

# Cl Electrode

Chloride

## Order information

REF	CONTENT	Analyzer(s) on which the electrode can be used
03246353001	Cl Electrode 1 (electrode)	<b>cobas c 311</b> analyzer <b>cobas 6000</b> analyzer series: <b>cobas c 501</b> module <b>cobas 8000</b> modular analyzer series: <b>cobas 8000</b> ISE 900 / 1800 module <b>cobas pure</b> integrated solutions: <b>cobas c 303</b> analytical unit <b>cobas pro</b> integrated solutions: <b>cobas pro</b> ISE analytical unit, <b>cobas</b> ISE neo 900 analytical unit, <b>cobas</b> ISE neo 1800 analytical unit

Materials required (but not provided):

03149501001	REF Electrode (1 electrode)	
11360981216	ISE Reference Electrolyte (5 x 300 mL) ①②	
10820652216	ISE Reference Electrolyte (1 x 500 mL) ③④	
08392013190	ISE Reference Electrolyte (2 x 2000 mL) ⑤⑥	
04522320190	ISE Internal Standard Gen.2 (5 x 600 mL) ①②	
04880455190	ISE Internal Standard Gen.2 (2 x 2000 mL) ③④⑤	
09137742190	ISE Internal Standard Gen.2 conc. (1 x 510 mL) ⑥	
05979854190	Internal Standard Insert - ISE (Set of 20) ①②	
04522630190	ISE Diluent Gen.2 (5 x 300 mL) ①②	
04880480190	ISE Diluent Gen.2 (2 x 2000 mL) ③④⑤	
11298500316	ISE Cleaning Solution (5 x 100 mL)	
20763071122	ISE Deproteinizer (6 x 21 mL) ④⑤⑥	
03110435180	Deproteinizer (1 x 125 mL) ⑥	
04663632190	Activator (9 x 12 mL)	
11183974216	ISE Standard Low (10 x 3 mL)	Code 20502
11183982216	ISE Standard High (10 x 3 mL)	Codes 20503, 20763
12149435122	Precinorm U Plus (10 x 3 mL)	Code 20300
12149443122	Precipath U Plus (10 x 3 mL)	Code 20301
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392

ISE reagents on:

- ① **cobas c 311** analyzer
- ② **cobas 6000** analyzer series: **cobas c 501** module
- ③ **cobas 8000** modular analyzer series: **cobas 8000** ISE 900 / 1800 module
- ④ **cobas pure** integrated solutions: **cobas c 303** analytical unit
- ⑤ **cobas pro** integrated solutions: **cobas pro** ISE analytical unit
- ⑥ **cobas pro** integrated solutions: **cobas** ISE neo 900 analytical unit, **cobas** ISE neo 1800 analytical unit

## English

## System information

	ACN (Serum/ plasma)	ACN (Urine)	ACN (Plasma)	ACN (Serum)
	<b>ISE CL</b>	<b>ISE CL-U</b>	<b>ISE CL-P</b>	<b>ISE CL-S</b>
<b>cobas c 311</b> analyzer, <b>cobas c 501</b> module, <b>cobas 8000</b> ISE 900 / 1800 module	991	991	---	---

	ACN (Serum/ plasma)	ACN (Urine)	ACN (Plasma)	ACN (Serum)
	<b>ISE CL</b>	<b>ISE CL-U</b>	<b>ISE CL-P</b>	<b>ISE CL-S</b>
<b>cobas c 303</b> analytical unit, <b>cobas pro</b> ISE analytical unit	29090	29091	29092	29093

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	ACN (Serum/ plasma)	ACN (Urine)	ACN (Plasma)	ACN (Serum)
	CL	CL-U	CL-P	CL-S
cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit	29250	29251	29252	29253

## Intended use

The Cl Electrode is a device intended for the in-vitro quantitative determination of chloride in human origin serum, plasma and urine.

## Summary<sup>1</sup>

The chloride ion measurements may be useful for the diagnosis and monitoring purposes as an aid in diagnosing and monitoring chloride imbalance, including hypo- and hyperchloremia that can be associated with, or observed during a number of underlying disease states or pathological conditions.

## Test principle

Ion-selective electrode, using automatically diluted serum/plasma or urine specimens. The chloride electrode is based on an ion exchanger.<sup>2</sup>

## Calculation

The equation given below is used for the calculation of sample and/or QC results:

$$C_S = C_{IS} \times 10^{\frac{E_S - E_{IS}}{S}}$$

Where:

$C_S$	concentration of the ion in the sample
$C_{IS}$	concentration of the ion in the ISE Internal Standard
$E_S$	EMF of the sample
$E_{IS}$	EMF of the ISE Internal Standard
$S$	Slope of the electrode

The complete measurement system for a particular ion includes the ISE, a reference electrode and electronic circuits to measure and process the EMF to give the test ion concentration.

