

NaCl 0.9 %

Sodium Chloride 0.9 %



English

Intended Use

NaCl 0.9 % is used as a diluent for various *in vitro* coagulation assays.

Summary and principle

NaCl 0.9 % has been specifically prepared for coagulation assays but may be used in any laboratory test utilizing sodium chloride 0.9 %

Reagents

NaCl 0.9 %: liquid aqueous solution containing 0.9 % sodium chloride.

REF	CONTENT
4847127	1 x 25 mL

Precautions and warnings

For *in vitro* diagnostic use for health care professionals only.
Universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
Handle waste as potentially biohazardous material and dispose according to accepted laboratory instructions and procedures.
Discard all material in safe and acceptable manner in compliance with relevant local disposal regulations.
Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The reagent is ready to use.
Allow NaCl 0.9 % to stand at room temperature (18-25 °C) for 30 minutes, before use.
Do not use the reagent if you observe any change in appearance of components included in the kit or if you observe any damage in the packaging materials.
Visible turbidity and flocculation are signs of microbial contamination.
Carefully swirl the vial just before use to ensure homogeneity.
Avoid foam formation.

Reagent storage and stability

Store at 2-8 °C.
Unopened reagents are stable until the stated expiration date indicated on the label.
Store reagents upright in their packaging.
Stability of the opened reagent in original vial:

at 2-8 °C (Closed cap)	8 weeks
at 18-25 °C (Open vial)	5 days

Do not freeze.

Considering the numerous possible combinations of storage conditions (partly at 18-25 °C, partly at 2-8 °C), each laboratory should establish its own stability durations according to its practices if the reagent is stored partly at 2-8 °C. These durations should not exceed the figures mentioned above which have been determined under controlled conditions.

Procedure

Materials provided

See "Reagents" section.

Materials required (but not provided)

- General laboratory equipment
- Reagents for performing coagulation assays
- Coagulation analyzer such as Ceveron 100 series

Please note that the application on other analyzers can be validated by the manufacturer in accordance with the requirements of the Regulation (EU) 2017/746 under their responsibility as long as the intended purpose and performance are not modified.

Test procedure

For more details on the use of NaCl 0.9 %, please refer to the instructions for use, assay protocols and instrument manual for the respective assay/instrument combination to be used.

With analyzers of the Ceveron 100 series, after opening of the solution bottle, load it into the instrument according to the recommendations of the instrument manual in positions R1-R4.

Symbols

The following symbols and signs are used in addition to those listed in the ISO 15223-1 Standard:

 Global Trade Item Number

 Content

For users in the European Union and in countries following Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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A point (period/stop) is always used in this instructions for use 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.

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This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.

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