

CerTest

› Simple › Accurate › Specific



# › Product Catalogue

visual one-step tests



# We are always one step ahead

› CERTEST BIOTEC is an independent biotechnology company formed in 2002. In spite of being recently created the company staff has a long experience in the development of diagnostic kits. The company is based in Zaragoza (Spain) halfway between Madrid and Barcelona.

CERTEST BIOTEC develops and manufactures a wide range of lateral flow diagnostic tests. Frequent contact with customers is the key element of our strategy for the production of kits to continue to meet market needs and exceed performance expectations.

As part of our ongoing commitment to improve customer service, ISO 13485 quality system has been implemented in the company. CERTEST BIOTEC complies with the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical devices.





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# Products

- › Fecal Antigens
- › Respiratory Antigens
- › Inflammatory and Tumor Markers
- › hCG
- › DOA

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# Fecal Antigens

One-step coloured chromatographic immunoassays  
for qualitative antigen detection in stool samples

## › VIRUS

- ROTAVIRUS
- ADENOVIRUS
- ASTROVIRUS
- ROTA-ADENO
- ENTEROVIRUS
- HEPATITIS A (HAV)

## › BACTERIA

- H. PYLORI
- E. COLI 0157
- CAMPYLOBACTER
- SALMONELLA
- LISTERIA
- SHIGELLA

## › PARASITES

- CRYPTO
- GIARDIA
- CRYPTO-GIARDIA



# Test Procedure

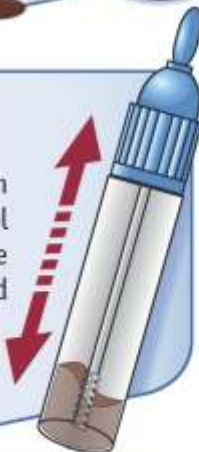
## step 1

Unscrew the cap and use the stick to pick up a little sample.



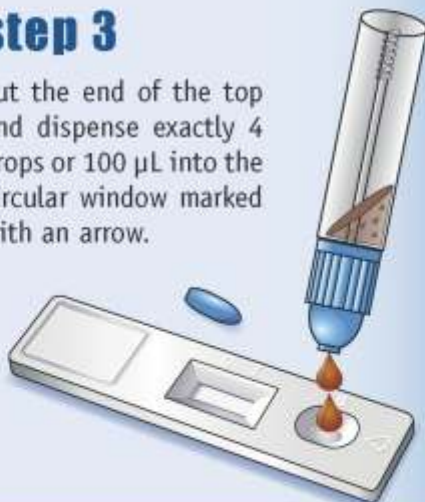
## step 2

Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.



## step 3

Cut the end of the top and dispense exactly 4 drops or 100 µL into the circular window marked with an arrow.



## step 4

Wait for coloured bands to appear. Read the result at 10 minutes.



## Interpretation of Results

NEGATIVE



ROTA-ADENO  
POSITIVE



ADENOVIRUS  
POSITIVE



ROTAVIRUS  
POSITIVE



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REF X820001V

IVD In Vitro diagnostic device

20

Contains sufficient for 20 tests





# Respiratory Antigens

One-step coloured chromatographic immunoassays for qualitative antigen detection in swab samples

- INFLUENZA A+B
- INFLUENZA A
- RSV
- ADENOVIRUS RESPIRATORY
- RSV-ADENO
- STREP A

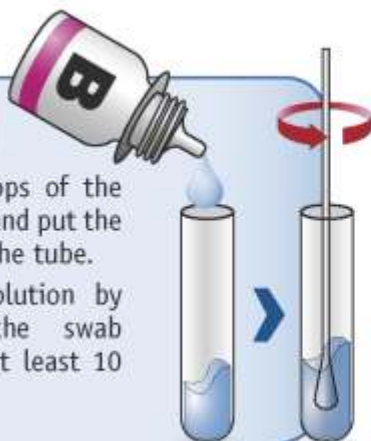


# Test Procedure

## Step 1

Add 15 drops of the Reagent B and put the swab into the tube.

Mix the solution by rotating the swab forcefully at least 10 times.



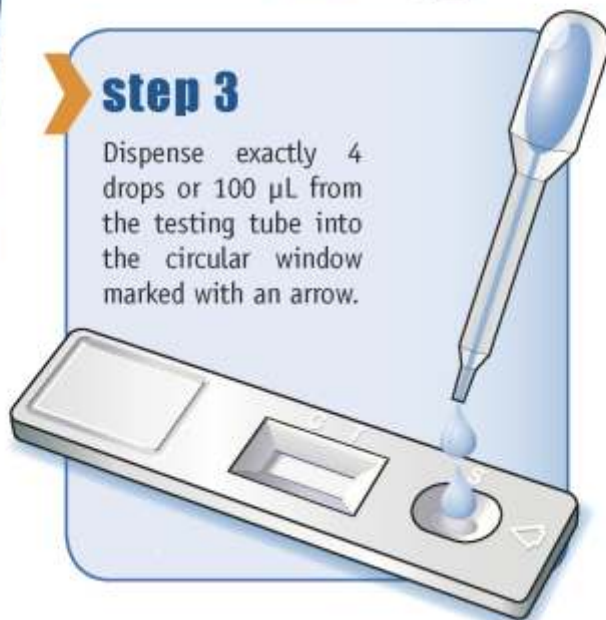
## Step 2

Extract the liquid with the pipette.