## Precautions and warnings

For in vitro diagnostic use for trained laboratory technicians.

### Warning

- Samples containing material of human origin are potentially infectious. Wear personal protective equipment when replacing or installing electrodes at analyzers. If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- If sample or waste contacts with your skin, wash the affected area immediately with soap and water, then apply a disinfectant. Consult a physician.
- When disposing of used electrodes, treat them as biohazardous.

### Caution

- Do not use electrodes after the shelf life or on-board stability period has expired. Otherwise, it may lead to unstable sodium, potassium, and chloride results due to the unstable potential reading of electrodes.
- Perchlorate medication may result in falsely high chloride results due to an interference of perchlorate with the Cl Electrode determinations.
- Perform electrode flow path cleaning as stated in the Instructions for Use for applicable analyzers, at the end of a daily sample run. Improper electrode flow path cleaning may cause unstable reading of electrodes and it results in calibration failures.

As with any diagnostic test procedure, results should be interpreted taking all other test results and the clinical status of the patient into consideration.

In addition, pay attention to all precautions and warnings listed in the operator's manual of the analyzer.

**NOTE:** Boric acid (CAS Registry No. 10043-35-3) is contained in the gel solution inside the electrode at 0.2 % of the total weight as a preservative.

## Storage and stability

Store at 7-40 °C.

See labels for expiration dates.

## On-board stability

After installation the electrode is stable for the following time period: 2 months or 9000 tests, whichever comes first.

The electrodes should be replaced after this time period has expired. For replacement refer to instructions in the operator's manual of the applicable analyzers.

**NOTE:** When replacing the electrode in **cobas pro** or **cobas pure**, the user should scan the barcode affixed on the rear side of the package instead of the barcode placed on the product's label.

**Slope range** -40 to -68 mV/dec

**NOTE:** Due to the negative charge of the chloride ion, the slope is negative.

## Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

It is important to follow tube manufacturers recommended procedures at and after blood collection.

Separate from cells if analysis is not performed within 4 hours.<sup>3</sup>

## Serum

For chloride determinations, serum is the specimen of choice.

**CAUTION:** Serum separator tubes have to be used in accordance with the tube manufacturer's recommended procedures. If these procedures are not considered, it is possible to coat the sample probe with gel (interfering with proper sample level detection), or even to aspirate gel into the ISE system (resulting in a clogged system).

**Plasma:** Lithium heparin plasma

**CAUTION:** Inadequate mixing of plasma tubes can cause introduction of fibrin microclots into and subsequent clogging of the ISE.

**NOTE:** It is strongly recommended to avoid silicone-type gels, due to risk of silicon oil contaminations. In addition, tubes that exhibit a layer of clear liquid, which rises to the top of the serum after centrifugation, should not be used, in order to prevent coating the sample probes and interfering with ISE system. It is possible to clog the sample probes or the ISE tubing with gel or clots if these precautions are not taken.

**Urine:** Collect 24-hour urine without addition of preservatives and/or stabilizers. Store refrigerated during collection.

**NOTE:** Each laboratory should establish guidelines for determining acceptability of specimens and the corrective action to be taken if a specimen is considered unacceptable. Compile a laboratory-specific guideline.

## Sample stability (serum, plasma):<sup>4</sup>

7 days at 15-25 °C  
7 days at 2-8 °C  
stable at (-15)-(-25) °C

Freeze/thaw only once.

## Sample stability (urine):<sup>4,5</sup>

7 days at 15-25 °C  
stable at (-15)-(-25) °C

up to 6 freeze-thaw cycles possible.<sup>6</sup>

See the limitations and interferences section for details about possible sample interferences.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature<sup>4</sup> and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references

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and/or its own studies to determine specific stability criteria for its laboratory.

### Materials provided

See "Order information" section

### Materials required (but not provided)

See "Order information" section

General laboratory equipment

### Application for serum, plasma and urine

#### Test definition

#### Serum/plasma

	Sample dilution	
Sample volume	Sample	Diluent
<i>cobas c 311 analyzer, cobas c 501 module</i>		
Normal	9.7 µL	291 µL / ISE Diluent
<i>cobas 8000 ISE 900 / 1800 module, cobas c 303 analytical unit, cobas pro ISE analytical unit</i>		
Normal	15 µL	450 µL / ISE Diluent
<i>cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit</i>		
Normal	15 µL	450 µL / System Water

Measuring range on *cobas c 311 analyzer, cobas c 501 module, cobas 8000 ISE 900 / 1800 module, cobas c 303 analytical unit, cobas pro ISE analytical unit, cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit*: 60-140 mmol/L

Analysis of chloride on ISE analytical units listed with serum and plasma specimens should yield a linear relationship from 60-140 mmol/L with a deviation from the linear line of less than 5 %.

The sample volumes given above under "Normal" are for samples, calibrators, and quality controls.

