	37.6 (A)	5.14	2.50 (S)	0.102	38.92	0.55	3.64
	Instrument	159	38.4 (A)	3.03	2.56 (S)	0.116		0.19	1.25
	Method	479	37.6 (A)	4.82	2.51 (S)	0.105		0.51	3.43
ALP Alkaline Phosphatase U/L	Method	406	79.3 (A)	11.3	6.00 (S)	0.554	102.9	3.93	29.77
	Instrument-Method	142	74.9 (A)	5.73	6.00 (S)	0.450		4.67	37.41
alpha-Amylase U/L	General	407	79.7 (A)	9.02	8.33 (S)	0.445	87.8	0.97	10.15
	Instrument	136	79.2 (A)	2.99	8.33 (S)	0.254		1.03	10.85
ALT (GPT) U/L	Method	364	53.3 (A)	8.94	4.44 (S)	0.312	48.2	-1.15	-9.58
	Instrument-Method	100	50.9 (A)	5.68	4.25 (S)	0.362		-0.65	-5.39
AST (GOT) U/L	Method	362	42.7 (A)	8.02	2.99 (S)	0.225	40.2	-0.84	-5.88
	Instrument-Method	94	40.4 (A)	4.94	2.83 (S)	0.257		-0.07	-0.52
Bilirubin Direct µmol/L	General	624	14.7 (A)	15.5	1.47 (S)	0.115	14.9	0.13	1.27
	Instrument	172	15.4 (A)	11.4	1.47 (S)	0.167		-0.31	-2.99
	Method	56	14.9 (A)	13.2	1.47 (S)	0.335		-0.01	-0.09
Bilirubin Total µmol/L	General	662	27.0 (A)	13.5	1.98 (S)	0.178	26.8	-0.08	-0.58
	Instrument	174	24.8 (A)	5.56	1.82 (S)	0.131		1.07	7.87
Iron (Fe) µmol/L	General	368	16.0 (A)	6.58	2.00 (S)	0.0686	21	2.52	31.51
	Instrument	127	16.1 (A)	4.62	2.00 (S)	0.0833		2.44	30.26
Chloride (Cl) mmol/L	General	431	98.7 (A)	4.36	2.67 (S)	0.260	94.1	-1.71	-4.62
	Instrument	34	98.8 (A)	2.72	2.67 (S)	0.575		-1.76	-4.74
Cholesterol mmol/L	General	666	3.78 (A)	4.89	0.217 (S)	0.00894	3.69	-0.39	-2.26
	Instrument	166	3.76 (A)	2.93	0.217 (S)	0.0107		-0.33	-1.92
CK Creatinkinase U/L	General	324	148 (A)	15.2	7.39 (S)	1.57	155.7	1.06	5.3
	Instrument	122	161 (A)	3.50	8.06 (S)	0.639		-0.68	-3.4
	Reagent	130	161 (A)	3.71	8.05 (S)	0.654		-0.65	-3.23

- **Summary of Statistical Indices for the Reported Analytes**

3

Analyte-specific Information (for quantitative surveys)



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CC12 / Clinical Chemistry 12

LAB ESFEQA TEST: XI5234 (LABORATORY CODE) · Creatinine - mg/dL (ANALYTE) · 08/09/2026 (DISPATCH)

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent (LAB CONFIGURATION) · 11/09/2026 / 1 (PROCESSING DATE / VERSION)

sample: **CC12_2026_08_a**

FREQUENCY HISTOGRAM

STATISTICAL INDEXES

Evaluation	Number of results	Target value (AlgoA)	robust CV (%)	σ_{pt} (set by coordinator)		Uncertainty	Lab Result	Z-Score	BIAS [%]
General	722	1.29	9.71	0.0814	——	0.00582	1.24	-0.56	-3.54
Method	359	1.26	8.33	0.0800	——	0.00696		-0.28	-1.78
Instrument-Method	122	1.24	5.17	0.0788	——	0.00731		-0.06	-0.37

- **Frequency Histogram**
- **Individual Statistical Indices**

STRUCTURE OF ESfEQA REPORTS

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Statistical Comparison (for quantitative surveys)

CC12 / Clinical Chemistry 12

LAB ESFEQA TEST

XI5234	Creatinine - mg/dL	08/09/2026
LABORATORY CODE	ANALYTE	DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent — 11/09/2026 / 1

