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PATHFAST™ B·R·A·H·M·S PCT

<REAGENT FOR PATHFAST>

60 Tests

English

▪ Intended use

PATHFAST B·R·A·H·M·S PCT is a product for in-vitro diagnostic use with the in vitro diagnostic (IVD) automated analyser PATHFAST for the quantitative measurement of Procalcitonin (PCT) in human serum, heparinized or EDTA whole blood and plasma.
PATHFAST B·R·A·H·M·S PCT is intended to be used:

- as an aid in the early detection and differential diagnosis of clinically relevant bacterial infections,
- as an aid in the assessment of the degree of septic severity and in the risk stratification of patients with systemic bacterial infection, sepsis, severe sepsis and septic shock,
- as an aid in decision making on antibiotic therapy for patients with lower respiratory tract infections (LRTI) and patients with suspected or confirmed sepsis,
- by laboratory technician, nurse or physician,
- in hospital including emergency room, doctor's office and clinical laboratory.

PATHFAST B·R·A·H·M·S PCT is a device for near patient testing (NPT).

▪ Summary

PCT is a 116 amino acids protein, which is the prohormone of calcitonin. PCT is mainly produced by parafollicular cells (C cells) of the thyroid gland and is immediately cleaved into calcitonin, katacalcin and N-terminal fragment after secretion. Therefore, PCT is not detected in blood of healthy individuals. On the other hand, in several bacterial infections, PCT is produced and secreted in the variety of organs such as lung and liver by stimuli of proinflammatory cytokine. Therefore, it is known that PCT is to be a useful biomarker for host response to bacterial infection (1-3).
PCT is useful as an aid in the diagnosis of sepsis, severe sepsis and septic shock in systemic inflammatory response of bacterial infection (3-8) as well as in the assessment of the degree of septic severity and in the risk stratification of critically ill septic patients (9, 10).
PCT is also useful in decision making for initiating and stopping antibiotic treatment in patients with acute respiratory tract infections and sepsis (11-17).

▪ Test principle

The PATHFAST B·R·A·H·M·S PCT procedure is based on chemiluminescent enzyme immunoassay (CLEIA) and MAGTRATION. All required components for performing the testing are packed in one reagent cartridge. By loading PATHFAST B·R·A·H·M·S PCT into the in vitro diagnostic system PATHFAST, PCT can be accurately quantified within 17 min. In this procedure, alkaline phosphatase labelled anti-PCT monoclonal antibody (MoAb) and anti-PCT MoAb coated magnetic particles are mixed with the sample. PCT contained in the specimen binds to the anit-PCT antibodies forming an immunocomplex with enzyme labelled antibody and antibody coated magnetic particles. After removing the unbound enzyme labelled antibody, a chemiluminescent substrate is added to the immunocomplex. After a short incubation, the luminescence generated by enzyme reaction is detected. The PCT concentration in the specimen is calculated by means of a standard curve.
*"MAGTRATION" is technology of B/F separation where magnetic particles are washed in a pipette tip and is a trademark or registered trademark of Precision System Science Co., Ltd.

▪ Package composition of materials provided

Reagent cartridge 6 cartridges x 10 trays
The reagent cartridge consists of 16 wells. All wells with the exclusion of the sample well (# 1) and counting well (# 10) are covered with an aluminium seal having a bar code. All reagents for the test are filled in each well of the reagent cartridge. Do not reuse a reagent cartridge. This is designed for single use only.

Wells	Form	Ingredient	Quantity	Source
# 1	Empty	Sample well	-	-
# 2	Liquid	Alkaline phosphatase conjugated anti-PCT MoAb 2-methyl-4-isothiazolin-3-one* (0.0015 - < 0.01%)	50 µL	Micro-organism Mouse
# 7	Liquid	anti-PCT MoAb coated magnetic particles	50 µL	Mouse
# 13	Liquid	Chemiluminescent substrate, CDP-Star	100 µL	-
# 11	Liquid	Sample dilution buffer 2-methyl-4-isothiazolin-3-one* (0.0015 - < 0.01%)	50 µL	-
# 3, 4, 5	Liquid	Washing buffer Na azide (< 0.1%), Triton X-100 (< 0.1%)	400 µL	-

1, 6, 8, 9, 10, 12, 14, 15, 16 are empty wells.
"CDP-Star" is a trademark or registered trademark of Applied Biosystems, LLC.
* Classification according to Regulation (EC) 1272/2008: Skin sensitisation (Category 1A).
Refer to hazard and precautionary statement on kit box label.