#### Urine

	Sample dilution	
Sample volume	Sample	Diluent
<i>cobas c 311 analyzer, cobas c 501 module</i>		
Normal	9.7 µL	291 µL / ISE Diluent
Decreased	6.5 µL	291 µL / ISE Diluent
<i>cobas 8000 ISE 900 / 1800 module</i>		
Normal	10 µL	450 µL / ISE Diluent
Increased	15 µL	450 µL / ISE Diluent
<i>cobas c 303 analytical unit, cobas pro ISE analytical unit</i>		
Normal	15 µL	450 µL / ISE Diluent
Decreased	10 µL	450 µL / ISE Diluent
<i>cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit</i>		
Normal	15 µL	450 µL / System Water
Decreased	10 µL	450 µL / System Water

Measuring range on *cobas c 311 analyzer, cobas c 501 module, cobas c 303 analytical unit, cobas pro ISE analytical unit, cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit*: 20-250 mmol/L

Analysis of chloride on ISE analytical units listed with urine specimens should yield a linear relationship from 20-250 mmol/L with a deviation from the linear line of less than 10 %.

Determine samples having higher concentrations via the rerun function. Dilution of samples via rerun function is a 1:46 dilution. Results from samples diluted using the rerun function are automatically multiplied by the dilution factor.

Measuring range on *cobas c 311 analyzer, cobas c 501 module, cobas c 303 analytical unit, cobas pro ISE analytical unit, cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit for urine samples with decreased sample volume (Rerun)*: 251-375 mmol/L.

Analysis of chloride on ISE analytical units listed with urine specimens should yield a linear relationship from 251-375 mmol/L with a deviation from the linear line of less than 10 %.

The sample volumes given above under "Normal" are for samples, calibrators, and quality controls.

Measuring range on *cobas 8000 ISE 900 / 1800 module*: 60-350 mmol/L

Analysis of chloride on **cobas** 8000 ISE 900 / 1800 module with urine specimens should yield a linear relationship from 60-350 mmol/L with a deviation from the linear line of less than 10 %.

Determine samples having lower concentrations via the rerun function. Dilution of samples via rerun function is a 1:31 dilution. Results from samples diluted using the rerun function are automatically multiplied by the dilution factor.

Measuring range on *cobas 8000 ISE 900 / 1800 module for urine samples with increased sample volume (Rerun)*: 20-59.9 mmol/L

Analysis of chloride on **cobas** 8000 ISE 900 / 1800 module with urine specimens should yield a linear relationship from 20-59.9 mmol/L with a deviation from the linear line of less than 10 %.

The sample volumes given above under "Normal" are for samples and quality controls.

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

### Lower limits of measurement

#### Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 10 mmol/L

Limit of Detection = 10 mmol/L

Limit of Quantitation = 20 mmol/L

The Limit of Blank, the Limit of Detection and the Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95<sup>th</sup> percentile value from  $n \geq 60$  measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 30 %. It has been determined using low concentration chloride samples.

Values below Limit of Quantitation are not reliable due to possible higher uncertainty.

### Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

### Calibration

Calibration requires the following calibrators: ISE Standard Low (S1), ISE Standard High (S2), and ISE Standard High (S3).

The slope of the calibration curve is calculated from Standards 1 and 2. ISE Internal Standard / ISE Internal Standard conc. is measured to provide  $E_{IS}$  for all measurements. Refer to the operator's manual of the analyzer for detailed calibration instructions.

Traceability: ISE Standard Low and ISE Standard High are prepared gravimetrically from highly purified inorganic salts.

Purity of these salts has been certified by argentometric titration, acidimetric titration or perchloric acid titration.

### Calibration frequency

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### Calibration

- every 24 hours
- after ISE washing and maintenance
- after changing the reagent bottle ①
- after changing ISE Reference Electrolyte and/or Internal Standard conc. (depending on AutoCal settings) ②
- after replacing any electrode
- as required following quality control procedures

### ISE reagents on:

① **cobas c** 311 analyzer, **cobas c** 501 module, **cobas** 8000 ISE 900 / 1800 module, **cobas c** 303 analytical unit, **cobas pro** ISE analytical unit

② **cobas** ISE neo 900 analytical unit, **cobas** ISE neo 1800 analytical unit

Refer to the operator's manual for a detailed description of the Calibration/AutoCal function.

### Quality control

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

Serum/plasma:      PreciControl ClinChem Multi 1, PreciControl  
ClinChem Multi 2  
Precinorm U Plus, Precipath U Plus

Urine:                Quantitative urine controls are recommended for  
routine quality control.

Quality controls should be performed daily and after every additional calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Refer to appropriate value sheets/package inserts for additional information.

Traceability: Each Roche Diagnostics control listed above has been standardized against ISE Standard Low and ISE Standard High.

### Limitations - interference

Criterion: Recovery within  $\pm 10\%$  of initial value.

