

Convergys® ISE Cal-1 1-point calibration solution Code: 1100-1014

1. Intended Use:

Convergys® ISE Calibrator-1 is a stabilized saline standard solution, intended for calibration of all Convergys® ISE Analyzers. For complete information on operation refer to the Convergys® ISE Analyzers User Manuals.

2. Clinical Significance:

The measurement of Ion Selective Electrolytes in Serum, Plasma, Whole Blood and Urine is performed to determine concentration of K⁺, Na⁺, Cl⁻, Ca⁺⁺, Li⁺ Electrolytes and the pH acid-base balance.

3. ISE method:

The measuring method is a ISE(Ion Selective Electrolyte) method.

4. Principle and theory of measurement and calibration:

The operation of ion selective electrodes(ISE) is based on the fact that there is a linear relationship between the electrical potential developed between an ISE and a reference electrode immersed in the same solution, and the Logarithm of the **activity** (or "effective concentration") of the ions in the solution. This relationship is described by the Nernst equation:

$$E = E^0 + (2.303RT/nF) \times \text{Log}(a)$$

Where E = the total potential (in mV) developed between the sensing and reference electrodes.

E⁰ = is a constant which is characteristic of the particular ISE/reference pair.

(It is the sum of all the liquid junction potentials in the electrochemical cell)

2.303 = the conversion factor from natural to base10 logarithm.

R = the Gas Constant (8.314 joules/degree/mole).

T = the Absolute Temperature.

n = the charge on the ion (with sign + or -).

F = the Faraday Constant (96,500 coulombs per mole).

Log(a) = the logarithm of the activity of the measured ion.

Note that 2.303RT/nF is the **Slope(S)** of the line and this is an important diagnostic characteristic of the electrode - generally the slope gets lower as the electrode gets old or contaminated and the lower the slope the higher the errors on the sample measurements - e.g.: at S=55, a 1mV error in reading will make about a 4% difference in concentration; at S=26 the difference will be more like 8%. Because of the logarithmic relationship, the slope can most easily be determined as the difference between the voltages measured in two solutions which differ by one order of magnitude - usually expressed as mV/decade. The theoretical value for the slope at 25°C is 59.2 for monovalent ions and 29.6 for divalent ions - but in practice these can vary considerably. The critical factor is not so much the actual value of the slope but that this should be as high as possible and remain constant over the range of concentrations and the time period required for the analysis.

The **activity** of an ion in solution is a measure of the number of ions taking part in any given reaction, in this case those interacting with the ISE membrane. It is always less than the actual number of ions present in the solution (i.e. concentration) because the mobility of the ions is reduced by the presence of other ions in the solution. The higher the concentration of other ions, whether the same or different from the species being measured, (i.e. the Ionic Strength of the solution) then the stronger is this retarding effect and the greater the difference between activity and concentration. However, it must be noted that in dilute solutions with low Ionic Strength this difference is small and can be ignored in many practical applications – i.e. the calibration can be made and sample results calculated using the more convenient concentration units.

The relationship between activity and concentration is defined by the **Activity Coefficient** as $f = a / c$. This is dependent on the **ionic Strength** of the solution, the valence and ionic radius of the ion being measured.

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Note that the activity coefficient is always less than one, and the lower the value the bigger the difference between activity and concentration.

The **Ionic Strength (I)** can be calculated from $I = 0.5 \times \text{Sum} (c_i \times Z_i^2)$
Where c is the concentration in Moles and Z is the valence.

The **Activity Coefficient (f)** can then be found from:

$$-\text{Log} (f) = \left[\frac{(0.51 \times Z^2 \times \text{SQR} (I))}{(1 + (3.29 \times d \times \text{SQR} (I)))} \right] - (0.1 \times Z^2 \times I)$$

Where: Z = the ionic charge, I = the ionic strength of the solution, d = the ionic radius in nanometers.

Note that this formula is only accurate up to about I = 0.6 Molar. At higher ionic strength other factors come into play, which make the calculation of activity coefficients virtually impossible.