LAB CONFIGURATION — PROCESSING DATE / VERSION

sample: **CC12_2026_08_a**

Statistical Comparison

	Evaluation	Number of results	Target value (AlgoA)	σ_{pt} (set by coordinator)		Uncertainty *	robust CV (%)
General							
1	General	722	1.29	0.0814	–	0.00582	9.71
Method							
2	Dry chemistry	32	1.40	0.0885	–	0.0399	12.9
3	Enzymatic	178	1.34	0.0848	–	0.0104	8.32
4	GOD-PAP	7	1.36	0.0863	–	0.0874	13.6
5	Jaffe (Picrate)	359	1.26	0.0800	–	0.00696	8.33
6	Jaffe compensated (kinetic)	70	1.23	0.0780	–	0.0149	8.03
7	Other	76	1.26	0.0799	–	0.0237	13.0
Instrument-Method							
8	ABBOTT Alinity Enzymatic	8	1.24	0.0784	–	0.0208	3.79
9	ABBOTT Architect Enzymatic	10	1.24	0.0783	–	0.00805	1.65
10	ABBOTT Architect Jaffe (Picrate)	8	1.28	0.0814	–	0.0215	3.78
11	BECKMAN COULTER AU Enzymatic	18	1.43	0.0904	–	0.0495	11.8
12	BECKMAN COULTER AU Jaffe (Picrate)	29	1.20	0.0758	–	0.0232	8.35
13	BECKMAN COULTER AU Jaffe compensated (kinetic)	8	1.23	0.0782	–	0.0499	9.14
14	BIOSYSTEMS Jaffe (Picrate)	10	1.25	0.0794	–	0.0573	11.6
15	BIOTECNICA INSTRUMENTS BT Series Jaffe (Picrate)	6	1.29	0.0817	–	0.0858	13.0
16	DIASYS Respons Series	7	1.35	0.0855	–	0.0594	9.32

5

Shewhart chart

CC12 / Clinical Chemistry 12

LAB ESFEQA TEST

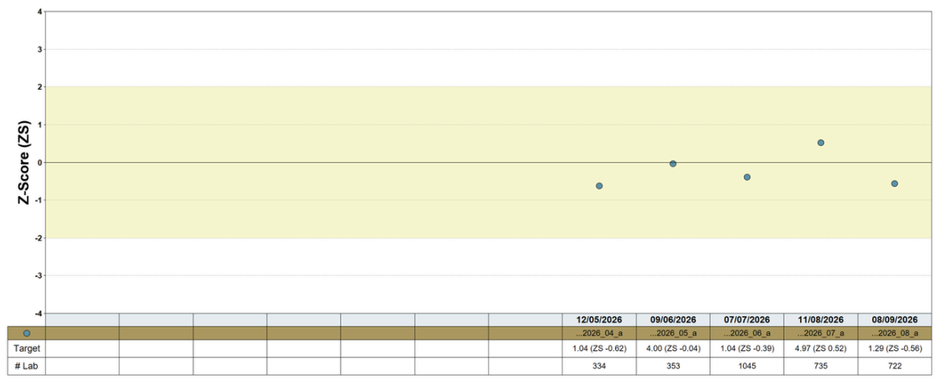
XI5234	Creatinine - mg/dL	08/09/2026
LABORATORY CODE	ANALYTE	DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent — 11/09/2026 / 1

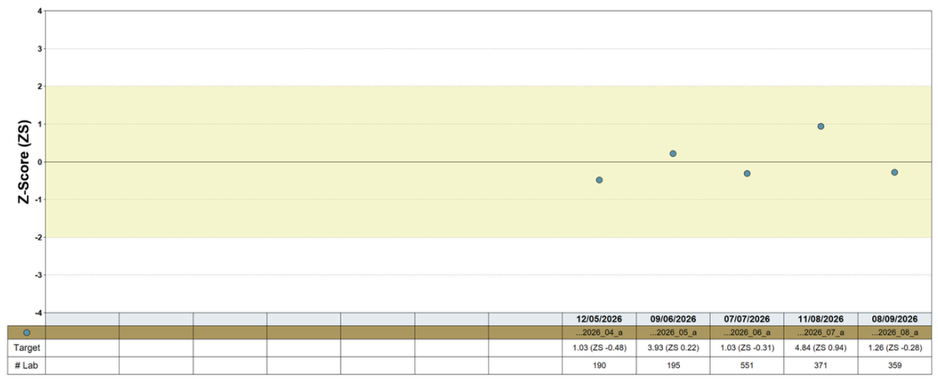
LAB CONFIGURATION — PROCESSING DATE / VERSION

SHEWHART

General



Method



STRUCTURE OF ESfEQA REPORTS

6

Summary Page (for qualitative surveys)

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INF4 / Infectious Disease Combination Control 4

LAB ESFEQA TEST		
XI5234	18/05/2026	03/06/2026 / 1
LABORATORY CODE	DISPATCH	PROCESSING DATE / VERSION

REPORT SUMMARY

sample: **INF4_2026_02_a**

ANALYTE	Lab Result	Expected Result(s)	Evaluation
anti-HCV	negative	negative	Passed
anti-HIV / p24 antigen	negative	negative	Passed

sample: **INF4_2026_02_b**

ANALYTE	Lab Result	Expected Result(s)	Evaluation
anti-HCV	negative	negative	Passed
anti-HIV / p24 antigen	positive	positive	Passed

- **Summary of Qualitative Results**
- **Evaluation approval**

7

Analyte-specific Information (for qualitative surveys)

