

1 Identification of the IVD reagent

Name	Hypochlorite Solution
Ref. No.	04-4019
UDI-DI	04250878904818
Content	250 mL, ready to use

2 Intended purpose

IVD

Hypochlorite Solution is intended to clean the sample pathway by reducing possibly remaining blood and/or protein residuals from prior sample measurements in Sysmex Partec clinical flow cytometers. Hypochlorite Solution is ready to use and will be fed to the instrument via sample port manually or via automated loading system. Hypochlorite solution is an accessory solution and does not provide any diagnostic information.

Handling with Hypochlorite Solution is restricted to lab technicians and trained FCM operators.

3 Principle of the procedure

Hypochlorite solution, as an accessory solution for flow cytometry, is used to reduce possible residual proteins in the sample pathway of Sysmex Partec clinical flow cytometers after measurement.

For further information, please refer to the Instructions for Use (IFU) of your Sysmex Partec clinical flow cytometer.

4 Storage and shelf life

4.1 Unopened product

Store Hypochlorite Solution at 18-30 °C, do not freeze or expose to elevated temperatures. Under these storage conditions the reagent will be stable until the expiration date printed on its label. Do not use the reagent beyond its shelf life.

4.2 Product after first opening

The shelf life after first opening is the same as the shelf life for unopened reagent if stored at stated storage conditions and used according to the Instructions for Use (IFU).

5 Components

Hypochlorite Solution is an aqueous solution containing < 40 g/L of sodium hypochlorite (CAS no. 7681-52-9).

6 Evidence of deterioration

Hypochlorite Solution is a clear liquid. Do not use Hypochlorite Solution after appearance of any kind of turbidity or contamination.

For questions regarding to the performance or quality of the product received, please contact your local Sysmex representative.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the component authority of the Member State in which the user is located.

7 Precautions and warnings

Appropriate safety precautions and handling procedures must be applied in accordance with applicable laws and regulations.

Refer to the Safety Data Sheet (SDS) for a complete list of warnings and precautions.

7.1 Warning symbols



GHS05
Corrosive

7.2 *Signal word*

DANGER

7.3 *Hazards*

H314	Causes severe skin burns and eye damage.
H412	Harmful to aquatic life with long lasting effects.

7.4 *Precautions*

P260	Do not breathe mist/vapours/spray.
P264	Wash thoroughly after handling.
P280	Wear protective gloves/eye protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P501	Dispose of contents/container to a facility in accordance with local and national regulations.

8 **Additional required equipment**

Instrument: Sysmex Partec clinical flow cytometer, such as the CyFlow™ Counter (Ref. No. CY-S-3023)
 For further information, please refer to the instruction for use (IFU) of the flow cytometer.

Laboratory equipment: A calibrated pipette and pipette tips
 Sample tube(s) compliant to the flow cytometer
 Personal protective equipment

9 **Disposal**

Disposal procedure should meet requirements of applicable local regulations.











10 **Manufacturer**



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11 **Symbols**

 REF	Reference number		Manufacturer	 LOT	Batch code
	Temperature limit		In vitro diagnostic medical device		Use-by date
	Consult instructions for use		CE-mark		Unique device identifier
	Contains sufficient for <n> tests				

12 **Date of issue or revision**

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