BIOSYNEX
Easy Diagnostics for Life

Digitally signed by Bolea Petru
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Location: Moldova

DECLARATION DE CONFORMITE
EC DECLARATION OF CONFORMITY

Nous/ *We* : BioSynex 22 Boulevard Sebastien Brant - 67400 Illkirch Graffenstaden (Tél : +33 (0)3 88 78 78 87, Fax : +33 (0)3 88 77 90 68)
assurons et déclarons que le produit décrit ci-dessous est conforme aux exigences essentielles figurants à l'annexe I de la Directive 98/79/CE du parlement européen et du conseil du 27 octobre 1998 relative aux dispositifs médicaux de diagnostic in vitro. /
herewith declare on our sole responsibility that the above mentioned product is conform with the Essential Requirements according to Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices.

Produit et références / *Product and references* :
Produit/Product: BIOSYNEX® CryptoPS
Référence/ Reference: 1120001

Information complémentaire / *Additional information* :
Classification / *Classification* : *Non listé dans la Directive IVD 98/79/CE*
Not listed in the IVD 98/79/CE Directive

Evaluation de la conformité/*Conformity assessment Route*:
suit la procédure énoncée à l'annexe *III de la Directive 98/79/CE*
Follow the procedure referred to in Annex III of the IVD 98/79/EC Directive

Nom et signature du responsable de la société / *Name and signature of the senior company officier* :

Date et lieu de déclaration *Date and declaration place*	Nom *Name*	Fonction *Title*	Signature *Signature*
Biosynex, le 07/06/2018	Thierry PAPER	Directeur général *General manager*	

BIOSYNEX CryptoPS

Ref: 1120001

EN

RAPID TEST FOR THE SEMI-QUANTITATIVE DETECTION AND TITRATION OF *Cryptococcus sp.* CAPSULAR ANTIGENS IN SERUM, PLASMA, WHOLE BLOOD AND CSF.
For professional in vitro diagnostic use only.

CE

1 I OBJECTIVES

BIOSYNEX CryptoPS is a rapid, single use, immunochromatographic test for the semi-quantitative detection and titration of *Cryptococcus sp*. capsular antigens in serum, plasma, whole blood and CSF.
BIOSYNEX CryptoPS plays a part in the diagnosis of cryptococcal infections, particularly in the case of meningitis. This test is intended for *in vitro* diagnosis use exclusively by health professionals.
BIOSYNEX CryptoPS can be used for the following objectives:

- diagnosis of infection with *Cryptococcus sp*. in symptomatic patients
- identification of patients presenting a high concentration of capsular antigens in the blood, (serum, plasma, whole blood) by the visualisation of the T2 line for poor prognosis, which can be confirmed by titration.
- diagnosis of infection with *Cryptococcus sp* in asymptomatic patients presenting a CD4 level of less than 200 cells/µL.

2 I INTRODUCTION

Cryptococcosis is an opportunist, cosmopolitan illness due to a yeast of the *Cryptococcus species*, the most common of which in human pathology is *Cryptococcus neoformans*. High-risk patients are immunodepressed (mainly people infected with HIV and those who have recently undergone grafts). Most often infection is through inhalation of spores.
The most common clinical expression of the illness is meningoencephalitis. There are about 1 million new cases each year throughout the world, including 625 000 deaths linked to cryptococcal meningitis[1]. The large majority of cases (>70%) occur in sub-Saharan Africa, followed by Asia. Cryptococcosis is the second cause of mortality in immunodepressed patients (HIV, grafts).

3 I TEST PRINCIPLE

BIOSYNEX CryptoPS is a lateral flow immunochromatographic test for the semi-quantitative determination and titration of the *Cryptococcus sp*. antigen in serum, plasma, whole blood and CSF.
The test uses specific polysaccharide capsular antibodies of *Cryptococcus sp*. (clone 18B7) which are coated on the test lines (T1 and T2). During the test procedure, the antigens present in the patient sample react with the anti-polysaccharide antibodies conjugated with gold particles, present in a non-visible part of the test. The complex thus formed migrates and interacts with the antibodies coated on the test lines.
The presence of a colored line in the test line(s) (T1 or T1 & T2) indicates a positive result whilst the absence of a test line indicates a negative result. The line T2 will appear if there is a high concentration of capsular antigens.
A colored line will always appear in the control line region (C). It serves as a procedural control, confirming good migration.