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European Society for External Quality Assessment

INF12 / Infectious Disease Combination Control 12

LAB ESFEQA TEST		
XI5234	anti-HCV	07/07/2026
LABORATORY CODE	ANALYTE	DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas e 601 | METHOD: Electrochemiluminescence (ECLIA) | REAGENT: ROCHE Reagent

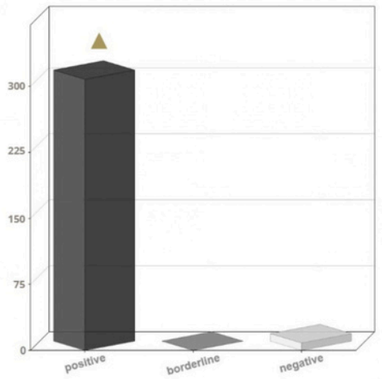
LAB CONFIGURATION	PROCESSING DATE / VERSION
	13/07/2026 / 1

sample: **INF12_2026_06_a**

Expected Result(s): **positive**

Lab Result: **positive**

Evaluation	positive	borderline	negative
General	310	0	2
Instrument			
ABBOTT Alinity	20	0	1
DIASORIN LIAISON XL	17	0	0
MACCURA i-series	4	0	0
MINDRAY CL System	1	0	0
NONE - MANUAL TESTING	158	0	0
ORTHO CLINICAL DIAGNOSTICS Vitros	3	0	0
ROCHE Cobas (c, e, ISE module)	71	0	1
SIEMENS ATELLICA	7	0	0
SIEMENS ATELLICA IM 1300/1600	3	0	0
SNIBE MAGLUMI	25	0	0
YHLO iFlash	1	0	0
Method			
Chemiluminescence (CLIA/CMIA)	105	0	1
Electrochemiluminescence (ECLIA)	422	0	1
Immunochromatography	163	0	0



- **Table of Qualitative Results**
- **Bar Chart for the Analyte**

STRUCTURE OF ESfEQA REPORTS

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Cycle Report

This tool will be implemented soon.

- **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.**

Cover Page

1 → EUROPEAN RECOGNITION · DAkkS Deutsche Akkreditierungsstelle D-EP-19851-01-00

ESfEQA European Society for External Quality Assessment

2 → **Final Report for Clinical Chemistry 12, Survey 08, Cycle 2026**

1. GENERAL REMARKS

EQA Provider: ESfEQA Heidelberg, Germany
Study Coordinator: Dr. Dieter Groche, ESfEQA ← 3
Sample: 4 → CC12_2026_08_a
Deadline for data entry: September 8th, 2026 ← 5

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

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6 → **2. STATISTICS**

For the assessment of the laboratory performance, various results were merged into one group. Whenever possible, the results obtained by the same instrument and method (I, M group) were grouped. The minimum number of results for one group must be 5 results.

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

If the minimum number of 5 results was not obtained in the survey, the individual result has to be compared to the robust mean of the next larger group that could be evaluated. Usually, this is the group consisting of participants using the same method (M group) or the general group containing the results of all participants.

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

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Bilirubin-conjugated	± 1,45 µmol/l up to 5 µmol/l; ± 29% > 5 µmol/l
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Creatinine	± 19 µmol/l up to 100 µmol/l; ± 19% > 100 µmol/l
Copper	± 36%
γ-GT	± 8,4 U/l up to 40 U/l; ± 21% > 40 U/l
Glucose	± 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	± 6 µmol/l up to 25 µmol/l; ± 24% > 25 µmol/l
Lactate	± 0,36 mmol/l up to 2 mmol/l; ± 18% > 2 mmol/l
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LDL	± 0,4 mmol/l up to 2 mmol/l; ± 20% > 2 mmol/l
Lipase	± 16 U/l up to 60 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

← 7

8 → Final Report CC12_2026_08_a, Version 001

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Cover Page

1 DAkkS : German national accreditation body
EA MLA – European recognition of accreditation

2 EQA Program Name

3 Study Coordinator

4 Sample ID: EQA_Frequency_Year_Event_Sample
Example: CC12_2026_08_a
- CC = EQA name
- 12 = frequency (12 = monthly, 4 = quarterly, 2 = semiannual)
- 2026 = year
- 08 = event number within the year
- a/b/c/d = sample (monthly schemes have only sample a)

See the EQA Catalogue for further details.

5 Deadline for data entry : Available in the current **Report Calendar** in the Esfeqa homepage.

6 Statistical Procedure : Accoding ISO 13528

7 Medical Relevance Ranges : For most quantitative analytes, ESfEQA, in collaboration with scientific advisors, defines a relative permissible deviation (in %) and, below a specified concentration threshold, an absolute permissible deviation (expressed in the analyte's unit, e.g., U/L or mmol/L).

8 Sample name and version

Summary Page

The summary page lists all analytes that were determined by the participant and that were statistically evaluated.

