



- ✓ Accurato
- ✓ Facile da usare
- ✓ Risultato rapido

# Self Test Ferritina

Cassetta Per Test Rapido Ferritina  
(Sangue Intero da Dito)

contiene 1 test

**RISULTATO IN 5 MINUTI**



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](http://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



# EC Certificate

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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#, Yin Hai Street, Hangzhou Economic and Technological  
Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF  
CHINA

## 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: Ferritin Rapid Test Cassette

Cat. No.: OFE-402

Analyte: Ferritin in human serum/ plasma/whole blood

Model: Cassette

Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 6)

EDMA Code: 12 70 01 90 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

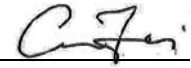
**General applicable directives:**

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 ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of First Issue of DOC in Hangzhou on 18/12/2019

Date of Issue of DOC on 22/02/2022

Signature: 

Name: GAO FEI (Position: General Manager)

|                                                 |                                       |
|-------------------------------------------------|---------------------------------------|
| 杭州奥泰生物技术股份有限公司 Hangzhou AllTest Biotech Co.,Ltd | 文件号 Document No.: ZTC-QC-005-R-005    |
| 其他类 COA The Other COA                           | 生效日期 Effective Date: 2018 年 07 月 02 日 |

## Certificate of Analysis

**Product Name: Ferritin Rapid Test Cassette (WB)**

**Catalog No.: OFE-402H**

**Batch No.: FRT25020018**

**Quantity:1000PCS**

**Expiry Date:2027-01**

**Date of Sampling:2025-03-03**

**Date of Analysis: 2025-03-03**

**Other information:**

**Buffer Lot: 25025029,EXP:2027-01**

| QC Item                |                 | QC Criterion | QC Result     | Conclusion |
|------------------------|-----------------|--------------|---------------|------------|
| Physical               | Appearance      | Good         | Good          | Pass       |
| Functional Performance | Positive Sample | Positive     | 100% Positive | Pass       |
|                        | Negative Sample | Negative     | 100% Negative | Pass       |

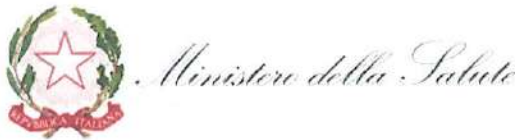
|               |   |
|---------------|---|
| <b>Others</b> | / |
|---------------|---|

|                             |                                            |
|-----------------------------|--------------------------------------------|
| <b>Final QC Conclusion:</b> | This batch of product met the QC Criteria. |
|-----------------------------|--------------------------------------------|

**QC supervisor:** Freeman.zhong

**Date: 2025.03.03**





[Stampa](#) | [Scarica il dataset](#)

Elenco dei dispositivi medici

Criteri di ricerca:  
Denominazione fabbricante:  
Codice fiscale fabbricante:  
Partita IVA / VAT number fabbricante:  
Codice nazione fabbricante:  
Denominazione mandatario:  
Codice fiscale mandatario:  
Partita IVA / VAT number mandatario:  
Codice nazione mandatario:  
Tipologia dispositivo:  
Identificativo di registrazione attribuito dal sistema BD/RDM:  
Codice attribuito dal fabbricante: **verify OFE-402H**  
Nome commerciale e modello:  
Classificazione CND:  
Descrizione CND:  
Normativa:  
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:02/03/2025

| DISPOSITIVO MEDICO/ASSEMBLATO |                     |                           |                                                   |                                      |                            |                    |                                                               |                             |                                         | FABBRICANTE/ASSEMBLATORE |                                             |                   |                              |      |
|-------------------------------|---------------------|---------------------------|---------------------------------------------------|--------------------------------------|----------------------------|--------------------|---------------------------------------------------------------|-----------------------------|-----------------------------------------|--------------------------|---------------------------------------------|-------------------|------------------------------|------|
| TIPOLOGIA<br>DISPOSITIVO      | IDENTIFICATIVO      |                           | CODICE ATTRIBUITO DAL<br>FABBRICANTE/ASSEMBLATORE | NOME<br>COMMERCIALE CND<br>E MODELLO |                            | NORMATIVA          | CLASSE CE                                                     | DATA PRIMA<br>PUBBLICAZIONE | DATA FINE<br>IMMISSIONE<br>IN COMMERCIO | RUOLO<br>AZIENDA         | DENOMINAZIONE                               | CODICE<br>FISCALE | PARTITA<br>IVA/VAT<br>NUMBER | NAZI |
|                               | DI<br>REGISTRAZIONE | ISCRITTO AL<br>REPERTORIO |                                                   |                                      |                            |                    |                                                               |                             |                                         |                          |                                             |                   |                              |      |
| Dispositivo                   | 2750513             | N                         | VERIFY OFE-402H VERIFY                            | VERIFY SELF<br>TEST<br>FERRITINA     | W0102070102<br>- FERRITINA | D.L.vo<br>332/2000 | ST - Test<br>autodiagnostics<br>(non inclusi<br>nell'alt. II) | 25/02/2025                  |                                         | FABBRICANTE              | HANGZHOU<br>ALLTEST<br>BIOTECH CO.,<br>LTD. |                   |                              | CI   |
|                               |                     |                           |                                                   |                                      |                            |                    |                                                               |                             |                                         | MANDATARIO               | MEDNET EC-REP<br>GMBH                       |                   | DE126042714                  | D    |

FARMADATI ITALIA Srl

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29121 PIACENZAUfficio Parafarmaco  
Tel. 0523 336933  
Fax 0523 336667  
[parafarmaco@farmadati.it](mailto:parafarmaco@farmadati.it)

L'Ufficio PARAFARMACO è a Vs disposizione dal lunedì al venerdì (8:30 -18:30) per: attribuzione codici paraf, aggiornamento anagrafica prodotti e prezzi e consulenza e informazioni.

Nella Tabella sono riportati i codici base 10 e base 32 attribuiti ai prodotti per l'elaborazione del Barcode tipo 39 in base 32.

N.B. nel codice base 32 non sono utilizzabili le lettere: A,E,I,O. I codici paraf notificati con il presente modulo sono univoci e validi per tutto il territorio nazionale. La variazione della grammatura o della descrizione del prodotto, comporta l'attribuzione di un nuovo paraf.

| Codice base 10 | Codice base 32 | Codice a barre | Codice EAN    | Descrizione prodotto      | Ditta       | Codice articolo (ditta) | Iva | Prezzo al pubblico indicativo | Data prezzo al pubblico | Data inizio commercio |
|----------------|----------------|----------------|---------------|---------------------------|-------------|-------------------------|-----|-------------------------------|-------------------------|-----------------------|
| 950086342      | WB2BQ6         |                | 6936983170482 | VERIFY FERRITINA SELFTEST | VERIFY Srls | OFE-402H                | 22  | 9,90                          | 01/12/2024              | 01/12/2024            |