### Hemolysis - serum/plasma

Hemolysis:<sup>7</sup> No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621  $\mu\text{mol/L}$  or 1000 mg/dL).

### Hemolysis - urine

Hemolysis:<sup>7</sup> No significant interference up to a hemoglobin concentration of 621  $\mu\text{mol/L}$  or 1000 mg/dL.

### Icterus - serum/plasma

Icterus:<sup>7</sup> No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026  $\mu\text{mol/L}$  or 60 mg/dL).

### Lipemia - serum/plasma

Lipemia (Intralipid, SMOFlipid):<sup>7</sup> No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

### Drugs

The following drugs have been tested and caused no significant interference when added to aliquots of pooled normal human serum up to the indicated concentration. Falsely high chloride values have been reported from patients receiving perchlorate medication. This is due to an interference of perchlorate ions with chloride ISE determinations.

### Serum/plasma

Acetaminophen (Paracetamol)	200 mg/L
Acetylsalicylic acid	1000 mg/L
Ampicillin-Na	1000 mg/L
Ascorbic acid	300 mg/L

Cefoxitin	2500 mg/L
Cyclosporine	5 mg/L
Doxycyclin	50 mg/L
Heparin	5000 IU/L
Ibuprofen	500 mg/L
Intralipid	10000 mg/L
Levodopa	20 mg/L
Methylidopa	20 mg/L
Metronidazole	200 mg/L
N-Acetylcysteine	1660 mg/L
Phenylbutazone	400 mg/L
Rifampicin	60 mg/L
Theophylline	100 mg/L

### Urine

Acetaminophen (Paracetamol)	3000 mg/L
Ascorbic acid	4000 mg/L
Cefoxitin	12000 mg/L
Gentamycine sulfate	400 mg/L
Ibuprofen	4000 mg/L
Levodopa	1000 mg/L
Methylidopa	2000 mg/L
N-Acetylcysteine	10 mg/L
Ofloxacin	900 mg/L
Phenazopyridine	300 mg/L
Salicylic acid	6000 mg/L
Tetracycline	300 mg/L

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

### ACTION REQUIRED

**Special Wash Programming:** The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

### Expected values<sup>8</sup>

Serum, Plasma	Adult	98-107 mmol/L
	>90 y	98-111 mmol/L
Urine 24 h	Infant	2-10 mmol/24 h
	Child <6 y	15-40 mmol/24 h
	6-10 y, M	36-110 mmol/24 h
	6-10 y, F	18-74 mmol/24 h
	10-14 y, M	64-176 mmol/24 h
	10-14 y, F	36-173 mmol/24 h
	Adult	110-250 mmol/24 h
>60 y	95-195 mmol/24 h	

The urinary excretion of chloride varies significantly with dietary intake. The values given here are typical of people on an average diet.

**NOTE:** It is recommended that each laboratory establishes and maintains its own reference ranges. The values given here are only to be used as a guideline.

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### Precision

see precision data of the following analyzers in "Appendix 1: Precision":

**cobas c 311 analyzer**

**cobas 6000 analyzer series: cobas c 501 module**

**cobas 8000 modular analyzer series: cobas 8000 ISE 900 / 1800 module**

**cobas pure integrated solutions: cobas c 303 analytical unit**

**cobas pro integrated solutions: cobas pro ISE analytical unit, cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit**

### Method comparison

see method comparison data of the following analyzers in "Appendix 2: Method comparison":

**cobas c 311 analyzer**

**cobas 6000 analyzer series: cobas c 501 module**

**cobas 8000 modular analyzer series: cobas 8000 ISE 900 / 1800 module**

**cobas pure integrated solutions: cobas c 303 analytical unit**

**cobas pro integrated solutions: cobas pro ISE analytical unit, cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit**

### Maintenance

*ISE washing procedure for cobas c 311 analyzer, cobas c 501 module, cobas 8000 ISE 900 / 1800 module, cobas c 303 and cobas pro ISE analytical unit.*

The system maintenance procedures and frequencies stated in the operator's manual of the respective analyzer must be performed each day at the end of the daily sample run or after an elevated sample throughput.

**cobas c 311:** The specially designated positions on the sample disk are used.

Position W1: ISE Cleaning Solution

Position W2: Activator

The ISE Wash procedure has to be manually selected out of maintenance items.

**cobas c 501:** The specially labeled wash rack (green) is used.

Position 1: Multiclean (not necessary when only the ISE is cleaned)

Position 2: ISE Cleaning Solution

Position 3: Activator

The system recognizes the wash rack and switches automatically to cleaning mode.

**cobas 8000 ISE:** The specially labeled wash rack (green) is used.

Position 1: Cell Cleaning Solution (not necessary when only the ISE is cleaned)

Position 2: ISE Cleaning Solution

Position 3: Activator

The system recognizes the wash rack and switches automatically to cleaning mode.

