CHLORIDE Colorimetric method
Reagent for quantitative determination of chloride ions in human serum and plasma, urines or cerebrospinal fluid (CSF).

REF K1005 R1 8 x 20 mL
REF K2005 R1 8 x 50 mL

SAFETY CAUTIONS
• Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
• Verify the integrity of the contents before use.
• Waste disposal: Respect legislation in force in the country.
• All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

SAFETY CAUTIONS
• Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION
Ready for use.

STABILITY AND STORAGE
Stored away from light, well cap in the original vial at 18-25°C, reagent is stable when stored and used as described in the insert:
Unopened,
• Until the expiry date stated on the label of the Kit.
Once opened,
• Reagent is stable at least 2 years.
Discard any reagent if cloudy or if absorbance at 505 nm is > 0.100.

SPECIMEN COLLECTION AND HANDLING (2) (6)
Unhemolysed serum or heparinized plasma.
Urines or CSF.
Chloride is stable in the specimen for:
✓ 1 week at room temperature or 2-8°C.

LIMITS (3)
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED
1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE
REFERENCE INTERVALS (2)

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>mEq/L [mmol/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>In serum or plasma</td>
<td></td>
</tr>
<tr>
<td>In cord</td>
<td>96-104 [96-104]</td>
</tr>
<tr>
<td>Premature</td>
<td>95-110 [95-110]</td>
</tr>
<tr>
<td>0 to 30 days</td>
<td>98-113 [98-113]</td>
</tr>
<tr>
<td>up to 90 years</td>
<td>98-107(108) [98-107(108)]</td>
</tr>
<tr>
<td>&gt; 90 years</td>
<td>98-111 [98-111]</td>
</tr>
<tr>
<td>In 24 h Urines</td>
<td>mEq/L [mmol/L]</td>
</tr>
<tr>
<td>Newborn</td>
<td>2-10 [2-10]</td>
</tr>
<tr>
<td>Child &lt; 6 years</td>
<td>15-40 [15-40]</td>
</tr>
<tr>
<td>6-10 years, M</td>
<td>36-110 [36-110]</td>
</tr>
<tr>
<td>10-14 years, F</td>
<td>18-74 [18-74]</td>
</tr>
<tr>
<td>10-14 years, M</td>
<td>64-176 [64-176]</td>
</tr>
<tr>
<td>Adult</td>
<td>36-173 [36-173]</td>
</tr>
<tr>
<td>&gt; 60 years</td>
<td>110-250 [110-250]</td>
</tr>
<tr>
<td>In CSF</td>
<td>mEq/L [mmol/L]</td>
</tr>
<tr>
<td>Child</td>
<td>110-130 [110-130]</td>
</tr>
<tr>
<td>Adult</td>
<td>118-132 [118-132]</td>
</tr>
</tbody>
</table>

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza ONE, 505 nm, 37°C

Detection limit: approx. 1.8 mEq/L

Linearity Range: between 70 and 140 mEq/L

Precision:

<table>
<thead>
<tr>
<th></th>
<th>Within-run Mean (mEq/L)</th>
<th>Between-run Mean (mEq/L)</th>
<th>S.D. mEq/L</th>
<th>C.V. %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low level</td>
<td>80.7</td>
<td>82.9</td>
<td>0.9</td>
<td>1.1</td>
</tr>
<tr>
<td>Normal level</td>
<td>103.1</td>
<td>106.1</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>High level</td>
<td>123.1</td>
<td>122.1</td>
<td>0.9</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Analytical Sensitivity: approx. 0.042 abs for 10 mEq/L

Comparison studies with commercially available reagent:

Realized on automated analyzer with specimens (n=69) between 69 and 129 mEq/L

\[ y = 1.0391x - 2.9153 \quad r = 0.9944 \]

Interferences:

- Turbidity: Positive interference from 0.067 OD
- Total bilirubin: Positive interference from 558 μmol/L
- Direct bilirubin: No interference up to 24 μmol/L
- Ascorbic acid: No interference up to 2500 mg/dL
- Glucose: No interference up to 1044 mg/dL
- Hemoglobin: Positive interference from 76 μmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 14 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

Performances and stability data on Kenza 240TX/ISE and Kenza 450TX/ISE are available on request.

CALIBRATION (7)

- REF 95015 Multicalibrator traceable to SRM 909

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N level I
- REF 95011 EXATROL-P level II
- REF 95012 Urinary controls

External quality control program.

It is recommended to control in the following cases:

- At least one a run
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the Kenza Analyzer used

CALCULATION

The analyzer provides directly final result.

Refer to the instruction of use of Kenza analyzer.

REFERENCES

7. SRM: Standard Reference Material®