ESfEQA European Society for External Quality Assessment

CC12 / Clinical Chemistry 12

LAB ESFEQA TEST

XI5234	08/09/2026	11/09/2026 / 1
LABORATORY CODE	DISPATCH	PROCESSING DATE / VERSION

REPORT SUMMARY

sample: CC12_2026_08_a

ANALYTE	Evaluation	Number of results	Target value	robust CV (%)	σ_{pt}	U	Lab Result	Z-Score	BIAS [%]
Albumin (CC) g/L	General	569	37.6 (A)	5.14	2.50 (S)	0.102		0.55	3.64
	Instrument	159	38.4 (A)	3.03	2.56 (S)	0.116	38.92	0.19	1.25
	Method	479	37.6 (A)	4.82	2.51 (S)	0.105		0.51	3.43
ALP Alkaline Phosphatase U/L	Method	406	79.3 (A)	11.3	6.00 (S)	0.554	102.9	3.93	29.77
	Instrument-Method	142	74.9 (A)	5.73	6.00 (S)	0.450		4.67	37.41
alpha-Amylase U/L	General	407	79.7 (A)	9.02	8.33 (S)	0.445	87.8	0.97	10.15
	Instrument	136	79.2 (A)	2.99	8.33 (S)	0.254		1.03	10.85
ALT (GPT) U/L	Method	364	53.3 (A)	8.94	4.44 (S)	0.312	48.2	-1.15	-9.58
	Instrument-Method	100	50.9 (A)	5.68	4.25 (S)	0.362		-0.65	-5.39
AST (GOT) U/L	Method	362	42.7 (A)	8.02	2.99 (S)	0.225	40.2	-0.84	-5.88
	Instrument-Method	94	40.4 (A)	4.94	2.83 (S)	0.257		-0.07	-0.52
Bilirubin Direct µmol/L	General	624	14.7 (A)	15.5	1.47 (S)	0.115	14.9	0.13	1.27
	Instrument	172	15.4 (A)	11.4	1.47 (S)	0.167		-0.31	-2.99
	Method	56	14.9 (A)	13.2	1.47 (S)	0.335		-0.01	-0.09
Bilirubin Total µmol/L	General	662	27.0 (A)	13.5	1.98 (S)	0.178	26.8	-0.08	-0.58
	Instrument	174	24.8 (A)	5.56	1.82 (S)	0.131		1.07	7.87
Iron (Fe) µmol/L	General	368	16.0 (A)	6.58	2.00 (S)	0.0686	21	2.52	31.51
	Instrument	127	16.1 (A)	4.62	2.00 (S)	0.0833		2.44	30.26

Header

1. Dispatch: The deadline for result submission is displayed
2. The processing date and version indicate when the statistical evaluation of the survey was performed and which version of the evaluation is provided. Typically, only a single version (version 1) is available