Calibrator 1 (CAL-1)	2.0 mL x 1 bottle (liquid, Na azide < 0.1%)
Calibrator 2 (CAL-2)	For 1.0 mL x 2 vials (lyophilized)
Calibrator diluent	1.0 mL x 2 bottles (liquid, Na azide < 0.1%)
MC ENTRY CARD	1 sheet
Instruction for use	1 sheet

Materials required but not provided
PATHFAST Analyser (Product #: 300929) and consumables
PATHFAST TIP (Product #: 300936)
PATHFAST WASTE BOX (Product #: 300950)
PATHFAST B·R·A·H·M·S PCT Control (Product #: PF0221C)

▪ Precautions and warnings

1. Do not peel off the aluminium seal of the reagent cartridge.
2. Handle the reagent cartridge by holding the edge of it and do not touch the aluminium seal or the black well with your fingers.
3. When the reagent cartridge is dropped and damaged, do not use it.
4. Avoid contamination of saliva in the black well.
5. Avoid contamination of foreign substances such as fungi, bacteria and detergent into specimen.
6. After a certain period of storage or shipment, there may be some reagents adhered to the aluminium seal. If such a condition is observed, gently tap the cartridge on the table before use.
7. Store the reagent cartridges in an upright position at all times.
8. Used reagent cartridges contain human bodily fluids. Handle with appropriate care to avoid skin contact and injection.
9. Azide can react with copper and lead used in some plumbing systems to form explosive salts. When disposing of azide-containing materials, they should be flushed away with large volumes of water.
10. Dispose of all measured reagents and materials according to the standard disposal method. For example, autoclave at 121 °C for 20 minutes. Follow general precautions and handle all components as if capable of transmitting infectious agents.
11. The PATHFAST reporting system contains error codes to warn the operator of specific malfunctions. Any reports containing such error codes should be held for follow-up. See the PATHFAST operator's manual.
12. Patient samples may contain heterophilic antibodies that could react in immunoassay to give a falsely high or low result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.
13. The results should be evaluated in context of all laboratory findings and the total clinical status of the patient. In cases where the laboratory results do not match the clinical picture or history, additional tests should be performed.
14. When any serious incident occurs in relation to the product, report to the manufacturer and the competent authority in which the user and/or the patient is located.

Storage and expiration

1. Store at 2 - 8 °C.
2. Store the cartridge tray with the label side up.
3. Avoid water damage during storage.
4. Do not open the cartridge tray until just before use.
5. Avoid contamination and exposure to direct sunlight.

6. CAL-1 can be used until the expiration date after opening.
7. CAL-2 is stable for 1 month at 2 - 8 °C and 2 months at -20 °C or lower after reconstitution.
8. The expiration date is listed on each reagent cartridge and kit box label.
9. Do not use reagents beyond the indicated expiration date.

Sample collection
Use serum, whole blood or plasma collected with qualified collection tube. Whole blood and plasma should be collected with tube containing Na-heparin, Li-heparin or EDTA.

Sample stability
Whole blood sample is stable under the conditions below:

15 to 25 °C:	8 hours
2 to 8 °C:	24 hours

Plasma and serum samples are stable under the conditions below:

15 to 25 °C:	8 hours
2 to 8 °C:	24 hours
-20 °C or lower:	2 months (freeze only once)

Sample volume: 100 µL

▪ Preparation and procedure
Refer to the PATHFAST operator's manual for detailed information of the analyser operation.

Reagent preparation
1. Reagent cartridge: Ready to use.
2. CAL-1: Ready to use. (Limited to use with reagent of the same lot.)
3. CAL-2: Transfer the whole volume of one bottle of calibrator diluent into one vial of CAL-2. Do not use different lots of calibrator diluent to dissolve CAL-2. Stand for 15 minutes at room temperature after the reconstitution. Mix gently and ensure that calibrator is completely dissolved. (Limited to use with reagent of the same lot.)

