INSTRUCTIONS FOR USE

HELICOBACTER PYLORI CONTROLLI

POSITIVE AND NEGATIVE CONTROL FOR REF. VT82000, VT82001 AND VC1150

1 – CLINICAL SIGNIFICANCE AND INTENDED USE

For ***in Vitro*** diagnostic use only

Good Laboratory Practice recommends the use of positive and negative controls to assure functionality of reagents and proper performance of assay procedure. Positive and negative controls will monitor the entire assay are provided in the kit.

Positive and negative controls should be tested once for each new test kit opened and as otherwise required by your laboratory's standard quality control procedures.

It can be used either as the internal quality control of the immunochromatographic test kit.

HELICOBACTER PYLORI CONTROLLI is a kit with a stabilized buffer enriched preparation of H. pylori. It is intended for accuracy control for rapid test procedures for the detection of Helicobacter pylori antigens.

2 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
HELICOBACTER PYLORI CONTROLLI CND: W0105080801; EDMA: 15.50.01.01.00; RDM: 1555781/R	Controls for immunocromatographic tests	**UD80005** (2 x 1 mL)	1 glass bottle with red dropper containing Positive Control: stabilized enriched preparation of H. pylori, with biological additives and bacteriostatic agents. (1.0 mL) 1 glass bottle with green dropper containing Negative Control: stabilized liquid control, contain Sodium azide <0.1% (1,0 mL) Secondary packaging: cardboard box.

3 - MATERIALS REQUIRED BUT NOT PROVIDED

Immunochromatographic test.

4 - PRECAUTIONS AND WARNINGS

- HELICOBACTER PYLORI CONTROLLI is a kit for *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel.
- Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.
- The sensitivity of the test may be reduced at low temperatures. Allow the reagents and samples to reach room temperature (15-30ºC/59-86ºF) before use.
- Do not use after expiration date or if the packaging is damaged. The quality of the reagent cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.
- Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state, provincial or national regulations. Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- This product is classified as not dangerous according to current European legislation.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.masciabrunelli.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.
- Notify Mascia Brunelli Spa and the Relevant Authorities of any serious incidents occurring in connection with the in vitro diagnostic device. complaint@masciabrunelli.it

5 - STORAGE CONDITIONS AND SHELF LIFE

All the kit components will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Reagents deterioration: Presence of particles and turbidity

6 - TEST PROCEDURE

Allow the components of the kit to reach to room temperature (15-30ºC/59-86ºF) prior to testing.

Use as samples following the instructions for use of the kits.

7 – READING, INTERPRETATION AND CALCULATION

Interpret the results as indicated in the IFUs of the kits to be tested.

In any case, with tests for the determination of H. pylori, the positive control must give the presence of the test band, confirming the success of the test. The negative control must not give any test band.

TABLE OF APPLICABLE SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 4	Updated layout and content	2022/12

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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