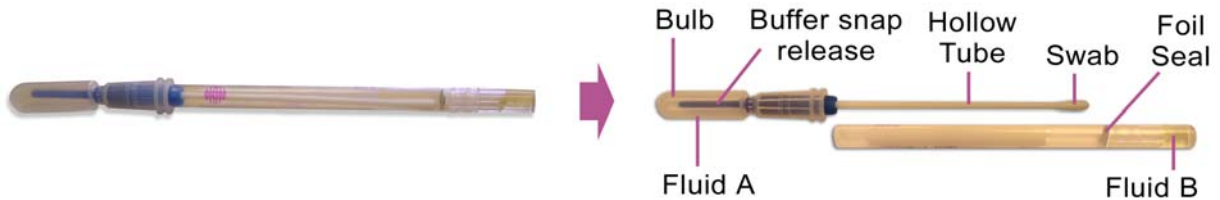


# Self Testing Diagnostic System for Chlamydia

## ABOUT THE TEST



The SureScreen test for Chlamydia is a rapid self-contained, two-step enzyme detection system for the qualitative detection of Chlamydia. This test utilizes a chemical solution, which in the presence of a specific Chlamydia enzyme causes a reaction, which coupled with a developer, causes a dark purple or dark mottled purple colour change.

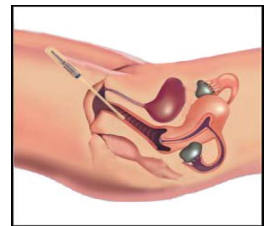
### READ ALL THE INFORMATION IN THESE INSTRUCTIONS CAREFULLY BEFORE PERFORMING THE TEST

- Do not open the pouch until you are ready to start the test
- Do not use after the expiry date printed on the back of the box or pouch
- Do not perform this test during the menstrual period or if blood is 'spotting', as this will invalidate the test.
- Do not use if the tip of the swab is discoloured or if the tip of the swab has broken through the foil barrier in the tube
- Store the test in a dry place between 2°C and 25°C. Do not freeze
- Do not use if the pouch is damaged or open
- Keep out of reach from children
- For *in vitro* diagnostic use only, do not use orally
- Do not reuse the test
- Check with your doctor if the test is negative but symptoms still persist

## HOW TO COLLECT THE SAMPLE

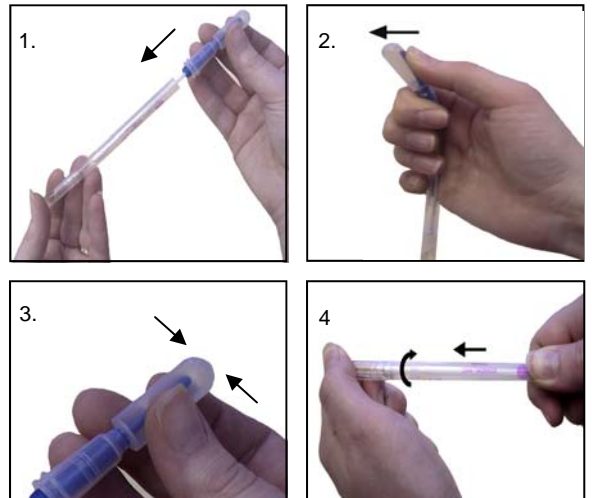
To take your own vaginal sample your hands need to be clean and dry

1. Open the pouch and remove the test
2. Gently remove the swab from the tube DO NOT touch the cotton bud with your fingers
3. The advised posture for collecting the sample is lying on your back
4. Holding the bulb insert 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 will result in poor colour change and may cause invalid results.



## HOW TO TEST

1. Once the sample has been collected, insert the swab back into the tube. DO NOT push the swab through the foil barrier at the bottom of the tube.
2. To release fluid 'A' bend the bulb to an angle of 45° until you hear a snap
3. Gently squeeze the bulb a couple of times to empty fluid 'A' down the tube and into the swab. Stand the test upright. Wait 10 minutes, and no longer than 30 minutes.
4. Holding the two ends of the tube, push the swab through the foil barrier whilst twisting. This requires some force. Once through, turn the test bulb side down and tap the end of the test to coat the swab in fluid 'B'. Quickly turn the test upright again and tap again to remove the excess fluid 'B'. DO NOT SOAK IN FLUID 'B'



## READING RESULTS

5. After 2 minutes have elapsed, read the colour of the swab through the plastic tube by comparing the swab to the colours on the chart opposite.

A POSITIVE result will be indicated by a very strong, VIVID PURPLE. If the result is not vivid, your test is negative. Any other colour or pale shade is a negative.

Please note that colours may vary slightly from those shown below, positive results will show vibrant, bright purple. The nature of the test means that the positive material in the sample may be randomly distributed on the swab, this can give a mottled appearance to the colour change).

**Read the result by looking at the colour of the swab, not the colour of the solution.**

## RESULTS CHART

Negative		Positive

## KIT CONTENTS

- Sealed pouch containing 1 x test
- 1 x product insert

Bulb reagent: Peptide - 0.03%, buffer pH8.3 - 74.1%, solvent - 25.9%.  
Chamber reagent: Colour developer - 0.62%, HCL - 3.7%, DI water - 95.68%

REF Cat. No. CHLCSEU (English) 0336

CHLCSEU Chlamydia Wand Test End User Instructions -18/02/05 Issue3

Index of Symbols					
	Attention, see instructions for use		Tests per kit		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

Medical Packaging Corporation  
Camarillo,  
CA,  
USA 93012

D.R.M Green  
European Compliance Services Ltd  
Oakdene House, Watchfield,  
Swindon, Wilts. SN6 8TD. UK