Installation of master calibration curve
1. Installation of a master calibration curve is necessary when a new reagent lot is used.
2. Install the master calibration curve by reading the barcode on MC ENTRY CARD, which is enclosed in each package, with the hand-held bar code reader of PATHFAST.

User calibration
1. User calibration is necessary when a new reagent lot is used after installation of the master calibration curve from MC ENTRY CARD.
2. User calibration is also necessary every 4 weeks after the first user calibration. (MC ENTRY CARD is not required.)
3. The calibrators, CAL-1 and CAL-2, must be tested both in duplicate. Therefore, 4 reagent cartridges, two for CAL-1 and two for CAL-2 are necessary for user calibration.
4. Place the reagent cartridges in the cartridge rack, and then dispense approximately 100 µL of CAL-1 and CAL-2 in sample wells to load onto PATHFAST.
5. Push the START button of PATHFAST and perform assay for the calibration.

Quality Control assay (QC assay)
1. QC assay is indispensable for assuring validity of sample results. QC assay is performed after every calibration to check the calibration curves and to obtain data from QC samples for quality control. After each calibration, with each new shipment of previously calibrated test kit, or whenever the institution wishes to verify the performance of the system, analyse two levels of quality control material with known concentrations of PCT.
2. Good laboratory practice recommends the use of appropriate quality controls. It is recommended to follow national, federal, and local guidelines for quality control. If controls do not perform as expected, do not use the test results. Repeat the test or call your authorized PATHFAST distributor for technical service.

Sample assay
1. Place the reagent cartridge in the cartridge rack, then dispense approximately 100 µL of sample into a sample well of a cartridge.
2. Load the cartridge rack onto PATHFAST and push the START button of PATHFAST to perform sample assay.

Note
1. When a whole blood sample is used, the whole blood contained in a blood collection tube should be mixed gently just before dispensing. (Do not use vortex mixer.) After dispensing the whole blood sample and loading the cartridge on PATHFAST, the assay must be started immediately.
2. When fibrin threads or clots and other insoluble materials are present in serum and plasma samples, such material must be removed by centrifugation or filtration.
3. When samples are left for more than 5 minutes after dispensing into a sample well, a lower result will be obtained analysing whole blood because of blood sedimentation and a higher result will be obtained analysing plasma and serum because of increasing PCT concentration by evaporation.
4. When a whole blood sample is used, input of an individual haematocrit value of the sample in PATHFAST is optional.
5. Samples with result above 100 ng/mL should be diluted with normal plasma or serum and retested if a quantitative result is desired or alternatively, they can be reported as > 100 ng/mL.

▪ Specific performance data
Representative performance data on PATHFAST are given below.

Metrological traceability
This method has been standardized against the B・R・A・H・M・S PCT sensitive KRYPTOR assay.

Precision (repeatability)
Precision was assessed with whole blood, plasma and serum samples at each 4 concentration levels. The sample were tested in 20 consecutive replicates. The following results were obtained.

Whole blood	Mean (ng/mL)	S.D. (ng/mL)	C.V. (%)
Level-1	0.481	0.037	7.7
Level-2	2.13	0.104	4.9
Level-3	9.51	0.762	8.0
Level-4	63.1	5.45	8.6

Plasma	Mean (ng/mL)	S.D. (ng/mL)	C.V. (%)
Level-1	0.493	0.018	3.7
Level-2	2.10	0.081	3.9
Level-3	10.9	0.484	4.4
Level-4	70.2	3.61	5.1

Serum	Mean (ng/mL)	S.D. (ng/mL)	C.V. (%)
Level-1	0.553	0.029	5.2
Level-2	2.04	0.075	3.7
Level-3	10.6	0.276	2.6
Level-4	80.4	4.82	6.0

Precision (reproducibility)
Serum samples at 4 concentration levels within the measurement range were assayed in duplicate in each run, 2 runs per day, for 20 days with 1 reagent lot on 1 instrument, for a total of 40 runs. The within-run and total coefficient of variations (C.V.) were calculated with standard deviations (S.D.) according to the CLSI EP5-A2 protocol. The following results were obtained.