4 I MATERIALS

Provided materials

- Test cassettes, individually packaged in an aluminium pouch with a desiccant
- Capillary pipettes (MicroSafe® 20 µL)
- Dropper bottle of buffer
- Bottle of buffer for the titration protocol
- Vial of positive control
- Instructions for use

Materials required but not provided

- Timer
- Lancets, alcohol wipes and sterile pads (for capillary blood collection)
- Micropipette
- Tubes for dilutions (titration protocol)
- Vortex

5 I STORAGE AND STABILITY

Store in the original packaging at room or refrigerated temperature (2-25°C). This test is stable until the expiry date printed on the packaging. Do not use after the expiry. The test must remain in its sealed pouch until use. Do not freeze the components of the kit.

6 I PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Single use only. Do not re-use.
- For best results, carefully follow the procedure and the storage instructions.
- The volume of the sample to be transferred in the sample well (S) and the number of drops of buffer must be strictly respected.
- Samples collected in heparin tubes can give a lower signal on the T2 line compared to samples collected in EDTA tubes.
- Plasma samples can generate higher results intensities than whole blood samples.
- Do not use the test if its pouch is damaged.
- Do not open the aluminium pouch until it is at room temperature to prevent condensation. Damp and high temperatures may affect results.
- Follow Good Laboratory Practices.
- The samples and the equipment used when performing the test must be considered as potentially infectious and treated as such. Dispose of the test components and samples according to the procedure applicable to potentially infectious waste.
- Do not spill samples into the reaction area. Do not touch the device reaction area to prevent contamination.
- Do not mix and interchange the reagents from various batches.

7 I SAMPLE COLLECTION AND STORAGE

Capillary blood collection:

Use the provided capillary pipette and collect 20 µL of blood following the steps below. The sample should be used immediately.

Prick the finger using a lancet. Rub along the finger to form a large drop of blood.

Collect the drop by approaching horizontally the capillary pipette **without pressing the bulb.**

Repeat the previous step until the volume of blood reaches the line.

Whole blood (venipuncture), serum, plasma, CSF:

Collect aseptically, in accordance to recommended procedures. Handle those samples using a laboratory pipette and tips. Blood or plasma collected in EDTA or heparin can be used. The sample may be used immediately.

Sample storage:

Do not leave the samples at room temperature for long periods.

- Capillary blood collected by finger puncture must be used immediately.
- Whole blood collected by venipuncture must be stored at 2-8°C if the test is performed within 2 days. Do not freeze samples of whole blood.
- Serum, plasma and CSF samples may be stored for 8 hours at 15-30°C or at 2-8°C for 1 day. For longer storage, the samples must be stored at -20°C.

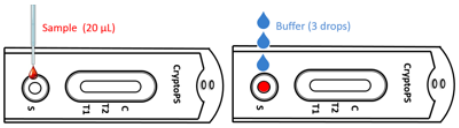
Bring the samples to room temperature before performing the test. The frozen samples must be completely thawed or be mixed well before being tested. Avoid repeated cycles of freezing/thawing of samples.

8 I TEST PROCEDURE

Bring the complete kit and the samples to room temperature (15-30°C) before performing the test.

Semi-quantitative procedure

1. Open the aluminium pouch, remove the cassette from its packaging and place it on a horizontal and flat surface. Perform the test immediately.
2. Transfer 20 µL of sample (whole blood, serum, plasma or CSF) to the sample well (S) of the cassette.
3. Open the bottle of buffer and add 3 drops of buffer to the sample well. Avoid trapping bubbles to the sample well and spilling the liquid into the result reading window.
4. Start the timer. A reddish migration front should appear and migrate along the membrane. Read the result at 10 minutes. A positive result can appear within the first minutes. Do not interpret after 15 minutes.



