CE

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Probe Cleaning Kit

For *In vitro* Diagnostic Use

This document is a translation of its original Spanish and English versions. If you have any questions about its interpretation, please consult the original document at www.vitro.bio or request a copy from regulatory@vitro.bio

Probe Cleaning Kit

1 AVAILABLE PRODUCT FORMATS

The presentation available for this product is:

VITRO, S.A. Ref.	BIOCARE Ref	Components	VITRO, S.A. Ref. components	BIOCARE Ref components	Quantity x Volume
MAD-PCLKBC	NPRI10009KC10	Probe Cleaning Solution 1	MAD-PCL1BC	NPRI10012C10	1 vial x 44mL
		Probe Cleaning Solution 2	MAD-PCL2BC	NPRI10013C10	1 vial x 5.5 mL
		Probe Cleaning Solution 3	MAD-PCL3BC	NPRI10014C10	1 vial x 5.5 mL
		Probe Cleaning Solution 4	MAD-PCL4BC	NPRI10015C10	1 vial x 49 mL

Table 1. References and presentation.

2 INTENDED PURPOSE OF THE PRODUCT

For *in vitro* diagnostic use. The Probe Cleaning Kit is available in a ready-to-use format and is specifically designed for automated use in the NeoPATH Pro. The purpose of the Probe Cleaning Kit is to clean the dispensing circuit by removing the DAB and wax residues after staining a number of slides stablished and controlled by the equipment's software.

3 SUMMARY AND EXPLANATION

The MAD-PCLK Probe Cleaning Kit includes reagents that clean the tube circuits by removing DAB precipitates and wax residues in the NeoPATH Pro Inmunostainer. The kit will indicate the schedule and the procedure to correctly perform this type of cleaning to avoid interference with the performance of the IHC protocol.

4 RECONSTITUTION, MIXING, DILUTION

This product is provided in a ready-to-use format. It is not necessary to reconstitute, mix or dilute it.

5 ADDITIONAL REQUIRED MATERIAL NOT SUPPLIED

- NeoPATH Pro

6 SUPPLIED AS

Four separate aqueous solutions for gentle cleaning of the instrument dispensing circuit.

7 STORAGE AND STABILITY CONDITIONS

Component	Use conditions
Storage conditions	Store at room temperature (15°-25°C) and keep away from sources of intense heat/cold until the expiration date of the product. Keep component PCL-3 away from direct light.

Component	Use conditions
In-use stability	Once open, keep at room temperature (15°-25°C) and keep away from sources of intense heat/cold until the expiration date of the product.
Shipping conditions	Shipment should be performed at room temperature (15-25°C).

Table 2. Storage and stability conditions.

The product is stable to the expiration date printed on the label when stored at 15°-25°C. Do not use after expiration date.

8 WARNINGS AND PRECAUTIONS

- **Read the instructions for use before using this product.** In case of atypical or unexpected results, please contact your Authorized Supplier/Distributor.
- **Professional Use.** This product is only intended for professional laboratory purposes, and it is not intended for pharmacological, domestic or any other type of use. When the product is used as an aid to diagnosis it should only be handled by trained users and in authorized laboratories.
- Do not use reagent after the expiration date printed on the label.
- Rx Only **Physician prescribed test.** This product is for professional use only on prescription by a physician or other healthcare professional.
- **Serious incident.** Any serious incident related to the use of this product that involves or may involve a serious deterioration, temporary or permanent, of the state of health of a patient, user or other person, or even death, or a serious threat to public health, must be reported as soon as possible to the manufacturer by e-mail at regulatory@vitro.bio and to the competent Health Authority of the EU member state where the user or patient is established. If the user is located in USA, report any serious incidents related to this device by contacting the local distributor (information identified on the product labelling) and the applicable competent authority of the Member State. Incidents caused by misuse of the product or by the use of the product beyond the useful life established on its labeling will be the responsibility of the user.
- **The safety and disposal precautions are described in the Safety Data Sheet of this product.** The current version of the Safety Data Sheet (SDS) of this product can be downloaded in the web page www.vitro.bio or requested at regulatory@vitro.bio.
- **Waste disposal:** The handling of wastes generated by the use of the products commercialized by Vitro S.A. must be performed according to the applicable law in the country in which these products are being used. As reference, the following table indicates the classification of wastes generated by this kit according to the European Law, specifically according to the *European Commission Decision of December 18, 2014* amending decision 2000/532/CE on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council:

POTENTIAL WASTE GENERATED AFTER USING THIS PRODUCT	ELW* CODE	TYPE OF WASTE ACCORDING TO ELW*
Container for reagents used classified as dangerous (according to the Safety Data Sheet).	150110	"Containers containing waste or contaminated by dangerous substances"
Aqueous liquid waste containing hazardous substances (not solvents).	161001	"Liquids generated from the use of automatic IHC/HIS instruments: - Waste deposit of immunostainers. - used PT-Module buffers"
Consumables (tubes, tips, etc.). Any element that has been in contact with	180103	"Waste whose collection and disposal is subject to special requirements in order to

POTENTIAL WASTE GENERATED AFTER USING THIS PRODUCT	ELW* CODE	TYPE OF WASTE ACCORDING TO ELW*
tissue samples.		prevent infection"
Liquids containing solvents (xylol, haematoxylin, alcohol, eosin), generated from immunostaining techniques.	160506	"Laboratory chemicals consisting of or containing dangerous substances, including mixtures of laboratory chemicals"

Table 3. Classification of waste generated by the use of this kit according to the European Legislation. *ELW: *European Legislation of Waste.*

***Note: This classification is included as a general guideline of action, being under the final responsibility of the user the accomplishment of all the local, regional, and national regulations on the disposal of this type of materials**.

9 INSTRUCTIONS FOR USE

Place the different solutions from the Probe Cleaning Kit in the instrument and start the procedure indicated by the NeoPATH Pro software clinking on the Start Washing button**.**

10 TROUBLESHOOTING

If atypical results occur, contact Vitro's Regulatory Department at regulatory@vitro.bio. If the user is located in USA, contact the local distributor (information identified on the product labelling).

11 LABEL AND BOX SYMBOLS

Explanation of the symbols of the product label and box:

IVD	In vitro diagnostic medical device		Expiration date
REF	Catalog number		Temperature limit
LOT	Lot code		Manufacturer
	Refer to the instructions for use		Safety data sheet
	Distributor		Importer

12 CHANGELOG

Date	Description
2025-02-27	The document is updated to bring it in line with FDA and (EU) IVDR 2017/746 Regulation.