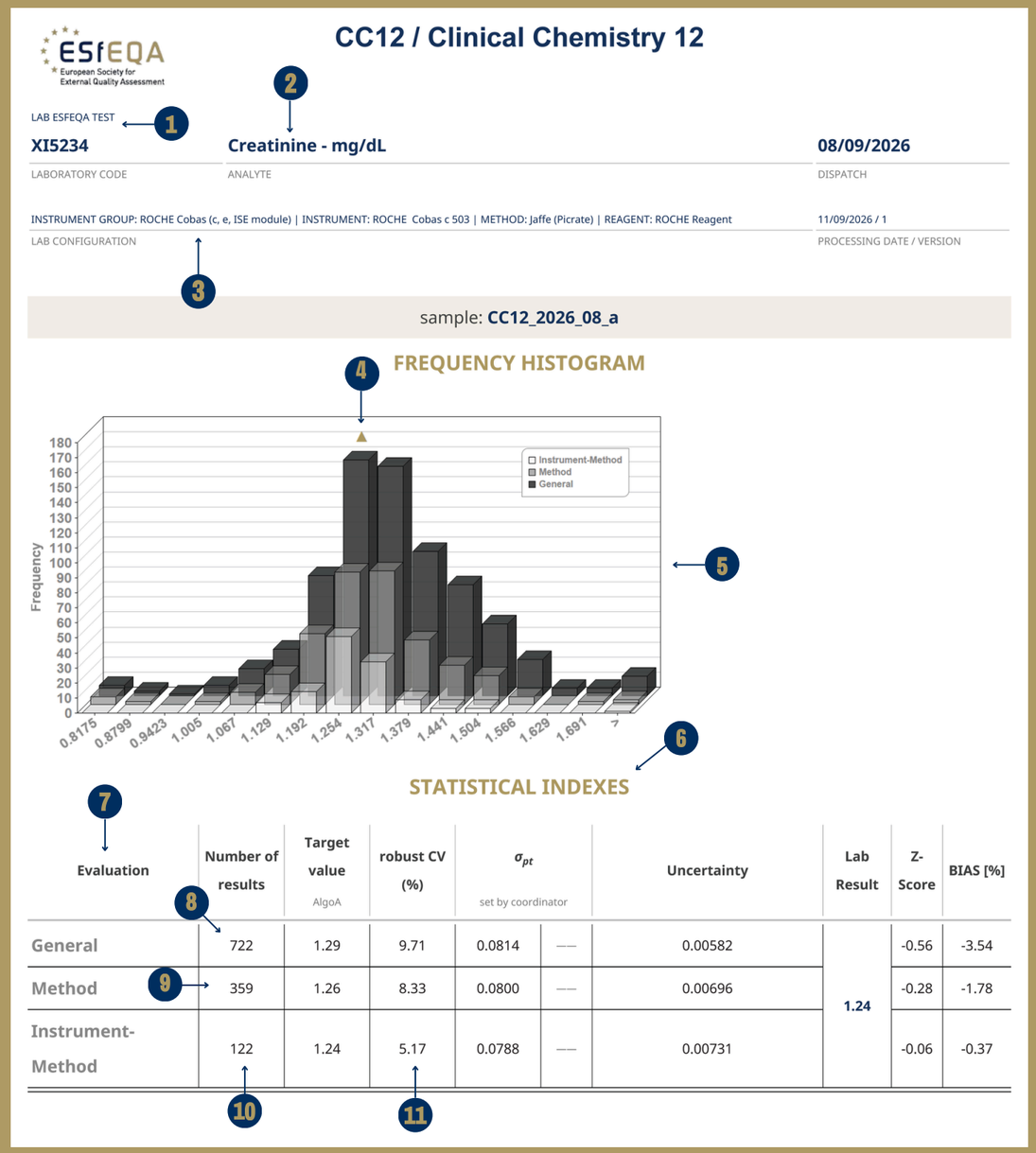
Report Summary

3. Sample ID
4. Units: Units indicated in the report reflect the units that were used by the participant for result submission
5. Evaluated groups: For this example (Albumin), results are reported for the general group, the instrument group and the method group (which may also refer to combinations between groups or reagent). The general group comprises all participants who submitted results for this analyte.
   The instrument (method or reagent) group includes all laboratories using the same instrument, method, or reagent as the participant in this report. ESfEQA defines the appropriate evaluation groups for each analyte
6. Target values of the evaluated groups: Target values may be group-specific; for example, the target value for the general group may differ from that of the instrument group, and target values across instrument groups may be instrument-specific
7. Statistical basis for the determination of target values:
   (A) = Calculated as robust mean (Algorithm A) according to ISO 13528
   (G) = Consensus value of expert group
   (R) = Certified reference material
   (C) = Reference value
   (S) = Set by survey coordinator
   (I) = Interquartile range
8. CVrobust: Robust Coefficient of Variation
   $$CV_{robust} = \frac{s^*}{X} \times 100$$
   where s* is the robust standard deviation calculated using Algorithm A and X is the target value
9. σpt (Standard Deviation for Proficiency Testing)
   σpt :Is calculated according to the applicable deviation type:
   Relative deviation: σpt = (permissible deviation [%] / 100) / 3 × X, where X is the target value.
   Absolute deviation: σpt = permissible deviation /3
   (E) = Determined by experiment
   (N)= Determined as non-robust SD
   (S) = Set by survey coordinator
   In most ESfEQA surveys, σpt for each analyte is derived from its medical relevance and reference interval. The permissible range for each analyte is indicated on the Cover Page
10. U = Uncertainty of the target value, calculated as:
    U = 1,25 · s*/√p (s* as robust standard deviation calculated by the Algorithm A and p as number of results). An uncertainty above 0,3 · σpt is not negligible and might result in an inappropriate calculation of the z-score
11. Number of laboratories that submitted results for this analyte in all the evaluated groups
12. Z-score, calculated as:
    ZS = (x-X)/ σpt (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 lab result to the target value in percentage
14. If all z-scores (e.g. for general, instrument or reagent group) for one analyte are above 2,0 or below -2,0 this symbol (!) will be displayed and shall be considered as a warning signal
15. If all z-scores (e.g. for general, instrument or reagent group) for one analyte are above 3,0 or below -3,0 this symbol (!) will be displayed and shall be considered as an action signal

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.

Analyte Specific Information (quantitative surveys)

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



ESfEQA
European Society for External Quality Assessment

CC12 / Clinical Chemistry 12

LAB ESFEQA TEST (1): **XI5234** — LABORATORY CODE

(2): **Creatinine - mg/dL** — ANALYTE

08/09/2026 — DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent — LAB CONFIGURATION (3)

11/09/2026 / 1 — PROCESSING DATE / VERSION

sample: **CC12_2026_08_a**

FREQUENCY HISTOGRAM (4)

STATISTICAL INDEXES

Evaluation (7)	Number of results (8)	Target value AlgoA	robust CV (%)	σ_{pt} set by coordinator		Uncertainty	Lab Result	Z-Score	BIAS [%]
General	722	1.29	9.71	0.0814	––	0.00582	1.24	-0.56	-3.54
Method (9)	359	1.26	8.33	0.0800	––	0.00696		-0.28	-1.78
Instrument-Method	122 (10)	1.24	5.17 (11)	0.0788	––	0.00731		-0.06	-0.37