**cobas c 303, cobas pro ISE:** The specially labeled wash rack (green) is used.

Position 1: ISE Cleaning Solution (used for weekly wash rack)

Position 2: ISE Cleaning Solution (used for daily wash rack)

Position 3: Activator

The system recognizes the wash rack and switches automatically to cleaning mode.

The ISE systems require conditioning after cleaning and prior to calibration.

**NOTE:** Always use fresh solutions for cleaning.

*ISE washing procedure for cobas ISE neo analytical unit*

**cobas ISE neo:** The ISE system wash tube holder is used.

Position CS: ISE Cleaning Solution

Position A: Activator

The maintenance task "ISE system wash" is scheduled and initiated automatically. For detailed description, refer to the operator's manual.

On-board stability of auxiliary reagents: ISE Cleaning Solution 4 days, Activator 4 days.

**NOTE:** Always exchange the tubes on the ISE tube holder, using new tubes for fresh reagents. **You must not refill them**, as this will lead to deterioration of the ISE measuring unit(s). Refer to the operator's manual for further information.

### Appendix 1: Precision

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

#### cobas c 311 analyzer

The data obtained on **cobas c 501 analyzer(s)** are representative for **cobas c 311 analyzer(s)**.

#### cobas 6000 analyzer series: cobas c 501 module

Repeatability and intermediate precision were determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP5 requirements (2 aliquots per run, 2 runs per day, 21 days). The following results were obtained:

Sample (on a cobas c 501)	Repeatability			Intermediate precision		
	Mean mmol/L	SD mmol/L	CV %	Mean mmol/L	SD mmol/L	CV %
Plasma low	68.5	0.2	0.3	68.5	0.6	0.8
Plasma medium	129.0	0.4	0.3	129.0	0.6	0.5
Plasma high	139.0	0.3	0.2	139.0	0.6	0.4
Precinorm U	86.2	0.2	0.3	86.2	0.5	0.6
Precipath U	119.2	0.3	0.2	119.2	0.5	0.4
Urine low	25.8	0.1	0.2	25.8	0.6	2.3
Urine medium	131.4	0.3	0.2	131.4	0.7	0.5
Urine high	243.4	0.6	0.2	243.4	1.8	0.7
Liquichek 1	97.5	0.2	0.2	97.5	1.6	1.6
Liquichek 2	198.2	0.4	0.2	198.2	2.3	1.2

#### cobas 8000 modular analyzer series: cobas 8000 ISE 900 / 1800 module

Repeatability and intermediate precision were determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP5 requirements (2 aliquots per run, 2 runs per day, 21 days). The following results were obtained:

Sample (on a cobas 8000)	Repeatability			Intermediate precision		
	Mean mmol/L	SD mmol/L	CV %	Mean mmol/L	SD mmol/L	CV %
Plasma low	67.1	0.3	0.4	67.1	0.6	1.0
Plasma medium	128.4	0.4	0.3	128.4	0.7	0.6
Plasma high	138.0	0.6	0.4	138.0	0.9	0.7
Precinorm U	77.1	0.3	0.4	77.1	0.6	0.8

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Sample (on a cobas 8000)	Repeatability			Intermediate precision		
	Mean mmol/L	SD mmol/L	CV %	Mean mmol/L	SD mmol/L	CV %
Precipath U	111.8	0.3	0.3	111.8	0.6	0.6
Urine low <sup>1)</sup>	21.6	0.2	1.0	21.6	0.8	3.7
Urine medium <sup>2)</sup>	167.6	0.5	0.3	167.6	1.1	0.7
Urine high <sup>2)</sup>	333.5	1.6	0.5	333.5	3.5	1.0
Liquichek 1 <sup>2)</sup>	97.5	0.5	0.5	97.5	0.9	0.9
Liquichek 2 <sup>2)</sup>	193.2	1.5	0.8	193.2	2.0	1.0

1) Data obtained with urine rerun function.

2) Data obtained with default urine mode.

### cobas pure integrated solutions: cobas c 303 analytical unit

The data obtained on **cobas pro** analyzer(s) are representative for **cobas c 303** analyzer(s).

### cobas pro integrated solutions: cobas pro ISE analytical unit

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas pro** ISE analytical unit.