Titration procedure

1. Prepare 10 tubes and number them from 1 to 10.
2. Transfer 225 µL of buffer from the bottle of buffer dedicated to titration procedure in the tube 1 and 120 µL in the tubes 2 to 10.
3. Add 25 µL of sample to the tube 1, to obtain a 1/10 dilution. Vortex to mix thoroughly.
4. Transfer 120 µL from tube 1 to tube 2 to obtain a 1/20 dilution. Vortex to mix thoroughly.
5. Continue the dilution procedure until tube 10 to get the following dilutions:

Tube 1	Tube 2	Tube 3	Tube 4	Tube 5	Tube 6	Tube 7	Tube 8	Tube 9	Tube 10
1/10	1/20	1/40	1/80	1/160	1/320	1/640	1/1280	1/2560	1/5120

6. Prepare 10 cassettes as described in step 1 of the semi-quantitative procedure.
7. Dispense 100 µL of the tube 1 (1/10) in the sample well (S) of the cassette 1. Dispense 100 µL of the tube 2 (1/20) in the sample well (S) of the cassette 2. Continue the same procedure for each tube until reaching the tube 10 (1/5120) and the cassette 10.
8. Start the timer and read the results at 10 minutes. Do not interpret after 15 minutes.

9 I INTERPRETATION OF THE RESULTS

Results are interpreted as negative, positive or invalid depending on the colored lines that appear in the C control area and T test areas.

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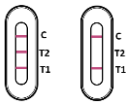
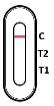
Semi-quantitative procedure interpretation

POSITIVE



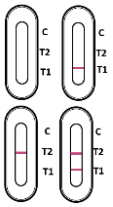
Strong positive: presence of 3 distinct colored lines. A line appears in the C control line area and two colored lines (even of low intensity) appear in T1 and T2 test lines areas.
Positive: presence of 2 distinct colored lines. A line appears in the C control line area and a coloured line (even of weak intensity) appears in the test line T1 area.

NEGATIVE



A single colored line appears in the C control line area. No line appears in the T1 and T2 test line areas.

INVALID



No visible colored line in the C control line area, even if line(s) appear(s) in T1 and/or T2 areas. The results of a test without a control line must be discarded. Review the procedure and repeat the test with a new cassette.
If there is a line in T2 and in C areas, without a line in T1 area, do not interpret, and repeat the test with a new cassette. If the problem persists contact your local distributor.

NB: Do not interpret T1 and T2 lines intensities as indicative for Cryptococcal load. A study[8] showed that the presence of a T2 band is "a potential useful surrogate diagnosis of cryptococcal meningitis that should prompt lumbar puncture and/or CM induction antifungal therapy".

Titration procedure interpretation

For reading refer to the previous paragraph (semi-quantitative procedure interpretation). Please take only the test line T1 into account.
The titer of *Cryptococcus* antigens corresponds to the last dilution allowing a positive result to be obtained.

10 I QUALITY CONTROL

Internal control:

A C control line is used as an internal control of the procedure. Its apparition indicates that the volume of the sample used is sufficient and the procedure has been followed correctly.

External control:

Good Laboratory Practices recommend using controls to ensure that the kit works correctly. A positive control is supplied in the kit. It should be tested often and at least when the kit is opened, according to the control procedures in place within the laboratory. Follow the positive control procedure:

1. Dispense 1 drop of positive control in the sample well (S) of the test cassette.
2. Add 3 drops of buffer.
3. Read the result at 10 minutes.

Note: The positive control must be positive. If the control does not function as expected, do not interpret the test results. Repeat the test or contact your local distributor.

11 I LIMITATIONS

1. As for any diagnostic test, the test result must be correlated with clinical results.
2. The test results should be interpreted taking into account the epidemiological, clinical and therapeutic contexts. Other reference techniques should be considered if necessary.

12 I PERFORMANCE

Analytical sensitivity with yeast suspension

Strains of *Cryptococcus neoformans* of four serotypes (A, B, C and D) were tested with BIOSYNEX CryptoPS. The test detects the four *Cryptococcus neoformans* serotypes.

Analytical sensitivity with purified antigen solution

Purified *Cryptococcus sp.* antigen was tested in serial dilutions to determine the limit of detection of BIOSYNEX CryptoPS.

- The test line T1 appears at 25 ng/mL of capsular antigens of *Cryptococcus sp.* in the CSF and 50 ng/mL of capsular antigen in the serum, plasma and whole blood.
- The test line T2 appears at 2500 ng/mL of capsular antigens of *Cryptococcus sp.*

Internal evaluation

The BIOSYNEX CryptoPS test has been compared with another rapid test. The results are as follows:

	Plasma	*Whole blood*
Relative sensitivity*	95.2% (20/21)	/
Relative specificity	100% (23/23)	100% (23/23)

*T1 line only

External evaluation[7]

The BIOSYNEX CryptoPS test has been compared to another rapid test using 100 samples of whole blood from the serum bank (50 positive samples and 50 negative samples). Relative sensitivity of 96% (48/50) and relative specificity of 96% (48/50) were obtained.