## Step 3

Dispense exactly 4 drops or 100 µL from the testing tube into the circular window marked with an arrow.



## Step 4

Wait for coloured bands to appear. Read the result at 10 minutes.



## Interpretation of Results

NEGATIVE



INFLUENZA A+B  
POSITIVE



INFLUENZA B  
POSITIVE



INFLUENZA A  
POSITIVE



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REF Z820001PC

IVD In Vitro diagnostic device

20

Contains sufficient for 20 tests





# Inflammatory and Tumor Markers

One-step coloured chromatographic immunoassays for qualitative inflammatory and tumor markers detection in stool samples

- HEMOGLOBIN (FOB)
- TRANSFERRIN
- LACTOFERRIN
- CALPROTECTIN



# Test Procedure

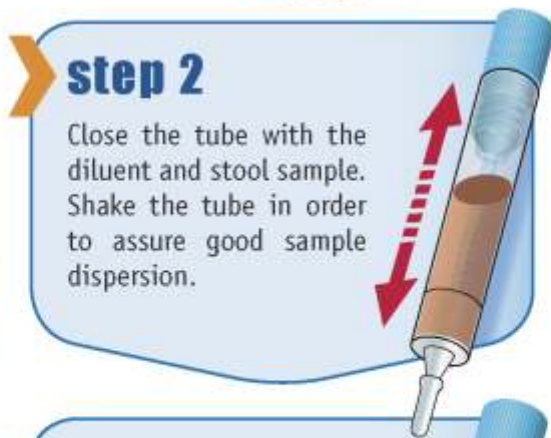
## step 1

Unscrew the cap and use the stick to pick up a little sample.



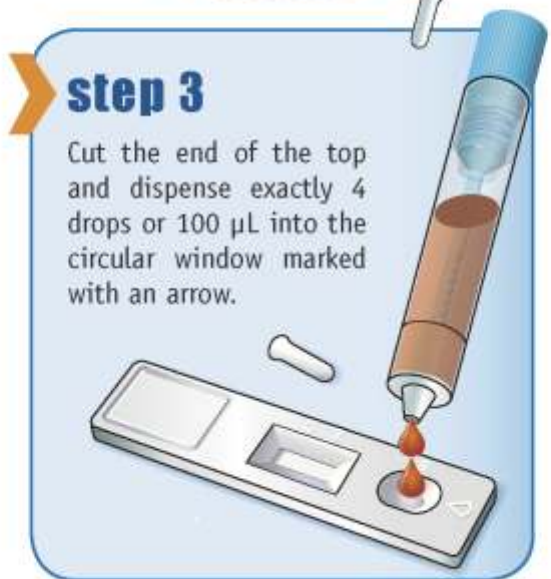
## step 2

Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.



## step 3

Cut the end of the top and dispense exactly 4 drops or 100 µL into the circular window marked with an arrow.



## step 4

Wait for coloured bands to appear. Read the result at 10 minutes.



## Interpretation of Results

NEGATIVE



CALPROTECTIN  
+ LACTOFERRIN  
POSITIVE



LACTOFERRIN  
POSITIVE



CALPROTECTIN  
POSITIVE



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BIOTEC

REF CL820001F

IVD In Vitro diagnostic device

20

Contains sufficient for 20 tests





# hCG

› Simple › Accurate › Specific

## Pregnancy Diagnosis

One-step coloured chromatographic immunoassays for qualitative hCG detection in urine samples to aid in the early detection of pregnancy

- hCG
- hCG s&u



# Test Procedure

## Step 1

Place the sample (urine) into a clean glass or plastic container.

No special pre-treatment is necessary.



## Step 2

For an easy use of the sample, use the provided plastic pipette to get some drops.



## Step 3

Slowly place 4 drops of sample (urine) onto the circular window marked with an arrow.



## Step 4

Wait for coloured bands to appear. Read the result at 3 minutes.



## Interpretation of Results

### NEGATIVE:

Only one BLUE band appears across the central window in the site marked with the letter C (control line).



### POSITIVE:

In addition to the BLUE control band, a RED band (test line) also appears in the site marked with the letter T (result line).



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REF H820201P

IVD In Vitro diagnostic device

20

Contains sufficient for 20 tests





# DOA › Simple › Accurate › Specific

## Drugs of Abuse

One-step coloured chromatographic immunoassays for qualitative DOA detection in urine samples

- COCAINE
- OPIATES
- ECSTASY
- MARIJUANA
- METHADONA
- BARBITURATES
- PHENCYCLIDINE
- AMPHETAMINE
- METHAMPHETAMINE
- BENZODIAZEPINES



# Test Procedure

## Step 1

Place the sample (urine) into a clean glass or plastic container.

No special pre-treatment is necessary.