Sample (on a cobas pro ISE analytical unit)	Repeatability			Intermediate precision		
	Mean mmol/L	SD mmol/L	CV %	Mean mmol/L	SD mmol/L	CV %
PCCC1 <sup>a)</sup>	82.5	0.31	0.4	82.5	1.22	1.5
PCCC2 <sup>b)</sup>	112	0.46	0.4	112	1.15	1.0
Human plasma 1	71.2	0.31	0.4	71.2	1.20	1.7
Human plasma 2	112	0.51	0.5	112	1.06	0.9
Human plasma 3	91.6	0.44	0.5	91.6	1.38	1.5
Human plasma 4	123	0.50	0.4	123	0.85	0.7
Human plasma 5	137	0.53	0.4	137	1.03	0.7
Human serum 1	73.4	0.23	0.3	73.4	1.08	1.5
Human serum 2	111	0.53	0.5	111	0.98	0.9
Human serum 3	91.4	0.35	0.4	91.4	1.17	1.3
Human serum 4	124	0.54	0.4	124	0.89	0.7
Human serum 5	133	0.62	0.5	133	0.82	0.6
Liquichek 1	95.2	0.41	0.4	95.2	1.18	1.2
Liquichek 2	184	0.69	0.4	184	1.79	1.0
Human urine 1	28.5	0.14	0.5	28.5	1.08	3.8
Human urine 2	139	0.58	0.4	139	1.44	1.0
Human urine 3	115	0.55	0.5	115	1.37	1.2
Human urine 4	207	0.93	0.5	207	1.92	0.9
Human urine 5	236	0.99	0.4	236	2.59	1.1

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

### cobas pro integrated solutions: cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas ISE neo** analytical unit.

Sample (on a cobas ISE neo analytical unit)	Repeatability			Intermediate precision		
	Mean mmol/L	SD mmol/L	CV %	Mean mmol/L	SD mmol/L	CV %
PCCC1 <sup>a)</sup>	85.9	0.56	0.7	85.9	1.21	1.4
PCCC2 <sup>b)</sup>	107	0.65	0.6	107	1.27	1.2
Human serum 1	68.0	0.32	0.5	68.0	1.07	1.6
Human serum 2	104	0.46	0.4	104	0.94	0.9
Human serum 3	97.8	0.46	0.5	97.8	0.94	1.0
Human serum 4	114	0.61	0.5	114	1.05	0.9
Human serum 5	138	0.65	0.5	138	1.11	0.8
Human plasma 1	65.0	0.30	0.5	65.2	1.20	1.8
Human plasma 2	101	0.63	0.6	101	1.07	1.1
Human plasma 3	94.5	0.54	0.6	94.4	1.02	1.1
Human plasma 4	110	0.50	0.5	110	1.14	1.0
Human plasma 5	135	0.74	0.5	135	1.28	0.9
Liquichek 1	82.3	0.40	0.5	82.0	0.99	1.2
Liquichek 2	193	1.14	0.6	193	2.12	1.1
Human urine 1	23.5	0.54	2.3	23.5	1.63	7.0
Human urine 2	132	0.57	0.4	132	1.33	1.0
Human urine 3	105	0.66	0.6	106	1.10	1.0
Human urine 4	201	0.93	0.5	202	2.01	1.0
Human urine 5	247	1.02	0.4	247	3.51	1.4

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

### Appendix 2: Method comparison

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

#### cobas c 311 analyzer

The data obtained on **cobas c 501** analyzer(s) are representative for **cobas c 311** analyzer(s).

#### cobas 6000 analyzer series: cobas c 501 module

ISE values for human plasma and urine samples obtained on **cobas c 501** analyzers (y) using ISE Standard High (compensated) as S3 Calibrator, were compared to those determined with the corresponding reference method (x) and with a **cobas c 501** analyzer using ISE Compensator as S3 Calibrator.

The reference method used was: Chloride Analyzer 926S for chloride.

Instruments	Sample Type/ N	Min.x	Max.x	P/B Regression <sup>9</sup>	Coeff. (r)
x: coulometry y: <b>cobas c 501</b> (S3 = ISE Standard High)	Plasma / 105	62.0	136	y = 1.033x - 1.800	0.998
Bias at 90 mmol/L = 1.170 (1.3 %)					
Bias at 112 mmol/L = 1.896 (1.7 %)					
x: <b>cobas c 501</b> (S3 = ISE Compensator) y: <b>cobas c 501</b> (S3 = ISE Standard High)	Plasma / 105	61.4	138	y = 1.000x + 0.500	0.999

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Chloride



Bias at 90 mmol/L = 0.500 (0.6 %)					
Bias at 112 mmol/L = 0.500 (0.4 %)					
x: coulometry	Urine / 105	22.0	248	$y = 1.020x - 1.700$	0.999
y: <b>cobas c 501</b> (S3 = ISE Standard High)					
Bias at 60 mmol/L = -0.500 (-0.8 %)					
Bias at 170 mmol/L = 1.700 (1.0 %)					
x: <b>cobas c 501</b> (S3 = ISE Compensator)	Urine / 105	21.2	250	$y = 0.989x + 0.669$	1.000
y: <b>cobas c 501</b> (S3 = ISE Standard High)					
Bias at 60 mmol/L = 0.009 (0.0 %)					
Bias at 170 mmol/L = -1.201 (-0.7 %)					

Bias at the medical decision level (MDL) was calculated as follows:

$$\text{Bias [mmol/L]} = \text{intercept} + (\text{slope} \times \text{MDL}) - \text{MDL}$$

$$\text{Bias [\%]} = (\text{Bias [mmol/L]} \times 100) / \text{MDL}$$

**cobas 8000 modular analyzer series: cobas 8000 ISE 900 / 1800 module**

ISE values for human plasma and urine samples obtained on a **cobas 8000** analyzer (y) using ISE Standard High as S3 Calibrator, were compared with those determined using the corresponding reference method (x) and with **cobas c 501** (x) using ISE Standard High as S3 Calibrator.

