

**English****ISE CALIBRATORS - Intended use**

The ISE Solutions 1, 2, 3, and the ISE Calibrators Direct and ISE Calibrators Indirect/Urine are in vitro diagnostic calibrators intended for the calibration of the COBAS INTEGRA ISE modules for the quantitative determinations of sodium, potassium, chloride, and lithium.

**Active ingredients****ISE Solution 1**

150 mmol/L sodium, 5 mmol/L potassium, 115 mmol/L chloride, 0.3 mmol/L lithium.

**ISE Solution 2**

110 mmol/L sodium, 1.8 mmol/L potassium, 72 mmol/L chloride, 0.3 mmol/L lithium.

**ISE Solution 3**

150 mmol/L sodium, 5 mmol/L potassium, 115 mmol/L chloride, 1.4 mmol/L lithium.

**ISE Calibrator Direct**

150 mmol/L sodium, 5 mmol/L potassium, 115 mmol/L chloride, 0.3 mmol/L lithium.

**ISE Calibrator Indirect/Urine**

25 mmol/L sodium, 0.8 mmol/L potassium, 19 mmol/L chloride, 0.05 mmol/L lithium.

**Shelf life**

Store all ISE calibrators at 15-25 °C. See label for expiration date.

**On-board stability**

ISE Solution 1, 2, and 3	2 weeks
ISE Calibrator Direct	8 weeks
ISE Calibrator Indirect/Urine	8 weeks

**ISE AUXILIARY REAGENTS - Intended use**

The ISE Reference Electrolyte is an in vitro diagnostic solution providing a strong stable ion reference potential in the reference electrode for the measurement of sodium, potassium, chloride, and lithium.

The ISE Deproteinizer and ISE Etcher are cleaning solutions intended for use with the COBAS INTEGRA ISE modules for cleaning the ion-selective electrodes.

The Activator is an auxiliary maintenance reagent required during the daily service tasks for the conditioning of the ISE electrodes, tubing and sample probes.

**Active ingredients**

ISE Reference Electrolyte	3.5 mol/L potassium chloride.
ISE Deproteinizer	Approximately 1.2 % sodium hypochlorite (NaOCl).
ISE Etcher	100 mmol/L ammonium hydrogen difluoride [(NH <sub>4</sub> )HF <sub>2</sub> ].

**Precautions and warnings**

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

**For ISE Deproteinizer and ISE Etcher:**

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

**Warning**

H315	Causes skin irritation.
H319	Causes serious eye irritation.

**Prevention:**

P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Product safety labeling primarily follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

**Shelf life**

Store ISE Reference Electrolyte and ISE Etcher at 15-25 °C. See label for expiration date.

Store ISE Deproteinizer at 2-8 °C. See label for expiration date.

For storage and stability of the Activator see package insert. See label for expiration date.

**On-board stability**

ISE Reference Electrolyte	8 weeks
ISE Deproteinizer	4 weeks*
ISE Etcher	8 weeks*
Activator	4 days*

\*Replace the bottle on alert from the system. Discard any remaining solution.

**Activator**

For ISE activation use the human serum provided as lyophilized product (REF 04663632190). The activator is placed in uncapped bottles in the appropriate position on the ISE rack.

**ELECTRODES - Electrodes life span**

After installation, the electrodes are stable for the following time period:

Sodium electrode	6 months
Potassium electrode	6 months
Lithium electrode	4 months
Reference electrode	2 years
Chloride electrode (REF 03003523001)	3 months

**Note:** The intensive use of plasma samples will reduce the operational life time of this chloride electrode. The life span specified above applies to the determination of serum samples only.

If a significant amount of samples is plasma the following chloride electrode is advised to be used:

Chloride electrode (REF 04581008001) 2 weeks or 2000 samples

The electrodes should be replaced after this time period is expired. Therefore the service counter has to be set accordingly.

**Slope ranges**

Sodium electrode	54 to 63 mV/dec
Potassium electrode	54 to 62 mV/dec
Lithium electrode	4.9 to 8.9 mV 4.4 to 8.4 mV
Chloride electrode (REF 03003523001)	-42 to -56 mV/dec
Chloride electrode (REF 04581008001)	-35 to -56 mV/dec direct mode -38 to -56 mV/dec indirect mode

**Note**

The slope ranges for newly installed electrodes should be in the upper half of the recommended electrode slope range.

**ISE SOLUTIONS SUMMARY****ISE Solution 1 - Location: ISE Rack**

Two-point calibration of sodium, chloride, and potassium.

Three-point calibration of lithium.

Begin-of-Day purposes (COBAS INTEGRA 800 analyzers only).

ISE module initialization.

**ISE Solution 2 - Location: ISE Rack**

Two-point calibration of sodium, chloride, and potassium.

Three-point calibration of lithium.

Begin-of-Day purposes (COBAS INTEGRA 800 analyzers only).

**ISE Solution 3 - Location: ISE Rack**

Three-point calibration of lithium.

Begin-of-Day purposes [with or without lithium] (COBAS INTEGRA 800 analyzers only).

**ISE Calibrator Direct - Location: ISE Module**

One-point calibration after each ISE direct measurement, which is performed once every ISE cycle when the module is in ISE direct mode.

Also used during ISE standby mode and for servicing purposes.

**ISE Calibrator Indirect/Urine - Location: ISE Module**

One-point indirect or urine ISE calibration, which is performed once every ISE cycle in indirect or urine mode.

**ISE Reference Electrolyte - Location: ISE Module**

Used in all ISE measurements of sodium, potassium, chloride, and lithium. Contained in a special bottle, located at the front of the ISE module. The bottle is connected directly by tubing to the ISE reference electrode.

**ISE Etcher - Location: ISE Rack**

A cleaning solution intended for use with the ISE module for cleaning the sodium electrode during ISE service.

**ISE Deproteinizer - Location: ISE Rack**

A cleaning solution intended for use with the ISE module for cleaning the ion-selective electrodes, ISE tower, and tubing during ISE service.

**Activator - Location: ISE Rack**

Activates the electrodes in ISE service actions. Also used for ISE module initialization. The activator is placed in uncapped bottles in the appropriate position on the ISE rack.

**Order information**

Type	Name	Cat. No.	Pack of
<b>Electrodes</b>	Sodium	21029371 001	1
	Potassium	21029355 001	1
	Chloride	03003523 001	1
	Chloride Gen.2	04581008 001	1
	Lithium	21044303 001	1
	Reference	21029398 001	1
	<b>ISE Calibrators</b>	ISE Solution 1	20738050 122
ISE Solution 2		20738069 122	6 x 9.5 mL
ISE Solution 3		20738077 122	6 x 9.5 mL
ISE Calibrator Direct		20763055 122	1 x 250 mL
ISE Calibrator Indirect/Urine		20763063 122	1 x 250 mL
<b>ISE Controls</b>	Precinorm U	10171743 122	20 x 5 mL
	Precipath U	10171778 122	20 x 5 mL
<b>ISE Auxiliary Reagents</b>	ISE Reference Electrolyte	20738085 122	1 x 250 mL
	ISE Deproteinizer	20763071 122	6 x 21 mL

	ISE Etcher	20763098 122	6 x 11 mL
	Activator	04663632 190	9 x 12 mL
<b>Bottles (empty)</b>	Activator Bottle Set	04745086 190	50 x 11 mL
<b>Tubing</b>	COBAS INTEGRA 400 Tubing Set	28144672 001	
	COBAS INTEGRA 800 Tubing Set	28146438 001	

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.

**Symbols**

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT

Contents of kit



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

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Additions, deletions or changes are indicated by a change bar in the margin.

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