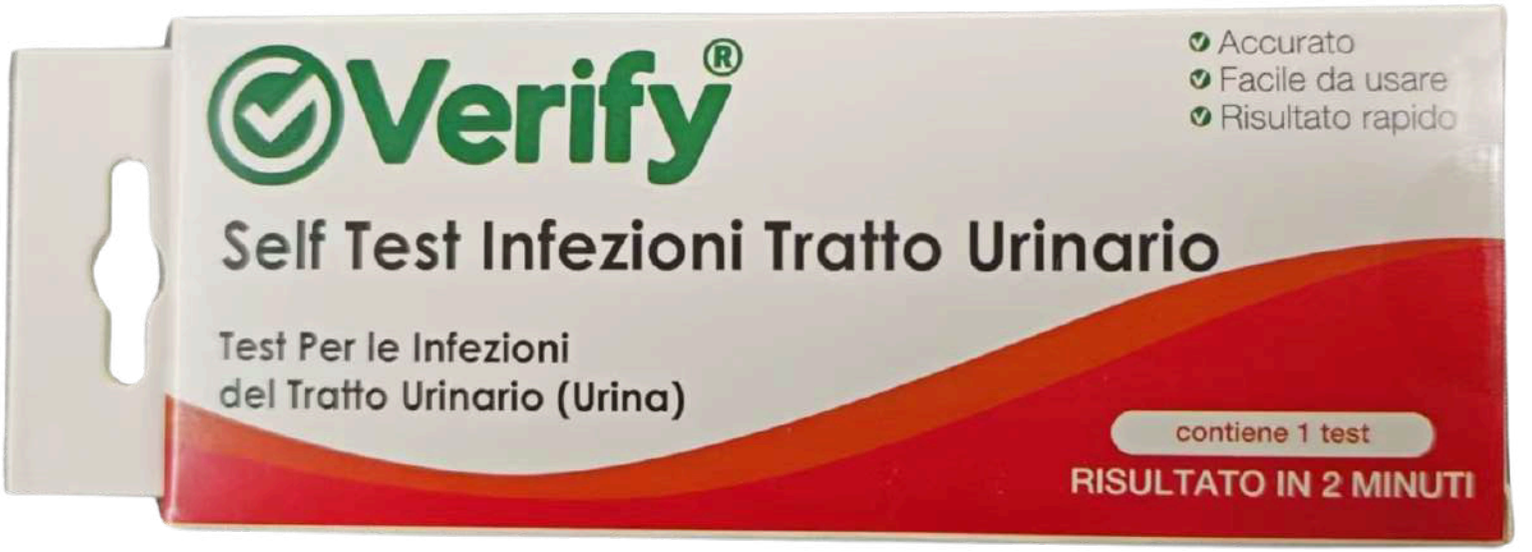
Verify®
Accurato
Facile da usare
Risultato rapido
Self Test Infezioni Tratto Urinario
Test Per le Infezioni
del Tratto Urinario (Urina)
contiene 1 test
RISULTATO IN 2 MINUTI

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Products for determination of infection markers tumor markers and products for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1 095123 0008 Rev. 04

Report no.: SH221064A02

Valid from: 2022-04-05
Valid until: 2025-05-26

Date, 2022-04-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 095123 0008 Rev. 04

Model(s):

Toxo IgG/IgM Rapid Test,
Rubella IgM Rapid Test,
CMV IgM Rapid Test,
ToRCH IgM Combo Rapid Test,
PSA Rapid Test,
PSA Qualitative Rapid Test,
Chlamydia Rapid Test,
Sperm Concentration Rapid Test,
SP-10 Male Fertility Rapid Test,
hCG Rapid Test,
Digital hCG Pregnancy Test
LH Rapid Test,
FSH Rapid Test,
Vaginal pH Rapid Test,
Ferritin Rapid Test,
TSH Rapid Test,
H.pylori Rapid Test,
Urinary Tract Infections Test,
FOB Rapid Test,
Vitamin D Rapid Test

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

EC Declaration of Conformity

Manufacturer:
Name: HANGZHOU ALLTEST BIOTECH CO., LTD.
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:
Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Urinary Tract Infections Test Dipstick
Cat. No.: U031-04H
Analyte: Leukocytes (LEU)/ Blood (BLO)/ Nitrite (NIT)/ Protein (PRO)
Model: Dipstick
Classification: Self-testing of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex IV
EDMA Code: 11 70 02 02 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.
DIRECTIVES
General applicable directives:
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016
Notified body: TUV SUD Product service GmbH, Ridlerstrasse 65, 80339 Munich, Germany (0123)
(EC) Certificate(s): V1 095123 0008 Rev.04
Expire date of the Certificate: 2025-05-26
Place, Date of First issue of DOC: in Hangzhou on 2017-09-12
The Date of Issue of DOC on 2022-04-05

Signature:
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou -310018, P.R. China

杭州奥泰生物技术股份有限公司
地址：杭州市经济技术开发区
银海街550号
邮编：310018

TEL：+86 571 56267891
EMAIL：info@alltests.com.cn
http:// www.alltests.com.cn

电话：+86 571 56267891
邮箱：info@alltests.com.cn
网址：www.alltests.com.cn

Certificate of Analysis

Product Name: Urinalysis Tract Infections Test (Urine)

Catalog No.: U031-04H

Batch No.: URS25020042

Quantity:1000PCS

Expiry Date:2027-01

Date of Sampling:2025-03-05

Date of Analysis: 2025-03-05

Other information:/

QC Item		QC Criterion	QC Result	Conclusion
Appearance	Good	Good	Pass	Appearance
Performance				
LEU	Standard sample	++	Meet the Criteria	Pass
	Negative	-	Meet the Criteria	Pass
BLO	Standard sample	++	Meet the Criteria	Pass
	Negative	-	Meet the Criteria	Pass
NIT	Standard sample	+	Meet the Criteria	Pass
	Negative	-	Meet the Criteria	Pass
PRO	Standard sample	++	Meet the Criteria	Pass
	Negative	-	Meet the Criteria	Pass

Others	

Final QC Conclusion：	This batch of product met the QC Criteria.

杭州奥泰生物技术股份有限公司 质检章

QC supervisor: Freeman.zheng

Date:2025.03.05

Control