Instruments	Sample Type/ N	Min.x	Max.x	P/B Regression <sup>9</sup>	Coeff. (r)
x: coulometry	Plasma / 100	65.0	123.0	$y = 1.075x - 6.025$	0.9902
y: <b>cobas 8000</b> (S3 = ISE Standard High)					
Bias at 90 mmol/L = 0.725 (0.8 %)					
Bias at 112 mmol/L = 2.375 (2.1 %)					
x: <b>cobas c 501</b> (S3 = ISE Standard High)	Plasma / 100	61.9	127.9	$y = 0.987x + 1.858$	0.9984
y: <b>cobas 8000</b> (S3 = ISE Standard High)					
Bias at 90 mmol/L = 0.688 (0.8 %)					
Bias at 112 mmol/L = 0.402 (0.4 %)					
x: coulometry	Urine <sup>2)</sup> / 108	66.0	313.0	$y = 1.036x - 4.891$	0.9995
y: <b>cobas 8000</b> (S3 = ISE Standard High)					
Bias at 60 mmol/L = -2.731 (-4.6 %)					
Bias at 170 mmol/L = 1.229 (0.7 %)					
x: <b>cobas c 501</b> (S3 = ISE Standard High)	Urine <sup>2)</sup> / 108	62.0	349.8	$y = 0.908x + 9.018$	0.9999
y: <b>cobas 8000</b> (S3 = ISE Standard High)					

Bias at 60 mmol/L = 3.497 (5.8 %)					
Bias at 170 mmol/L = -6.623 (-3.9 %)					
x: coulometry	Urine <sup>1)</sup> / 92	22.0	59.0	$y = 0.973x - 0.927$	0.9987
y: <b>cobas 8000</b> (S3 = ISE Standard High)					
Bias at 30 mmol/L = -1.737 (-5.8 %)					
x: <b>cobas c 501</b> (S3 = ISE Standard High)	Urine <sup>1)</sup> / 92	20.2	57.3	$y = 0.981x + 0.728$	0.9992
y: <b>cobas 8000</b> (S3 = ISE Standard High)					
Bias at 30 mmol/L = 0.158 (0.5 %)					

1) Data obtained with urine rerun function.

2) Data obtained with default urine mode.

Bias at the medical decision level (MDL) was calculated as follows:

$$\text{Bias [mmol/L]} = \text{intercept} + (\text{slope} \times \text{MDL}) - \text{MDL}$$

$$\text{Bias [\%]} = (\text{Bias [mmol/L]} \times 100) / \text{MDL}$$

**cobas pure integrated solutions: cobas c 303 analytical unit**

ISE values for human plasma and serum samples obtained on a **cobas c 303** ISE unit (y) were compared with those determined using **cobas pro** ISE analytical unit (x) and with a **cobas c 501** analyzer (x).

ISE values for human urine samples obtained on a **cobas c 303** ISE unit (y) were compared with a **cobas pro** ISE analytical unit (x) and with a **cobas c 501** analyzer (x).

Instruments	Sample Type/ N	Min.x	Max.x	P/B Regression <sup>9</sup>	Coeff. (r)
x: <b>cobas pro</b> ISE	Plasma / 120	65.5	137	$y = 0.996x + 0.276$	0.999
y: <b>cobas c 303</b> ISE					
Bias at 95 mmol/L = -0.110 (-0.1 %)					
Bias at 110 mmol/L = -0.171 (-0.2 %)					
x: <b>cobas c 501</b> ISE	Plasma / 120	66.4	138	$y = 1.000x - 1.20$	0.999
y: <b>cobas c 303</b> ISE					
Bias at 95 mmol/L = -1.20 (-1.3 %)					
Bias at 110 mmol/L = -1.20 (-1.1 %)					
x: <b>cobas pro</b> ISE	Serum / 118	62.2	138	$y = 1.000x - 0.200$	1.000
y: <b>cobas c 303</b> ISE					
Bias at 95 mmol/L = -0.200 (-0.2 %)					
Bias at 110 mmol/L = -0.200 (-0.2 %)					
x: <b>cobas c 501</b> ISE	Serum / 118	62.6	138	$y = 1.003x - 1.01$	1.000
y: <b>cobas c 303</b> ISE					
Bias at 95 mmol/L = -0.761 (-0.8 %)					
Bias at 110 mmol/L = -0.722 (-0.7 %)					