External evaluation[8]

The BIOSYNEX CryptoPS test has been compared to another rapid test using 186 samples of plasma, serum, urine and CSF from antiretroviral therapy (art)-naïve HIV patients. The percentages of agreement between both tests were respectively of 99.5%, 98.3%, 83.4% and 100%.

External evaluation

The BIOSYNEX CryptoPS test has been compared to another rapid test. using 35 samples of CSF (2 positive samples and 33 negative samples). Relative sensitivity of 100% (2/2) and relative specificity of 100% (33/33) were obtained.

Cross reactivity

Nine potentially cross-reacting samples representing 4 different diseases (histoplasmosis, coccidioidomycosis, aspergillosis and trichosporon sepsis) were tested with the BIOSYNEX CryptoPS. No cross-reactivity was observed with any of those clinical samples. However, extracts of *Trichosporon* cultures showed positive results.

Interfering substances

BIOSYNEX CryptoPS test was tested with potential interfering substances. Triloein concentration higher than 7.5 g/L may interfere and generate false negative results on the T2 line. Bilirubin concentration higher than 120 mg/L may interfere and generate false positive results on T1 line. Interference generating false positive results due to high concentration has been observed with clinical samples having concentration of urea and triglycerides above 2 g/L and 3.9 g/L respectively.

Hook effect

A hook effect was studied by testing by serial dilution from a high concentration (100 µg/mL) of purified *Cryptococcus sp*. antigen. All results demonstrated a downward trend of band intensity with increased antigen concentration. No hook effect was observed.

13 I BIBLIOGRAPHY

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2. McTaggart L, Richardson S., Seah C., Hoang L., Fothergill A. and Zhang S., Rapid Identification of *Cryptococcus neoformans* var. *grubii*, *C. neoformans* var. *neoformans*, and *C. gattii* by Use of Rapid Biochemical Tests, ifferential Media, and DNA Sequencing, Journal of clinical microbiology, July 2011, p. 2522–2527
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8. Temfack E. *et col*., Cryptococcal Antigen Screening in Asymptomatic HIV-Infected Antiretroviral Naive Patients in Cameroon and Evaluation of the New Semi-Quantitative Biosynex CryptoPS Test, Frontiers in Microbiology, March 2018, volume 9, article 409.

SYMBOLS

	Carefully read the Instructions for use	Σ	Tests per kit	REF	Product reference
IVD	For *in vitro* diagnostic use only	2°C 25°C	Store between 2°C and 25°C		Do not re-use
	Manufacturer	LOT	Batch no.		Expiry date
DIL	Diluent		Do not use if the packaging is damaged		

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Date of last revision: 11/2021

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002187 0005 Rev. 02

Holder of Certificate: **BIOSYNEX S.A.**

BIOSYNEX

22 boulevard Sébastien Brant
67400 ILLKIRCH-GRAFFENSTADEN
FRANCE

Certification Mark:

Scope of Certificate:

Design and development, production and distribution of rapid in vitro diagnostic reagents for Clinical Chemistry, Immunochemistry, Microbiology and Infectious Immunology.
Design and development, production, distribution and servicing of in vitro diagnostic instruments for Clinical Chemistry, Immunochemistry, Microbiology and Infectious Immunology.
The provision of Distribution Service for in vitro diagnostic reagents for Haematology and for active medical devices for monitoring of vital physiological parameters.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 002187 0005 Rev. 02

Report No.: 713228736

Valid from: 2022-03-16
Valid until: 2023-12-22

Date, 2022-03-16

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002187 0005 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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Design and development, production and distribution of rapid in vitro diagnostic reagents for Clinical Chemistry, Immunochemistry, Microbiology and Infectious Immunology.
Design and development, production, distribution and servicing of in vitro diagnostic instruments for Clinical Chemistry, Immunochemistry, Microbiology and Infectious Immunology.
The provision of Distribution Service for in vitro diagnostic reagents for Haematology and for active medical devices for monitoring of vital physiological parameters.

