

HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 13 tháng 06 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

Nguyễn Thị Kim Chi

Phadia™ Maintenance Solution

Directions for Use 52-5719-EN/01

INTENDED USE

Phadia Maintenance Solution is intended for cleaning of Phadia instruments.

REAGENTS AND MATERIAL

Reagents are packaged as described below, each purchased separately. The two-digit suffix (-xx) on the article number may vary between countries. All products are not available in all countries.

The expiration date and storage temperature are stated on the labels. Do not use reagents beyond their expiration dates or if damaged or incorrectly stored.

Reagents for Phadia instruments

- **Phadia Maintenance Solution Small** (Art No 10-9546-01: 10 x 1.5 l)
 - Phadia Maintenance Solution Small, 10 x 23 ml
- **Phadia Maintenance Solution Large** (Art No 10-9547-01: 8 x 5 l)
 - Phadia Maintenance Solution Large, 8 x 77 ml

Details of reagents

Phadia Maintenance Solution Small/Large	
<ul style="list-style-type: none"> • 2-aminoethanol, CAS No: 141-43-5; $\geq 2.5 - < 5\%$ • Sodium hydroxide, CAS No: 1310-73-2; $\geq 2.5 - < 5\%$ • Quaternary ammonium compound, benzyl-C12-16-alkyldimethyl, chlorides, CAS No: 68424-85-1; $\geq 1 - < 2.5\%$. 	Store at 2 – 32 °C until expiration date. Reconstitution, see below.

Additional material

- **Dilution well** (for use with Phadia 100 and Phadia 200), (Art No 14-5614-35: carriers of 18 wells)



Precautions

Phadia Maintenance Solution:



Danger

- May be corrosive to metals (H290).
- Causes severe skin burns and eye damage (H314).
- Causes serious eye damage (H318).
- Wear protective gloves/protective clothing/eye protection/face protection (P280).
- IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower (P303+P361+P353).
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338).
- Immediately call a POISON CENTER /doctor (P310).
- Store locked up (P405).
- Dispose of contents and container in accordance with local/regional/national/international regulations (P501).
- When preparing Phadia Maintenance Solution use tightly sealed goggles (EN166) and protective gloves (EN374). Use suitable respiratory protective device only when aerosol or mist is formed.

Disposal

Follow local disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of the products.

PROCEDURES

Preparation of Phadia Maintenance Solution Small, Art No 10-9546-01



When preparing Phadia Maintenance Solution Small use tightly sealed goggles (EN166) and protective gloves (EN374). Use suitable respiratory protective device only when aerosol or mist is formed.

1. Pour 1500 ml purified water (1, 2) or Clinical Laboratory Reagent water (CLRW, 3) into a glass beaker.
2. Add one bottle (23 ml) of Phadia Maintenance Solution Small to the water.
3. Mix gently. If possible, use a magnetic stirrer.

Prepared Phadia Maintenance Solution is stable for 3 days at 2-32 °C.

Preparation of Phadia Maintenance Solution Large, Art No 10-9547-01



When preparing Phadia Maintenance Solution Large use tightly sealed goggles (EN166) and protective gloves (EN374). Use suitable respiratory protective device only when aerosol or mist is formed.

1. Pour 5000 ml purified water (1, 2) or Clinical Laboratory Reagent water (CLRW, 3) into a glass beaker.
2. Add one bottle (77 ml) of Phadia Maintenance Solution Large to the water.
3. Mix gently. If possible, use a magnetic stirrer.

Prepared Phadia Maintenance Solution is stable for 3 days at 2-32 °C.

Maintenance procedure in Phadia instruments

For more information, see the instrument specific user manual.

WARRANTY

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Phadia AB may affect the results, in which event Phadia AB disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and fitness for use. Phadia AB and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

SYMBOLS

	Use-by date		Contains sufficient for <n> tests
	Batch code		In vitro diagnostic medical device
	Date of manufacture		Temperature limit
	Catalogue number		Consult instructions for use
	Caution		Biological risks
	Manufacturer		Danger

Full symbol glossary is available at: https://symbols_glossary.phadia.com.

REFERENCES

1. US Pharmacopeia & National Formulary, current edition.
2. European Pharmacopoeia, current edition.
3. CLSI. Preparation and Testing of Reagent Water in the Clinical Laboratory, Approved Guideline – Fourth Edition. CLSI document GP40-A4-AMD. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

Patents/Trademarks

The following designations are trademarks belonging to Phadia AB: ImmunoCAP, Phadia.