Header

1. Laboratory code and laboratory name
2. The name of the analyte and the configurated unit
3. Lab configuration: Analyte-specific configuration within the survey. The evaluated participant groups (e.g., General-Instrument – Method) are defined according to the kind of EQA and the participant's configuration. In this example, the groups are:
   - Instrument group: (ROCHE cobas [c, e, ISE modules]): Several comparable instruments from the same manufacturer may be combined into a single group if they have similar technical characteristics
   - Instrument: Specific participant instrument model (ROCHE cobas c 503)
   - Method: Technical-specific method (Jaffe picrate)
   - Reagent: Technical-specific reagent name (ROCHE Reagent)

Frequency Histograms

4. The triangle mark indicates the location of the value submitted by the participant
5. The FREQUENCY HISTOGRAMS indicate the result distributions of the relevance groups (e.g. general, method and instrument/ method) that were evaluated. In this example:

   • General (all participants in that survey)
   • Method: (all participants that use that specific method)
   • Instrument/Method group: All the participants that use the same combination of instrument and method.

Statistical Indices

6. 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 number of results that were considered for the statistical evaluation, the robust CV (%) , the σpt, the uncertainty of the assigned value. 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 percentage)
7. Groups in which the result of the participant was evaluated
8. Number of results submitted for the selected analyte (in this example, 'Creatinine') in the general group
9. Number of results submitted for the selected analyte (in this example, Creatinine) in the method group "Jaffe Picrate"
10. Number of results submitted for the selected analyte (in this example, 'Creatinine') in the instrument/ method group "Roche cobas c 503/ Jaffe Picrate"
11. CVrobust: Robust Coefficient of Variation

$$CV_{robust} = \frac{s^*}{X} \times 100$$

where s* is the robust standard deviation calculated using Algorithm A and X is the target value

Statistical Comparison (quantitative surveys)

LAB ESFEQA TEST

XI5234	Creatinine - mg/dL	08/09/2026
LABORATORY CODE	ANALYTE	DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent — LAB CONFIGURATION

