Name:	PACKAGE INSERT for KLEEYA® TRIGGER SOLUTIONS PACK
Purpose:	This solution is intended to generate a luminescent signal during a chemiluminescence immunoassay reaction in the KleeYa® instrument.
Product code:	226491-TRP
Catalog number:	10111184
Product size:	Trigger solution 1: 3 x 270 mL ; Trigger solution 2: 3 x 270 mL

1 INTENDED USE

INFO **For in vitro diagnostic use only.**

For professional use.

Trigger Solution 1 – Acid Reagent, Trigger Solution 2 – Base Reagent ("Trigger Solutions") are required to generate the luminescent light signal in the fully automated chemiluminescence immunoassay (CLIA) analyzer KleeYa®. The Trigger Solutions are designed for the flash system, which implies the usage of an acridinium-labeled conjugate. The acridinium ester label undergoes an oxidative reaction when exposed to peroxide (Trigger Solution 1 – Acid Reagent) and an alkaline solution (Trigger Solution 2 – Base Reagent). The oxidized product is in an excited form. The return to its ground state is indicated by the emission of light, which is measured in a few seconds and is expressed in relative light units (RLU) by the KleeYa® instrument.

Please refer to the KleeYa® instrument's Instruction for Use for further information.

2 INGREDIENTS

2.1 TRIGGER SOLUTION 1 – ACID REAGENT

The Trigger Solution 1 – Acid Reagent is supplied as a 3 x 270 mL ready to use reagent.

Brand name	Ingredients
Trigger Solution 1 – Acid Reagent	• hydrogen peroxide • nitric acid 0.5% 0.1N

2.2 TRIGGER SOLUTION 2 – BASE REAGENT

The Trigger Solution 2 – Base Reagent is supplied as a 3 x 270 mL ready to use reagent.

Brand name	Ingredients
Trigger Solution 2 – Base Reagent	• cetyltrimethylammonium surfactant • sodium hydroxide 0.25N

3 SAFETY INSTRUCTIONS

WARNING

H290, H315, H319
P280, P302+P352,
P305+P351+P338, P390

- For hazard and precautionary statements, please refer to the Safety Data Sheet (SDS).This instruction is provided for your safety and gives important instructions for the handling of the solution.
- Read Safety Data Sheet!
- Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas.
- Wear disposable gloves and laboratory coats when handling specimens and kit reagents. Avoid contact with eyes, skin and clothing.
- Avoid swallowing and contact with mucous membranes.
- In case of eye contact rinse immediately with plenty of water and consult a physician. Remove contact lenses, if present and easy to do. Continue rinsing.
- In case of skin contact wash skin immediately with plenty of water. In case of skin irritation or allergic reactions see a physician.
- Move to fresh air in case of accidental inhalation of vapors or decomposition products.
- If swallowed do NOT induce vomiting. Drink plenty of water and seek medical advice. Beware of aspiration if vomiting does occur.
- Do not use damaged, broken or chipped Dispense Cartridges.
- Do not use reagent once frozen.
- Do not mix the remains of reagents.
- Follow Good Laboratory Practices (GLP) when handling the reagents.
- Strictly follow the local and national provisions, legislation and laboratory regulations.

4 REAGENT PREPARATION AND USE

Prior to usage, allow the Trigger Solution 1 and Trigger Solution 2 to reach room temperature (15 - 25 °C).

Inspect the Trigger Solution 1 and Trigger solution 2 – prior to use.

- Do not use any articles whose direct packaging is damaged!
- Do not use any articles whose expiration date has been exceeded!
- Whenever the Trigger Solution 1 – Acid Reagent and Trigger Solution 2 – Base Reagent are replaced, follow the procedure described in the KleeYa® instrument's Instruction for Use.
- To avoid any mix-up, the labels for the Trigger Solutions are marked with Trigger Solution 1 – Acid Reagent (orange) and Trigger Solution 2 – Base Reagent (blue). Follow the color marking on the label when you place the bottles in the device. Correct positioning is essential.
- In case you observe any leakage, remove the Dispense Cartridge from the KleeYa® instrument and use a new one.
- Prime the new Trigger Solutions completely through the reagent lines.
- Do not shake violently to avoid bubble formation.
- Bottle should be stored in standing position till using

5 ENVIRONMENTAL CONDITIONS

5.1 TRIGGER SOLUTION 1 – ACID REAGENT

	Storage Conditions
Temperature:	Storage: 4°C to 25°C (40°F to 77°F) Transport: 4°C to 25°C (40°F to 77°F)
Shelf life:	Trigger Solution 1 – Acid Reagent is stable until the expiration date on the label (one year after manufacturing). Do not use reagent beyond the expiration date printed on the label!
In-use stability:	30 days after opening Discard opened Dispense Cartridge after 30 days!
Notes:	Protect from direct sunlight! Do not freeze!

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the Trigger Solution 1 – Acid Reagent. Refer to the SDS associated with the Trigger Solution 1 – Acid Reagent.

5.2 TRIGGER SOLUTION 2 – BASE REAGENT

	Storage Conditions
Temperature:	Storage: 4°C to 25°C (40°F to 77°F) Transport: 4°C to 25°C (40°F to 77°F)
Shelf life:	Trigger Solution 2 – Base Reagent is stable until the expiration date on the label (one year after manufacturing). Do not use reagent beyond the expiration date printed on the label!
In-use stability:	30 days after opening Discard opened Dispense Cartridge after 30 days!
Notes:	Protect from direct sunlight! Do not freeze!

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the Trigger Solution 2 – Base Reagent. Refer to the SDS associated with the Trigger Solution 2 – Base Reagent.

6 DISPOSAL AND DECONTAMINATION

NOTICE **Disposal of non-contaminated parts**

Material out of use (e.g. packaging material) should be properly disposed.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any local, State and Federal authority requirements / regulations.
Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor.

7 MANUFACTURER

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CE IVD

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