BIOSYNEX SWISS SA
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Site representation

BIOSYNEX SWISS SA
Route de Rossemaison 100, 2800 Delémont, SWITZERLAND

Distribution of rapid in vitro diagnostic medical devices and instruments for Clinical Chemistry, Immunochemistry, Haematology, Microbiology and diagnosis of Infectious Diseases.
The provision of Distribution Service for active medical devices for monitoring of vital physiological parameters.

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TÜV®

MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product name and reference

Biosynex® CryptoPS Ref: 1120001
RDT CryptoPS Ref: 70725

1.2. Product use

The test is an immunochromatographic test for the qualitative detection of Cryptococcus in serum, plasma, whole blood and cerebrospinal fluid. This kit is intended for use as an aid in the diagnosis of Cryptococcus infection.

1.3. Company identification

Biosynex
22, boulevard Sébastien Brant
67400 ILLKIRCH - GRAFFENSTADEN

Tel.: 0033 388 78 78 87
Fax: 0033 388 77 90 68
Mail: client.pro@biosynex.com
Internet: www.biosynex.com

1.4. Emergency call

France: SAMU : 15
Number ORFILA: 01 45 42 59 59 (provides access to the list of poison centers and their phone number)
Other country: See your local poison information center

2. HAZARD IDENTIFICATION

2.1 Classification of the mixture

- **Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] and EU Directives 67/548/ EEC or 1999/45/EC**

The product contains Sodium azide at a concentration ≤ 0.1 %. So this product is not a hazardous mixture as defined by the Regulation 1272/2008.
Information about the sodium azide being present in the product is related on parts 2.3 and 3.
The product also contains some substances from animal origin. It is therefore recommended to handle it according to the convenient procedures relative to infectious material.

2.2 Label elements

Regarding Regulation 1272/2008, no particular statement is required since the product is not considered as hazardous.

- **Labelling according Regulation (EC) No 1272/2008 [CLP]**

No need

- **According to European Directive 67/548/EEC as amended.**

No need

2.3 Other hazards (relative to sodium azide)
Even in small amount, Sodium azide may react with lead and cooper plumbing to form highly explosive metal azides. Sodium azide is also rapidly absorbed through skin.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Product information
Cf. description of hazardous and non-hazardous components

3.2. Hazardous components:

Description	CAS Number	Einecs Number	Origin	Concentration in the final product	Hazard classification and risk phrase*
Sodium azide	26628-22-8	247-852-1	Chemical	≤ 0,1 % of buffer	Regulation (EC) No 1272/2008 [CLP]: Acute toxicity 2, Acute aquatic toxicity 1, Chronic aquatic toxicity 1 H300, H410

*For the full text of H-statements mentioned in this section, see Section 16

3.3. Non-hazardous compounds:

- Strip: Nitrocellulose membrane, Glass fiber, latex particles, Goat anti-mouse, monoclonal anti-Cryptococcus antibodies
- Diluent: saline solution containing NaCl, BSA,…
- Packaging: Aluminum foil pouches, dessicant

3.4. Confidential compounds
N/A

4. FIRST AID MEASURES

General information Consult a physician. Show this safety data sheet to the doctor in attendance.

After inhalation Expose to fresh air.
If breathing difficult, give oxygen. Consult a physician.

After skin contact: Rinse with water and soap for at least 15 minutes. Consult a physician if irritation extended.

After eye contact: Flush with water for at least 15 minutes. If possible remove contact lenses. Consult doctor in case of prolonged irritation.

After swallowing: Rinse mouth. Contact the Poison Control Center.

5. FIRE FIGHTING MEASURES

Suitable extinguishing measures:	No special measures. Adapt the measure to the environment.
Extinguishing measures to avoid:	No special measures
Special risk:	Fire may produce dangerous products of decomposition like Carbon oxides, Nitrite oxides, Sodium oxides, and Nitrogen oxides in very negligible quantity. No more special risk
Special protective equipment for the firefighting :	Wear self-contained breathing if necessary.

6. ACCIDENTAL RELEASE MEASURES

If any doubt, contact the person in charge of hygiene and safety.