Sample	Mean (ng/mL)	Within-run precision		Total precision	
		S.D. (ng/mL)	C.V. (%)	S.D. (ng/mL)	C.V. (%)
Level-1	0.097	0.004	4.1	0.007	7.2
Level-2	2.02	0.105	5.2	0.113	5.6
Level-3	36.1	1.83	5.1	2.19	6.1
Level-4	80.5	4.30	5.3	5.05	6.3

Analytical sensitivity
Limit of blank (LoB): 0.005 ng/mL
Limit of detection (LoD): 0.010 ng/mL
Limit of quantitation (LoQ): 0.014 ng/mL (C.V. 20%), 0.028 ng/mL (C.V. 10%)

Linearity
PCT antigen was spiked into serum at 5 concentration levels (0.088, 1.78, 31.3, 85.7, 114 ng/mL). The samples were serially diluted with 5-fold using normal serum and assayed. The recovery rate against the theoretical value was within 90.8 - 107% up to 114 ng/mL.

Assay range: 0.02 - 100 ng/mL
The assay range was set from the results of LoD and linearity.

High dose hook effect
PCT antigen was spiked into serum at the concentration of approximately 4200 ng/mL. The samples were serially diluted with normal serum and assayed. There was no high dose hook effect for the samples with their PCT values up to 4000 ng/mL.

Analytical specificity

Interference of endogenous substances

The following factors were found to have an effect of less than 10% on the assay at the concentrations indicated in parentheses.

Free bilirubin	(25 mg/dL)
Conjugated bilirubin	(40 mg/dL)
Lipemia	(2500 FTU)
Triglyceride	(2000 mg/dL)
Haemoglobin (haemolysis)	(900 mg/dL)
Rheumatoid Factor	(1500 IU/mL)
Protein (Albumin)	(4 g/dL)
Biotin	(1500 ng/mL)

Interference of exogenous substances

The following drugs which might be used in target patients were found to have an effect of less than 10% on the assay at the concentration indicated in parentheses.

Imipenem	(1.18 mg/mL)
Cefotaxime	(90 mg/dL)
Vancomycin	(3.5 mg/mL)
Dopamine	(13 mg/dL)
Noradrenaline	(2 µg/mL)
Dobutamine	(11.2 µg/mL)
Heparin	(8000 U/L)
Furosemide	(2 mg/dL)

Cross-reactivity

The following substances have no significant cross-reactivity on the assay at the concentrations indicated in parentheses.

Calcitonin	(15 ng/mL)
Katacalcin	(20 ng/mL)
a-CGRP	(10000 ng/mL)
ß-CGRP	(10000 ng/mL)
Calcitonin Salmon	(30 µg/mL)
Calcitonin Eel	(30 µg/mL)

Correlation between samples of serum and other sample matrices

x	y		n	Slope	Intercept	r
Serum	Li-heparin	Plasma	51	1.01	-0.018	0.989
		Whole blood	51	1.01	-0.005	0.978
	Na-heparin	Plasma	51	0.96	-0.002	0.988
		Whole blood	51	0.97	0.001	0.977
	EDTA-2Na	Plasma	51	1.00	0.002	0.992
		Whole blood	51	1.03	-0.002	0.978
	EDTA-2K	Plasma	51	1.01	0.003	0.992
		Whole blood	51	1.03	0.000	0.988

The regression equation was calculated by Passing-Bablok fit.

Method Comparison

y= 0.95x – 0.001, r= 0.977, n= 191 (EDTA plasma samples, y: PATHFAST B・R・A・H・M・S PCT, x: B・R・A・H・M・S PCT sensitive KRYPTOR, Passing-Bablok fit).

Expected values

1. Reference limit
   The reference limit for the PATHFAST B・R・A・H・M・S PCT assay was determined by testing 150 apparently healthy individuals. The 95th percentile of the reference limit was determined to be 0.051 ng/mL.
2. Expected values of systemic bacterial infection/sepsis (3, 4, 9, 18)
   SIRS, sepsis, severe sepsis and septic shock were categorized according to the criteria of the consensus conference of the American College of Chest Physicians/Society of Critical Care Medicine.