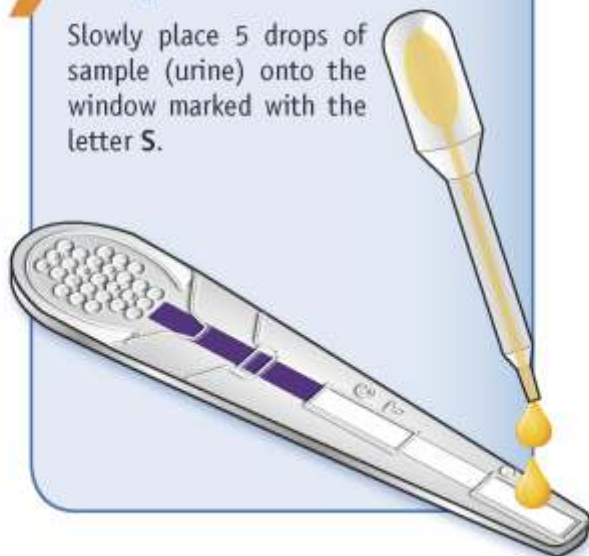
## Step 2

For an easy use of the sample use the provided plastic pipette to get some drops.



## Step 3

Slowly place 5 drops of sample (urine) onto the window marked with the letter S.



## Step 4

Wait for coloured bands to appear. Read the result at 10-20 minutes.



## Interpretation of Results

### POSITIVE:

Only one PINK band appears across the central window in the place marked with the letter C (control line).



### NEGATIVE:

In addition to the PINK control band, another distinguishable PINK band also appears in the place marked with the letter T (result line).



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REF COC630101P

IVD In Vitro diagnostic device

30

Contains sufficient for 30 tests





# IVD Blister\*

## Brilliant like aluminium



### Ten individually IVD Strips packed into an Aluminium Blister

CerTest Biotec presents a new revolutionary packaging system for IVD assays "The IVD blister" based on the pharmaceutical blistering technology.

**NO DESICCANT BAG IS NECESSARY**  
Desiccant is part of the strip

**SMALLER KIT SIZE, ONLY 1.5 cm<sup>2</sup>**  
Inside volume only 1 cm<sup>3</sup>  
Surface only 1,5 cm<sup>2</sup>

**STRONG PACK**  
Full humidity barrier  
Increased shelf life



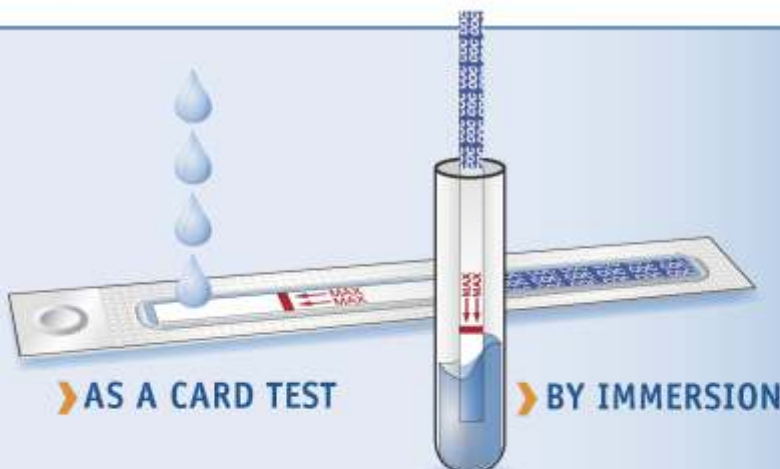
**PHARMACEUTICAL MATERIALS**  
45 µm cold-forming aluminium foil  
+20 µm peel-able sealing aluminium foil

**EACH TEST IS INDIVIDUALLY PACKED AND PRINTED**

## easy to perform

Cut the blister to obtain a single test pack, hold the non-sealed side and open it by peeling off the upper foil.

You can use a pipette to dispense sample drops directly into the blister or submerge the test in the sample.



## Products & Services

Our aim is to provide our customers with high quality diagnostic kits and superior standards of service and technical support. The main activity of CERTEST BIOTEC is the development, production and marketing of four different product lines:

1. Rapid tests for **clinical diagnostics**
2. Rapid tests for **food and feed diagnostics**
3. Rapid tests for **veterinary diagnostics**
4. Rapid tests for **environmental diagnostics**

We are convinced that all our products will meet or exceed your requirements with regard to:

- Quality
- Test Design
- Packaging
- Reliability
- Availability

## Technology

Our diagnostic assays are based on the latest scientific findings on coloured latex and magnetic particles based immunoassays, which contributes to the high reliability of our tests. Our philosophy is to optimize the whole production process from development to manufacture, by providing our customers with competent product and quality management as well as professional logistics systems.

CERTEST BIOTEC also offers manufacturing services for conjugates and colloidal preparations for diagnostic assays. Our R+D department is willing to find reliable solutions to meet companies needs.

## Distributors

CERTEST BIOTEC offers you the possibility of purchasing original CERTEST products, reagents or test kits under OEM basis in accordance with your specifications.

With the aim of further expanding our distribution network, CERTEST BIOTEC is always searching for new distributors world-wide.

## Location

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