

Certificate of Compliance



No. 2P150428.HABUS30

Certificate's
Holder:

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

Certification ECM
Mark:



Product:

In Vitro Diagnostic Kit for Detection of
Infectious Disease – Professional Use

Types:

(see the following annex I)

Verification to:

Standard:
EN ISO 13485:2012/AC:2012,
EN ISO 14971:2012, EN 13975:2003,
EN ISO 18113-1:2011, EN ISO 18113-2:2011,
EN 13612:2002/AC:2002, EN ISO 17511:2003,
EN ISO 15193:2009, EN ISO 15194:2009,
EN 13640:2002, EN 13641:2002, EN 1041:2008,
ISO 15223-1:2012

related to CE Directive(s):
98/79/EC (In Vitro Diagnostic Medical Devices)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.

Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification ECM Mark.

This certificate can be checked for validity at www.entecerma.it

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Expiry date 27 April 2020

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Annex I

No. 2P150428.HABUS30



- Types:
- Adenovirus Rapid Test (Feces),
 - Chagas Rapid Test (Whole Blood/Serum/Plasma),
 - Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma),
 - Dengue Rapid Test (Whole Blood/Serum/Plasma),
 - Dengue Combo Rapid Test (Whole Blood/Serum/Plasma),
 - Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma),
 - Gonorrhoea Rapid Test (Swab),
 - H.pylori Antibody Rapid Test (Serum/Plasma),
 - H.pylori Antibody Rapid Test (Whole Blood/Serum/Plasma),
 - H.pylori Antigen Rapid Test (Feces),
 - HAV Rapid Test (Serum/Plasma),
 - HBcAb Rapid Test Cassette (Serum/Plasma),
 - HBeAb Rapid Test (Serum/Plasma),
 - HBeAg Rapid Test (Serum/Plasma),
 - HBsAb Rapid Test (Serum/Plasma),
 - HEV IgG/IgM Rapid Test (Serum/Plasma),
 - HPV Rapid Test (Throat Swab),
 - Influenza A Rapid Test (Swab/Nasal Aspirate),
 - Influenza A+B Rapid Test (Swab/Nasal Aspirate),
 - Malaria P.f. Rapid Test (Whole Blood),
 - Malaria P.f./Pan Rapid Test (Whole Blood),
 - Malaria P.f./P.v. Rapid Test (Whole Blood),
 - MONO Rapid Test (Whole Blood/Serum/Plasma),
 - Rotavirus and Adenovirus Combo Rapid Test (Feces),
 - Rotavirus Rapid Test (Feces), Strep A Rapid Test (Throat Swab),
 - Strep B Rapid Test (Throat Swab),
 - Syphilis Rapid Test (Serum/Plasma),
 - Syphilis Rapid Test (Whole Blood/Serum/Plasma),
 - Tuberculosis Rapid Test (Whole Blood/Serum/Plasma),
 - Typhoid Rapid Test (Whole Blood/Serum/Plasma)