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Chloride

x: <b>cobas pro</b> ISE	Urine / 119	21.3	243	$y = 1.011x - 1.03$	1.000
y: <b>cobas c 303</b> ISE					
x: <b>cobas c 501</b> y: <b>cobas c 303</b> ISE	Urine / 118	21.3	249	$y = 0.984x + 2.29$	1.000

Bias at the medical decision level (MDL) was calculated as follows:

Bias [mmol/L] = intercept + (slope x MDL) - MDL

Bias [%] = (Bias [mmol/L] x 100) / MDL

### cobas pro integrated solutions: cobas pro ISE analytical unit

ISE values for human plasma samples obtained on a **cobas pro** ISE analytical unit (y) were compared with a **cobas c 501** analyzer (x).

ISE values for human urine samples obtained on a **cobas pro** ISE analytical unit (y) were compared with a **cobas c 501** analyzer (x).

Instruments	Sample Type/ N	Min.x	Max.x	P/B Regression <sup>9</sup>	Coeff. (r)
x: <b>cobas c 501</b> y: <b>cobas pro</b> ISE	Plasma / 118	60.5	140	$y = 0.997x - 0.127$	1.000

Bias at 95 mmol/L = -0.384 (-0.4 %)

Bias at 110 mmol/L = -0.423 (-0.4 %)

x: <b>cobas c 501</b> y: <b>cobas pro</b> ISE	Serum / 118	61.7	135	$y = 1.000x - 0.600$	1.000
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Bias at 95 mmol/L = -0.600 (-0.6 %)

Bias at 110 mmol/L = -0.600 (-0.5 %)

x: <b>cobas c 501</b> y: <b>cobas pro</b> ISE	Urine / 119	25.0	245	$y = 1.023x - 2.09$	1.000
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Bias at the medical decision level (MDL) was calculated as follows:

Bias [mmol/L] = intercept + (slope x MDL) - MDL

Bias [%] = (Bias [mmol/L] x 100) / MDL

### cobas pro integrated solutions: cobas ISE neo 900 analytical unit, cobas ISE neo 1800 analytical unit

ISE values for human plasma and serum samples obtained on a **cobas ISE neo** analytical unit (y) were compared with a **cobas c 501** analyzer (x) and with a **cobas pro** ISE analytical unit (x).

ISE values for human urine samples obtained on a **cobas ISE neo** analytical unit (y) were compared with a **cobas c 501** analyzer (x) and with a **cobas pro** ISE analytical unit (x).

Instruments	Sample Type/ N	Min.x	Max.x	P/B Regression <sup>9</sup>	Coeff. (r)
x: <b>cobas c 501</b> y: <b>cobas ISE</b> neo	Serum / 115	63.1	139	$y = 1.021x - 1.41$	0.998

Bias at 95 mmol/L = 0.593 (0.6 %)

Bias at 110 mmol/L = 0.908 (0.8 %)

x: <b>cobas pro</b> ISE y: <b>cobas ISE</b> neo	Serum / 115	63.1	136	$y = 1.045x - 2.77$	0.998
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Bias at 95 mmol/L = 1.52 (1.6 %)  
Bias at 110 mmol/L = 2.19 (2.0 %)

x: <b>cobas c 501</b> y: <b>cobas ISE</b> neo	Plasma / 119	62.4	137	$y = 1.010x + 0.152$	0.999
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Bias at 95 mmol/L = 1.14 (1.2 %)

Bias at 110 mmol/L = 1.29 (1.2 %)

x: <b>cobas pro</b> ISE y: <b>cobas ISE</b> neo	Plasma / 118	60.7	135	$y = 1.012x + 2.10$	0.999
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Bias at 95 mmol/L = 3.21 (3.4 %)

Bias at 110 mmol/L = 3.38 (3.1 %)

x: <b>cobas c 501</b> y: <b>cobas ISE</b> neo	Urine / 118	22.6	248	$y = 1.004x - 1.20$	1.000
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x: <b>cobas pro</b> ISE y: <b>cobas ISE</b> neo	Urine / 114	30.0	248	$y = 1.008x - 0.843$	1.000
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Bias at the medical decision level (MDL) was calculated as follows:

Bias [mmol/L] = intercept + (slope x MDL) - MDL

Bias [%] = (Bias [mmol/L] x 100) / MDL

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The Summary of Safety & Performance Report can be found here: <https://ec.europa.eu/tools/eudamed>

# Cl Electrode

Chloride

cobas®

## Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see [navifyportal.roche.com](http://navifyportal.roche.com) for definition of symbols used):

	Quantity contained in the package
	Quantity contained in the package
	Global Trade Item Number
	Latest date by which the electrode has to be installed on the analyzer
	Directive for the restriction of the use of certain hazardous substances in electrical and electronic equipment

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