

Index of Symbols:



Consult the instructions for use.



Contains sufficient for one test.



Manufactured by EnzteK Diagnostics, Inc.  
223 Montezuma Street, Rio Vista, CA 94571,USA

EC

REP

Authorised Representative in the European Community.  
**Gunter Karl GmbH, Von-Langen-Weg 10, D-48565 Steinfurt,Germany**

DISTRIBUTOR

Distributed by 1st Health Products Ltd  
Unit 2, Lynx Business Park, Colliers Green, Goudhurst, Kent. TN17 2LR

Xi

Irritant (acidic)

Use by.

LOT

Batch Code.

2°C

25°C

Storage temperature limitations.

CE

Identification of Notified Body

Do not reuse.

IVD

In Vitro Diagnostic Medical Device

CE

0459

Certified by Notified Body

Approved Distributor: 1st Health Products Ltd.  
Unit 2 Lynx Business Park, Colliers Green,  
Goudhurst, Kent TN17 2LR, UK  
Tel: +44 (0) 1580 212758  
Customer CareLine: +44 (0) 1580 211358  
enquiries@1sthealthproducts.co.uk  
www.1sthealthproducts.co.uk

SC8219A v.1



SELFCheck

Self Check is a rapid test to detect Chlamydia trachomatis. This test utilises a chemical, which in the presence of a specific Chlamydia enzyme causes the tip of the swab to turn blue.

**READ ALL THE INFORMATION IN THESE INSTRUCTIONS CAREFULLY BEFORE PERFORMING THE TEST**

Do not open the pouch containing the test device until you are ready to start the test

Do not use after the expiration date printed on the box or packaging

Do not perform this test during the menstrual period or if blood is ‘spotting’, as this will invalidate the test.

Do not use this test during early pregnancy

Do not use within 14 days of taking antibiotics.

Do not touch the swab tip or use if the swab tip is discoloured.

Do not use if either ampoule A or B is empty

Avoid contact with the liquid reagents enclosed at either end of the test device, avoid contact with skin, eyes, and clothing

Keep out of reach of children

For in vitro diagnostic use only, do not use orally

Store the test in a dry place between 2°C and 25°C

Do not reuse the test

Always consult your doctor if the test is positive or if it is negative and you remain concerned about your health, or if symptoms persist.

CONTENTS

Instructions For Use leaflet  
Sealed Pouch containing 1 test wand

Composition Reagent A: peptide 0.04%, buffer pH 8.3 74.1%, solvent 25.86%  
Composition Reagent B: colour developer 0.62%, HCL 3.7%, DI water 95.68%



HOW TO COLLECT THE SAMPLE

- To take your own vaginal sample your hands need to be clean and dry
1. Remove the test from the packaging.
  2. Gently remove the swab from the tube by grasping the red capped end which is connected to the swab. **DO NOT** touch the swab tip with your fingers.
  3. The advised posture for collecting the sample is lying on your back
  4. Insert swab into the vaginal canal approx 3-5cm (about half way along the swab)
  5. Rub the swab firmly 5 times against all sides of the vaginal canal wall. Firm contact must be made for proper specimen collection.
  6. Improper collection may result in poor colour change and may cause invalid results.



HOW TO PERFORM THE TEST



1. Once the sample has been collected, insert the swab back into the large tube.
2. Immediately release **RED** end Reagent A (clear liquid) by squeezing the ampoule firmly between first finger and thumb close to the base of the ampoule. Squeeze twice more after breaking ampoule to release fluid. **Important, hold device upright so that Reagent A will run down the swab and cover the swab tip.**
3. Keep the device in the upright position (do not turn device upside down). Wait 10 minutes.
4. After 10 minutes, turn the device upside down.
5. Immediately release **BLACK** end Reagent B (yellow liquid) by squeezing the ampoule firmly between the first finger and thumb close to the base of the ampoule near the swab tip. Squeeze only once after breaking ampoule to release fluid. Do not use excess force or you may cause leakage. The fluid is not harmful but may cause temporary staining, simply wash with soap and water. Keep the device upside down to allow Reagent B to soak into the swab tip.
6. Allow **BETWEEN 1AND 2 MINUTES** and then look for **any blue colour anywhere on the tip of the swab or in the rayon plug next to the swab tip. Waiting longer than 2 minutes may result in an incorrect result.**



Any BLUE colour is a positive result. If no blue colour is present, then the test result is negative.