11/09/2026 / 1 — PROCESSING DATE / VERSION

sample: **CC12_2026_08_a**

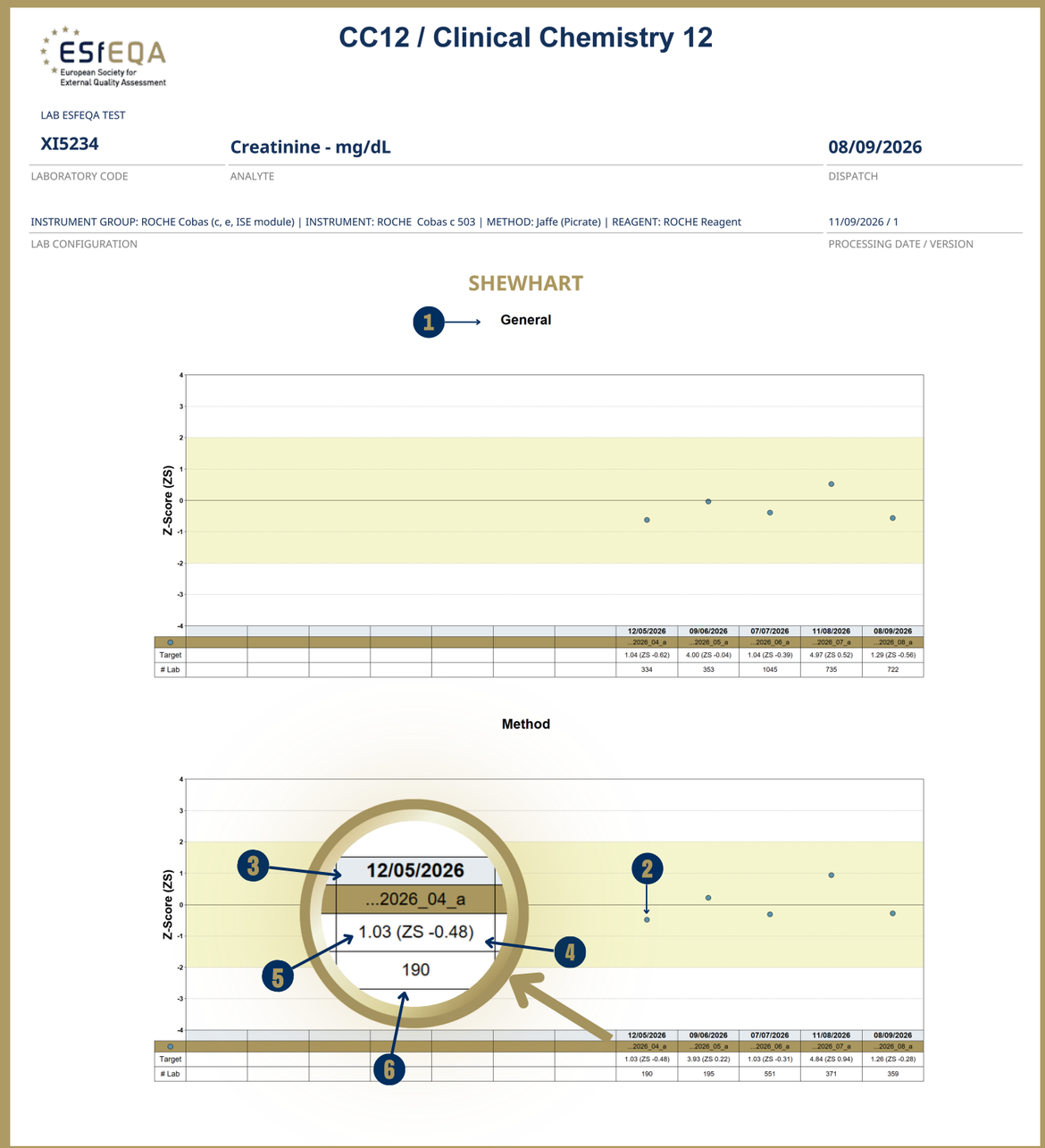
Statistical Comparison

Evaluation	Number of results	Target value (AlgoA)	σ_{pt} (set by coordinator)		Uncertainty *	robust CV (%)
General						
1 General	722	1.29	0.0814	–	0.00582	9.71
Method						
2 Dry chemistry	32	1.40	0.0885	–	0.0399	12.9
3 Enzymatic	178	1.34	0.0848	–	0.0104	8.32
4 GOD-PAP	7	1.36	0.0863	–	0.0874	13.6
5 Jaffe (Picrate)	359	1.26	0.0800	–	0.00696	8.33
6 Jaffe compensated (kinetic)	70	1.23	0.0780	–	0.0149	8.03
7 Other	76	1.26	0.0799	–	0.0237	13.0
Instrument-Method						
8 ABBOTT Alinity Enzymatic	8	1.24	0.0784	–	0.0208	3.79
9 ABBOTT Architect Enzymatic	10	1.24	0.0783	–	0.00805	1.65
10 ABBOTT Architect Jaffe (Picrate)	8	1.28	0.0814	–	0.0215	3.78
11 BECKMAN COULTER AU Enzymatic	18	1.43	0.0904	–	0.0495	11.8
12 BECKMAN COULTER AU Jaffe (Picrate)	29	1.20	0.0758	–	0.0232	8.35
13 BECKMAN COULTER AU Jaffe compensated (kinetic)	8	1.23	0.0782	–	0.0499	9.14
14 BIOSYSTEMS Jaffe (Picrate)	10	1.25	0.0794	–	0.0573	11.6
15 BIOTECNICA INSTRUMENTS BT Series Jaffe (Picrate)	6	1.29	0.0817	–	0.0858	13.0
16 DIASYS Respons Series	7	1.35	0.0855	–	0.0594	9.32

Statistical Comparison

The table STATISTICAL COMPARISON indicates the number of results, the target value, the σpt, the uncertainty of the calculated target value and the robust CV for each evaluated group for all the brands that participated

Shewhart chart



ESfEQA
European Society for External Quality Assessment

CC12 / Clinical Chemistry 12

LAB ESFEQA TEST

XI5234	Creatinine - mg/dL	08/09/2026
LABORATORY CODE	ANALYTE	DISPATCH

INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas c 503 | METHOD: Jaffe (Picrate) | REAGENT: ROCHE Reagent — LAB CONFIGURATION

11/09/2026 / 1 — PROCESSING DATE / VERSION

SHEWHART

1 General

	12/05/2026	09/06/2026	07/07/2026	11/08/2026	08/09/2026
	...2026_04_a	...2026_05_a	...2026_06_a	...2026_07_a	...2026_08_a
Target	1.04 (ZS -0.62)	4.00 (ZS -0.04)	1.04 (ZS -0.39)	4.97 (ZS 0.52)	1.29 (ZS -0.56)
# Lab	334	353	1045	735	722

Method

	12/05/2026	09/06/2026	07/07/2026	11/08/2026	08/09/2026
	...2026_04_a	...2026_05_a	...2026_06_a	...2026_07_a	...2026_08_a
Target	1.03 (ZS -0.48)	3.93 (ZS 0.22)	1.03 (ZS -0.31)	4.84 (ZS 0.94)	1.26 (ZS -0.28)
# Lab	190	195	551	371	359

Shewhart Chart

The SHEWHART CHART displays the z-scores of up to 12 previous surveys for the selected analyte of the EQA scheme, for all the evaluated groups in this example (General and Method)