5. **Reagent composition:**

Potassium (K ⁺)	4.00 mmol/L	Chemical Name: N/A
Sodium (Na ⁺)	140.00 mmol/L	Chemical Family: Salt Water Solutions
Chloride (Cl ⁻)	100.00 mmol/L	Concentration Ranges: Contains no hazardous ingredients with concentration greater than 1% or carcinogens with concentration greater than 0.1%
Calcium (Ca ⁺⁺)	1.25 mmol/L	
Lithium (Li ⁺)	1.00 mmol/L	
pH	7.4	

6. **Safety precautions and warnings:**

For *In Vitro* Diagnostic use only. Do not ingest. Do not pipette by mouth. Avoid overexposure; contact with solution may be irritating to eyes, skin and mucous membranes. Flush affected area with copious amounts of water. Consult a physician if symptoms persist or if the solution is ingested. Exercise the normal precautions required for handling laboratory reagents. Health and safety data sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

7. **Stability and preparation of reagent:**

Unopened stable until the expiry date when stored at +5 to +30°C.

Once opened, the reagent is stable for 60 days when stored on Convergys® ISE Analyzers (+15 to +30°C), if not contaminated while handling.

Note; High temperature can decrease the reagents working lifetime. To ensure optimum stability and avoid reagents waste, it is strongly recommended that the reagent be stored tightly capped when not in use with Convergys® ISE Analyzers.

Reagent colorless and clear. Do not use if turbid or if it displays other evidence of contamination.

8. **Materials provided:**

Convergys® ISE Calibrator-1, standard calibration solution

9. **Materials required but not provided:**

Convergys® ISE & BG Tri-Level Control Solution(REF 1100-1910)

10. **Quality Control:**

Convergys® ISE & BG Tri-Level Control Solution is recommended for daily quality control. Two levels of controls are recommended to run each day in Convergys® ISE Analyzers prior to reporting patient results. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and electrodes.
2. Check cleanliness of all equipment in use.
3. Check all reagents on contamination.

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4. Check expiry date of Reagents and contents.
5. Contact Convergent Technologies Technical support: info@convergent-technologies.de

11. Interferences:

There is no Interference considered to be significant if the reagent is used in closed reagent system, according to instructions in *Convergys®* ISE Analyzers User Manuals.

12. Normal calibration ranges:

Potassium (K ⁺)	+10~+20 ΔmV
Sodium (Na ⁺)	-3~-9 ΔmV
Chloride (Cl ⁻)	+3~+8 ΔmV
Calcium (Ca ⁺⁺)	+4~+12 ΔmV
Lithium (Li ⁺)	-3~-20 ΔmV
pH	+10~+30 ΔmV

13. Normal patient-sample ranges:

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

14. Linearity, Sensitivity and Precision

Parameter	Measuring range	Resolution	Precision	Accuracy
Potassium (K ⁺)	0.50 – 15.00 mmol/L	0.01 mmol/L	≤ 1.0 %	≤ 3.0 %
Sodium (Na ⁺)	80.00 – 200.00 mmol/L	0.10 mmol/L	≤ 1.0 %	≤ 3.0 %
Chloride (Cl ⁻)	60.00 – 200.00 mmol/L	0.10 mmol/L	≤ 1.0 %	≤ 3.0 %
Calcium (Ca ⁺⁺)	0.50 – 5.00 mmol/L	0.01 mmol/L	≤ 2.0 %	≤ 5.0 %
Lithium (Li ⁺)	0.10 - 4.00 mmol/L	0.01 mmol/L	≤ 3.0 %	≤ 5.0 %
pH	6.80 – 8.00	0.01	≤ 1.0 %	≤ 1.0%

15. Installation:

Convergys® ISE Calibrator-1 solution is to be installed by professional user on *Convergys®* ISE Electrolyte Analyzers as per instructions in Analyzers User Manual.

16. Technical Assistance: Tech. support and Customer service at: support@convergent-technologies.de

17. Manufactured by:

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