Trademark change: Phadia AB has changed the trademarks of the instrument platforms from "UniCAP™" and "ImmunoCAP™" to "Phadia™". The new name has been applied to the instruments and related items, e.g. software and user manuals. The trademark "ImmunoCAP™" has been removed from the System Reagents. This is a trademark change only; the change has no impact on performance or safety.

Addresses

AUSTRIA Thermo Fisher Diagnostics Austria GmbH
Dresdner Str. 89
A-1200 Vienna
Tel: +43-1 270 2020 Fax: +43-1 270 202020
BELGIUM Thermo Fisher Diagnostics NV
Guldensporenpark 26 Gebouw C
BE-9820 MERELBEKE
Tel: (FR) +32-9 272 5780 (NL) +32-9 272 5781

Fax: +32-9 272 5787

BRAZIL Phadia Diagnósticos Ltda.
Rua Eugênio de Medeiros, 303 cj 1101C
05425-000 São Paulo – SP
Tel: +55 0800 5515 355

CHINA Thermo Fisher Scientific (China) Co., Ltd.
Building 6-7
No. 27 Xin Jin Qiao Road
Shanghai 201102
P.R. China

Tel: +86 800 810 5118 Fax: +86 21 6100 2128

CZECH REPUBLIC Thermo Fisher Scientific, Phadia s.r.o.
Freyova 82/87
19000 PRAHA 9

Tel: +420 220 518 743 Fax: +420 220 518 743

DENMARK Thermo Fisher Diagnostics ApS
Gydevang 33
DK-3450 ALLERØD

Tel: +45-70 23 33 06 Fax: +45-70 23 33 07

FINLAND Thermo Fisher Diagnostics Oy

Ratastie 2

P.O. Box 100

FI-01620 VANTAA

Tel: +358 10 3292 110

FRANCE Thermo Fisher Diagnostics S.A.S.
CS60610

FR-78056 ST QUENTIN-YVELINES CEDEX

Tel: +33-1 61 37 34 30 Fax: +33-1 30 64 62 37

GERMANY Thermo Fisher Diagnostics GmbH

Munzinger Str. 7, D-79111 FREIBURG

Tel: +49-761 47 805-0 Fax: +49-761 47805-338

Mail: Thermo Fisher Diagnostics GmbH

Postfach 1050 DE-790 10 FREIBURG

HONG KONG Thermo Fisher Scientific (Hong Kong) Limited

Units 01, 09-13 & 15-18, Level 13, Tower 1

Kowloon Commerce Centre

No. 51 Kwai Cheong Road, Kwai Chung

New Territories, Hong Kong

Tel: +852 3107 7600 Fax: +852 2567 4447

INDIA Thermo Fisher Scientific India Pvt. Ltd

Unit No.07, 10 & 11, ground floor,

Splendor forum, plot no 03

Jasola, District Centre,

NEW DELHI-110025

Tel: +91 11 49375400

IRELAND Thermo Fisher Diagnostics (Ireland) Ltd.

Registered office

25/28 North Wall Quay, DUBLIN 1

Tel: +44 1800 62 51 67

ITALY Thermo Fisher Diagnostics S.p.A.

Via G. B. Tiepolo, 18

IT-20900 MONZA (MB)

Tel: +39 039 8389.1 Fax: +39 039 838 9329

JAPAN Thermo Fisher Diagnostics K.K.

Sumitomo Fudosan Mita Twin Bldg. East 4F

4-2-8 Shibaura, Minato-ku,

Tokyo 108-0023, Japan

Tel: +81 3 6872 6200 Fax: +81 3 6872 6220

KOREA Thermo Fisher Scientific Korea Ltd.

12FL, Suseo Office Building, 10

281, Gwanggyeong-ro, Gangnam-gu,

Seoul 06349, Korea

Tel: +82 2 6196 5556-9 Fax: +82 2 6196 5555

THE NETHERLANDS Thermo Fisher Diagnostics B.V.

Postbus 696

NL-3430 AR NIEUWEGEIN

Tel: +31-30 602 37 00 Fax: +31-30 602 37 09

NORWAY Thermo Fisher Diagnostics AS

Postboks 114, Smestad

NO-0309 OSLO

Tel: +47-21 67 32 80

PORTUGAL Thermo Fisher Diagnostics,

Sociedade Unipessoal Lda.

Lagoas Park - Edifício nº11 - Piso 0

PT-2740-270 PORTO SALVO

Tel: +351-214 23 53 50 Fax: +351-214 21 60 36