1. Group of comparation
2. The participant's result plotted as a z-score
3. Sample name and deadline
4. Target value for the comparison group in this example (Method group = 1,03 mg/dL)
5. Participant Z-score (Zs = -0,48)
6. Number of participants in that group (Method: Jaffe Picrate = 190)

Summary Page (qualitative surveys)

ESfEQA
European Society for External Quality Assessment

US4 / Qualitative Urine Analysis (Urine Stick) 4

LAB ESFEQA TEST		
XI5234	18/05/2026	14/07/2026 / 2
LABORATORY CODE	DISPATCH	PROCESSING DATE / VERSION

REPORT SUMMARY

sample: **US4_2026_02_a**

ANALYTE	Lab Result	Expected Result(s)	Evaluation
Bilirubin	negative	negative	Passed
Blood/Erythrocytes/Hemoglobin	negative	negative	Passed
Glucose	negative	negative	Passed
Ketone bodies	negative	negative	Passed
Leukocytes	negative	negative	Passed
Nitrite	Negative	Negative	Passed
1 pH	2 6,0	5,0 5,5 6,0 3	Passed 4
Protein, total	negative	negative	Passed
Specific Gravity	1,030	1,015 1,020 1,025	Not Passed
Urobilinogen	< 30 µmol/l (< 2 mg/dl)	< 30 µmol/l (< 2 mg/dl)	Passed

4 - 7

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.

Report Summary

1. Analyte
2. Participant result
3. Expected result = Defined by ESfEQA; generally derived from sample pre-distribution assay results and may include more than one option
4. Result evaluation: if the laboratory result matches the expected result, the evaluation is 'Passed'; if the laboratory result differs from the expected result, the evaluation is 'Not Passed'

Analyte Specific Information (qualitative surveys)

ESfEQA
European Society for External Quality Assessment

INF12 / Infectious Disease Combination Control 12

LAB ESFEQA TEST		
XI5234	anti-HCV	07/07/2026
LABORATORY CODE	ANALYTE	DISPATCH

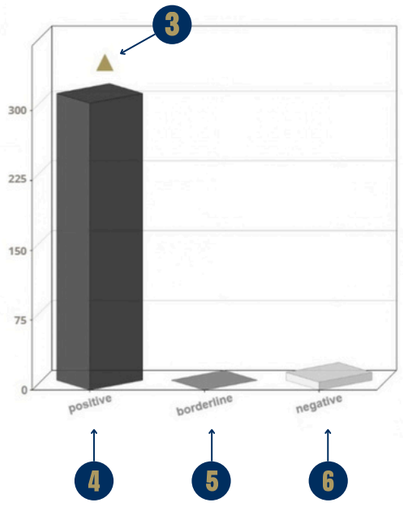
INSTRUMENT GROUP: ROCHE Cobas (c, e, ISE module) | INSTRUMENT: ROCHE Cobas e 601 | METHOD: Electrochemiluminescence (ECLIA) | REAGENT: ROCHE Reagent

	13/07/2026 / 1
LAB CONFIGURATION	PROCESSING DATE / VERSION

1 sample: **INF12_2026_06_a** 2

Expected Result(s): **positive** Lab Result: **positive**

Evaluation	positive	borderline	negative
General	310	0	2
7 Instrument			
ABBOTT Alinity	20	0	1
DIASORIN LIAISON XL	17	0	0
MACCURA i-series	4	0	0
MINDRAY CL System	1	0	0
NONE - MANUAL TESTING	158	0	0
ORTHO CLINICAL DIAGNOSTICS Vitros	3	0	0
ROCHE Cobas (c, e, ISE module)	71	0	1
SIEMENS ATELLICA	7	0	0
SIEMENS ATELLICA IM 1300/1600	3	0	0
SNIBE MAGLUMI	25	0	0
YHLO iFlash	1	0	0
Method 8			
Chemiluminescence (CLIA/CMIA)	105	0	1
Electrochemiluminescence (ECLIA)	422	0	1
Immunochromatography	163	0	0



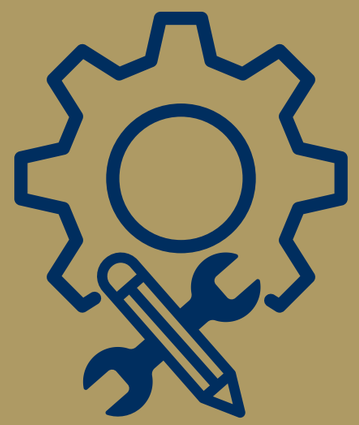
A table of results and a bar diagram illustrate the results for each analyte.

Analyte Specific Information (qualitative surveys)

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

1. Expected result = Defined by ESfEQA, usually derived from the results of predistribution testings of the sample
2. Lab result = Result submitted by participant
3. The triangle indicates the participant's result
4. Bar chart of results presented as "positive"
5. Bar chart of results presented as "borderline"
6. Bar chart of results presented as "negative"
7. Instruments that participated in the survey
8. Methods that were used in the survey

Currently under development



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