PCT (ng/mL)	Interpretation
< 0.5	Low risk for systemic bacterial infection, but local infection possible
≥ 0.5 - < 2.0	Moderate risk for the development of severe systemic infection (severe sepsis or septic shock)
≥ 2.0 - ≤ 10	High risk for the development of severe systemic infection (severe sepsis or septic shock)
> 10	Important systemic inflammatory response with very high risk of severe sepsis and septic shock

3. Decision making on antibiotic therapy for patients with LRTI and sepsis (11 - 17)

PCT (ng/mL)	Interpretation
< 0.1	Indicate absence of bacterial infection. Use of antibiotics strongly discouraged, also in the presence of impaired pulmonary reserve in acute exacerbation of chronic obstructive pulmonary disease (COPD).
≥ 0.1 - < 0.25	Bacterial infection is unlikely. The use of antibiotics is discouraged.
≥ 0.25 - < 0.5	Bacterial infection is possible. Advice to initiate antimicrobial therapy.
≥ 0.5	Suggestive of the presence of bacterial infection. Antibiotic treatment strongly recommended.

Antibiotic therapy should be considered regardless of PCT result if the patient is clinically unstable, is at high risk for adverse outcome, has strong evidence of bacterial pathogen, or the clinical context indicates antibiotic therapy is warranted. If antibiotics are withheld, reassess if symptoms persist/worsen and/or repeat PCT measurement within 6 to 24 hours (< 0.1, ≥ 0.1 - < 0.25 ng/mL).
In order to assess treatment success and to support a decision to discontinue antibiotic therapy, follow up samples should be tested once every 1 or 2 days, based upon physician discretion, taking into account the patients' evolution and progress. Antibiotic therapy may be adjusted using the discontinuation formula below (≥ 0.25 - < 0.5, ≥ 0.5 ng/mL):

PCT_{Peak}: Highest observed PCT concentration
$PCT_{Current}$: Most recent PCT concentration
ΔPCT: Calculated by the following equation:

$$\Delta PCT = (PCT_{Peak} - PCT_{Current})/PCT_{Peak} \times 100\%$$

Antibiotic therapy may be discontinued if the ΔPCT is > 80%, or if the $PCT_{Current}$ is

- < 0.25 ng/mL for LRTI patients
- < 0.5 ng/mL for suspected or confirmed septic patients.

Antibiotic therapy may be continued based upon other clinical findings, such as

- apparent progression on chest x-ray or ongoing/increasing toxicity for LRTI patients or
- failure to control a local infection, or ongoing physiologic instability for patients with suspected or confirmed sepsis.

If clinical picture has not improved and PCT remains high, re-evaluate and consider treatment failure or other causes.

Remark:
PCT < 0.5 ng/mL do not exclude an infection, on account of localized infections (without systemic signs) which may be associated with low concentrations or a systemic infection in its initial stages (< 6 hours). Moderate increased PCT levels (< 2 ng/mL) may occur without infection (e.g. in thyroid, pancreatic and lung cancer or COPD and cystic fibrosis). PCT concentrations should always be interpreted regarding the patient's history (11, 19). It is recommended to retest PCT within 6 - 24 hours in case of suspected bacterial infection and initial low PCT values.

The expected values/reference values may vary from laboratory to laboratory and from country to country depending on various factors. It is therefore recommended for each institution to establish corresponding reference values. In addition, laboratories should be aware of their institution's current practice for the evaluation of SIRS, sepsis, severe sepsis, septic shock and LRTI.

▪ References

1. Muller B, Becker KL, et al. Calcitonin precursors are reliable markers of sepsis in a medical intensive care. Crit Care Med 2000; 28(4): 977-983.
2. Bartolovic D, Ignjatovic S, Stankovic S, et al. Procalcitonin and Other Biomarkers of Sepsis in Newborns in the Intensive Care Unit. EJIFCC. 2011; 22(1): 24-30.
3. Harbarth S, Holeckova K, et al. Diagnostic value of procalcitonin, interleukin-6, and interleukin-8 in critically ill patients admitted with suspected sepsis. Am J Resp Crit Care Med 2001; 164(3): 396-402.
4. Wacker C, Prkno A, Brunkhorst FM, et al. Procalcitonin as a diagnostic marker for sepsis: a systematic review and meta-analysis. Lancet Infect Dis. 2013; 13(5) :426-435.
5. Pontrelli G, De Crescenzo F, Buzzetti R, et al. Accuracy of serum procalcitonin for the diagnosis of sepsis in neonates and children with systemic inflammatory syndrome: a meta-analysis. BMC Infect Dis. 2017; 17(1): 302.
6. Wu JY, Lee SH, Shen CJ, et al. Use of serum procalcitonin to detect bacterial infection in patients with autoimmune diseases: a systematic review and meta-analysis. Arthritis Rheum. 2012; 64(9): 3034-3042.