6.1. Measure for individual protection:
Use lab coat and gloves.

6.2. Measure for environmental protection:
Do not throw the diluent into the sink.

6.3. Measures for cleaning and waste collection:
Collect the test in containers according to official regulation.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling:
Use individual protective equipment (lab coat and gloves) for biological compound handling

7.2. Conditions for safe storage, including any incompatibilities:

Information about storage in one common storage facility:	The equipment must be stored between 2 and 25 ° C
Further information about storage condition:	Do not freeze

7.3. Particular use:
Professional in-vitro use only, See instruction for use.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION GEAR

8.1. Exposition cut off:
The product does not contain any element that exceeds the regulatory exposure limit value.
Sodium azide: VLE= 0,3 mg/m^3

Sodium azide: VME= 0,1 mg/m^3

8.2. Individual exposure control:

Respiratory exposure	NA
Hand exposure	Gloves recommended
Eyes exposure	NA
Skin exposure	Port of the coat

8.3. Environmental exposure control:

Collect dipstick and buffer in containers according to the official local regulation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information:

	Device	Diluent
Aspect	Solid	liquid
Color	white	colorless
Odor	N/A	N/A

9.2. Important information relatives to health, safety and environment:

pH	neutral
Boiling point/range	N/A
Melting point/range	N/A
Inflammability	None
Explosion limit	None
Ignition temperature	N/A
Self-ignition	N/A
Flash point	N/A
Danger of explosion	N/A
Explosion limit	N/A
Relative vapor density 20 °C	N/A
Density at 20 °C	N/A
Solubility in water at 20 °C	N/A

9.3. Other information

NA

10. STABILITY AND REACTIVITY

10.1. Chemical stability:

No decomposition if used according to specifications

10.2. Reactivity:

Avoid contact with acidic solutions and metal compounds

10.3. Conditions to avoid:
Do not freeze

10.4. Incompatible materials:
Halogenated hydrocarbon, Metals, strong Acid, Strong oxidizers, Acid chlorides

10.5. Hazardous decomposition products:
Vapors of chlorine, hydrochloric acid, hydrazoic acid can be formed in negligible quantities.

11. TOXICOLOGICAL INFORMATION

Immediate effects on health:	Possibility of irritation in contact buffer extraction with skin and eyes: Rinse thoroughly. Possibility of irritation if swallowed buffer extraction: Contact a poison control center.
Differed and chronic effects on health:	
Sensitization	no data available
Carcinogenicity	no data available
Mutagenicity	no data available
Toxicity for reproduction	no data available
Specific effects from particular compounds:	No more known effects than described in phrase risk.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
For Sodium azid: Toxicity to daphnia and other aquatic invertebrates:
EC50 - Daphnia pulex (Water flea) - 4,2 mg/l - 48 h
No more data available

12.2. Persistence and degradation
No data available

12.3. Bio accumulative potential
No data available

12.4. Mobility in soil
No data available

12.5. Results of PBT and vPvB assessment
No data available

12.6. Other adverse effects
Very toxic to aquatic life with lasting effects

13. DISPOSAL CONSIDERATION

Products - recommendation:
Disposal must be made according to official regulation of medical samples elimination.

Unclean packaging - recommendation:
Must be decomposed together with household garbage.

14. TRANSPORT INFORMATION

14.1 UN number
ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)
ADR/RID:- IMDG: - IATA: -

14.4 Packaging group
ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards
ADR/RID: no IMDG Marine Pollutant: no IATA: no

14.6 Special precautions for user
No data available

15. REGULATION

This MSDS complies with the requirements of Regulation (EC) No. 1907/2006

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
No data available

15.2 Chemical Safety Assessment
No data available. For this product, a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Text of H-codes mentioned in section 3

✓ Sodium azide

EC n°1272/2008 Regulation	
Hazards	Description
H300	Fatal if swallowed
H410	Very toxic to aquatic life with long lasting effects
P phrases	Description
P264	Wash thoroughly after handling
P273	Avoid release to the environment
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P501	Dispose of contents/container to an approval waste disposal plant
European Union Specific Hazard Statements	
EUH032	Contact with acids liberates very toxic gas

The product is intended for in vitro diagnostic and destined to be used by health professionals. The test does not contain any hazardous substances beyond the limits (<0.1%). Sodium azide is present in really small quantity, the toxic risk is then considerably reduced and acceptable. The information in this document is based on the state of our current knowledge of the product. This document is composed in accordance with the Rules and Regulations REACH 1907/2006/EC and Article 31 from Directive 2001/58/EC.