# ISE Reagent Pack (Ion Selective Method)

# Manual

【Product Name】

ISE Reagent Pack (Ion Selective Method)

【Model】

Sheet 1

| Model Name | Volume | Deviation |
|---|---|---|
| ISE Reagent Pack | Buffer A：460mL, Buffer B：360mL | ﹣5% |

【Intended Use】

To measure the concentration of potassium (K+), sodium (Na+) and chlorine (Cl-) in human serum, plasma or urine.

【Principle】

The electrolyte module obtains the electrode potential signal according to the ion-selective electrode system, which is analyzed and processed by the microprocessor to obtain the ion concentration of the sample. The measurement method is a kind of standard comparison method, A Standard Solution is used to calibrate the datum point, and B standard solution is used to calibrate the slope. From the measured potentials of the sample and the two standard solutions, the analysis results can be calculated. The calculation formula is as follows:

$$C_X = C_A \cdot 10^{(E_X - E_A)/S} \quad \text{-------（1）}$$

$$S = \frac{E_B - E_A}{\lg(C_B / C_A)} \quad \text{-------（2）}$$

$C_X$ is concentration of sample, $E_X$ is potential of sample；
$C_A$ is concentration of A Standard Solution, $E_A$ is potential of A Standard Solution；
$C_B$ is concentration of B Standard Solution, $E_B$ is potential of B Standard Solution；
S is slope of potential that measured by A & B standard solutions.

【Main Composition】

Sheet 2

| Model Name | Concentration（Unit：mmol/L） |
|---|---|
| ISE Reagent Pack | Buffer A: K+:4.0, Na+:140, Cl-:100；<br>Buffer B: K+:8.0, Na+:110, Cl-:70 |

【Storage conditions and expiry date】

Store at 5℃～35℃ to prevent the reagents from freezing. The validity period is 2 years from the date of manufacturing.

【Applicable instrument】

Suitable for Mindray BS series instruments.

【Sample Type】

Fresh human serum, plasma or urine.

【Reagent Installation】

1) Check and confirm that the model and specifications of the reagents to be installed must match the applicable instruments.

2) Remove the rubber cap on the mouth of the reagent pack, and insert the reagent pack when it is confirmed that there is no foreign matter at the interface of the reagent pack in the instrument.

3) After the reagent is installed, the procedure of replacing the reagent should be run, or at least 3 calibrations should be done to eliminate the residual reagent and air in the pipeline and stabilize the instrument.

【Verification】

Use any suitable instrument that is in good condition and calibrated to continuously measure the quality control product test solution with a fixed value for three times, and the deviation of the measurement result between the average value and the nominal value should be within the acceptable range.

【Power of Interpretation of Results】

The test results are produced by using special reagents through special instruments. Therefore, only when the instruments and reagents are in a qualified state at the same time can the qualified test results be produced. When the test result is inaccurate or out of tolerance, the integrity of the instrument state should be confirmed; if the test result is still inaccurate or out of tolerance when the instrument state is confirmed to meet the requirements of the inspection and use, the quality of the reagent is proved If the status is abnormal, stop using it and find out the cause.

【Limitation】

This reagent pack is for Mindray BS series instruments use only, can not be used for other instruments.

【Product performance index】

Relative deviation（Sheet 3）、Coefficient of variation 、Inter-assay precision（Sheet 4）、Urine index（Sheet 5）

Sheet 3

| Item | Relative deviation |
|---|---|
| $K^+$ | ≤3.0% |

| | |
|---|---|
| $Na^+$ | ≤3.0% |
| $Cl^-$ | ≤3.0% |

Sheet 4

| Item | Coefficient of variation | Inter-assay precision |
|---|---|---|
| $K^+$ | ≤1.5% | ≤0.20mmol/L |
| $Na^+$ | ≤1.5% | ≤3.0mmol/L |
| $Cl^-$ | ≤1.5% | ≤2.0mmol/L |

Sheet 5

| Item | Coefficient of variation | linearity | | |
|---|---|---|---|---|
| | | linearity range（mmol/L） | correlation coefficient（$R^2$） | Relative deviation |
| $K^+$ | ≤3.5% | 5-200 | $R^2$≥0.99 | ≤±14.5% |
| $Na^+$ | ≤3.5% | 10-500 | $R^2$≥0.99 | ≤±13% |
| $Cl^-$ | ≤3.5% | 15-400 | $R^2$≥0.99 | ≤±13% |

【Announcements】

a. This product for In-vitro Diagnosis use only.

b. The liquid in waste may has germs or viruses that cause harm to the human or the environment, thus the waste reagent pack must be disposed as biomedical waste.

c. Do not use any expired reagent pack, otherwise it may cause errors in the analysis results and cause indirect damage to the patient.

【Icons】

 Temperature range  Manual  In-Vitro Diagnostic

 Manufacturer  Lot Number  Expired Date  Manufacturing Date


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