7. Cabral L, Afreixo V, Almeida L, et al. The Use of Procalcitonin (PCT) for Diagnosis of Sepsis in Burn Patients: A Meta-Analysis. PLoS One. 2016; 11(12): e0168475.
8. Hoeboer SH, van der Geest PJ, Nieboer D, et al. The diagnostic accuracy of procalcitonin for bacteraemia: a systematic review and meta-analysis. Clin Microbiol Infect. 2015; 21(5): 474-481.
9. Arora S, Singh P, Singh PM, et al. Procalcitonin Levels in Survivors and Nonsurvivors of Sepsis: Systematic Review and Meta-Analysis. Shock. 2015; 43(3): 212-221.
10. Liu D, Su L, Han G, et al. Prognostic Value of Procalcitonin in Adult Patients with Sepsis: A Systematic Review and Meta-Analysis. PLoS One. 2015; 10(6): e0129450.
11. Christ-Crain M, Jaccard-Stolz D, et al. Effect of procalcitonin-guided treatment on antibiotic use and outcome in lower respiratory tract infections: cluster-randomised, single-blinded intervention trial. Lancet 2004; 363(9409): 600-607.
12. Schuetz P, Christ-Crain M, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. Jama 2009; 302(10): 1059-1066.
13. Schuetz P, Raad I, Amin DN. Using procalcitonin-guided algorithms to improve antimicrobial therapy in ICU patients with respiratory infections and sepsis. Curr Opin Crit Care 2013; 19(5): 453-460.
14. Schuetz P, Chiappa V, Briel M, et al. Procalcitonin algorithms for antibiotic therapy decisions: a systematic review of randomized controlled trials and recommendations for clinical algorithms. Arch Intern Med. 2011; 171(15): 1322-1331.
15. Schuetz P, Wirz Y, Sager R, et al. Procalcitonin to initiate or discontinue antibiotics in acute respiratory tract infections. Cochrane Database Syst Rev. 2017 Oct 12;10(10):CD007498.
16. Iankova I, Thompson-Leduc P, Kirson NY, et al. Efficacy and Safety of Procalcitonin Guidance in Patients With Suspected or Confirmed Sepsis: A Systematic Review and Meta-Analysis. Crit Care Med. 2018; 46(5): 691-698.
17. Wirz Y, Meier MA, Bouadma L, et al. Effect of procalcitonin-guided antibiotic treatment on clinical outcomes in intensive care unit patients with infection and sepsis patients: a patient-level meta-analysis of randomized trials. Crit Care. 2018; 22(1): 191.
18. American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Crit Care Med 1992; 20(6): 864-874.
19. Stocker M, van Herk W, et al. Procalcitonin-guided decision making for duration of antibiotic therapy in neonates with suspected early-onset sepsis: a multicentre, randomised controlled trial (NeoPIns). Lancet 2017; 390(10097): 871-881.

Symbols

LSI Medience Corporation uses the following symbols and signs in addition to those listed in the EN ISO 15223-1:2021 (Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements).

This symbol means “Device for near patient testing”.
(Symbols for self-testing and near-patient testing under the IVD Regulation 2017/746/EU. MedTech Europe. Dec. 13, 2018)

CARTRIDGE	: Reagent cartridge
CAL 1	: Calibrator 1
CAL 2	: Calibrator 2
DILUENT	: Calibrator diluent
MC ENTRY CARD	: Entry card for master calibration curve

* PATHFAST: JP Registered Trademark No.5982733
* B･R･A･H･M･S is Trademark of B･R･A･H･M･S GmbH.

Chemical Hazard & Precautionary statement(s)

Warning!
May cause an allergic skin reaction.
Avoid breathing mist. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water.
Contains 2-methyl-4-isothiazolin-3-one [EC No. 220-239-6, CAS No. 2682-20-4]

Summary of safety and performance is available from:
European Database on Medical Devices (EUDAMED).

Contact for technical assistance
www.pathfast.eu/contact

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