CHLAMYDIA T. CONTROLS

For *in Vitro* diagnostic use

INTENDED USE

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 control 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.

REAGENTS AND MATERIALS

N.1 vial with dropper: Chlamydia positive control is stabilized buffered solution containing non infectious components Solution contains 0.05 % of sodium azide (NaN3) as conservance.

N. 1 vial with dropper: of Negative Control, with biological additives and bacteriostatics agents

N.1 Instruction for use

STORAGE AND STABILITY

The Controls are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date or if there is visible evidence of microbial growth. Store tightly capped when not use. Do not freeze

PRECAUTIONS

1. For *in vitro* evaluation performance and research use and professional use only.
2. Do not use beyond expiry date stated on the label.
3. The control solution does not contain any biohazardous substances in reportable quantities.
4. After use, treat as other laboratory waste material.

PREPARATION.

Bring to room temperature for about 30 min before use.

Improper handing and/or storage can affect results.

Use the kit **Chlamydia Trachomatis REF VQ81406**

PROCEDURE FOR POSITIVE/NEGATIVE

- Follow instructions for specimen collection and extraction
- Remove Chlamydia Trachomatis card from its protective pouch and place on a level surface, clean and dry. Label the device with patient's name or control number.
- Add 3 drops (approx. 150 µl) of Negative/Positive Controls to the sample well.
- Wait for test band (S) to appear. The test results should be read in 10 minutes after adding controls to the sample well, positive result may be visible as soon as 1 minute. However, to confirm a negative result the complete reaction time of 15 minutes is required. **Do not interpret result after 15 minutes.**

.**READING TEST RESULTS**

Concentration of the chlamydia positive control is adjusted to produce an assay signal positive.

If assay procedure was correct, the test results should yield a pink color in the test area on the rapid test.

BIBLIOGRAPHY

1. Hackstadt T., Fischer E.R., Scidmore M.A., Rockey D.D. Heinen R.A. origins and functions of the chlamydial inclusion. Trends microbiol. 5 , 1997 : 288-293.

2. Centers for disease control and prevention. 1998 Guidelines for treatment of sexually transmitted diseases. MMWR MORB. Mortal Wkly rep. 1998; 47 : 1-118.

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

CONTENT	**REF. UD80350**
Positive Control (Red Cap)	1,0 ml
Negative Control (Green Cap)	1,0 ml
Instruction for use	1 item

EDMA CODE 15 50 01 9000 CE 0483 IVD

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