COPRO SYSTEM

System for direct microbial identification of intestinal pathogenic microorganisms.

ENGLISH

DESCRIPTION

COPRO SYSTEM is a 24-well system containing 12 x 2 desiccated biochemical substrata for direct microbial identification of pathogenic microorganisms from faecal samples such as: *Salmonella* spp., *Proteus* spp. *Pseudomonas* spp., *Yersinia* spp., *Shigella* spp., *Campylobacter jejunii, Escherichia coli, E.coli* O157, KES Group *(Klebsiella, Enterobacter, Serratia), Candida* spp. Each system allows the performance of 2 tests and is inoculated directly with the suspension of the sample and incubated at 36±1 °C for 18-24 hours. The tests for detection and microbial identification are interpreted by assessing the colour change of the various wells and confirmed with immunoserological tests and microscopic observation.

KIT CONTENTS

Ref. 71670	**Ref. 79670**
• 20 COPRO SYSTEM x 2 test • 40 Vials of Inoculum Solution (5 mL) • 20 Sealing films	• 4 COPRO SYSTEM x 2 test • 8 Vials of Inoculum Solution (5 mL) • 4 Sealing films

ITEMS NECESSARY BUT NOT INCLUDED IN THE KIT

PHYSIOLOGICAL SOLUTION (ref. 20095)	SHIGELLA ANTISERUM (ref. 96148)
VASELINE OIL (ref. 87006)	YERSINIA ENTEROCOLITICA ANTISERUM (ref. 96147)
KOVAC'S Reagent (ref. 87001)	E.COLI O157 LATEX KIT (ref. 96150)
OXIDASE TEST STICK (ref. 88029)	CAMPYLOBACTER LATEX KIT (ref. 96143)

CONFIGURATION OF THE SYSTEM

Well	**BIOCHEMICAL REACTIONS FOR MICROBIAL IDENTIFICATION**	
1-LDC ⌴	Lysine decarboxylation	*Salmonella* spp., *Citrobacter* spp., *Proteus* spp./ *Providencia* spp., *Yersinia enterocolitica*
2-H_2S ⌴	Hydrogen sulphide production	
3-UR ⌴	Urea hydrolysis	
Well	**MICROBIAL IDENTIFICATION**	
4-PRO	*Proteus* spp./*Providencia* spp.	
5-PSE	*Pseudomonas* spp.	
6-ESC	*Escherichia coli, E.coli* O157	
7-IND *	*Escherichia coli* - Indole Test	
8-KES	*Klebsiella, Enterobacter, Serratia* (Gruppo KES)	
9-SHI •	*Shigella* spp. - Immunoserological Test	
10-YER •	*Yersinia enterocolitica* - Immunoserological Test	
11-CAM •	*Campylobacter jejunii* - Immunoserological Test	
12-CAN	*Candida* spp.	

⌴ : After inoculation, cover each well with a drop of vaseline oil

* : After incubation, add the indicated reagent to execute the test

• : After incubation, perform the agglutination test

SPECIMENS COLLECTION AND CONSERVATION

Take the fecal sample with proper sterile containers for the collection. In special cases the collection of the fecal specimen with a swab may be useful. The samples to be tested must be collected according to standard microbiological methods suggested for fecal culture.

TEST PROCEDURE

1) PREPARATION OF THE CLINICAL SPECIMEN

A) FECES

- Homogenize with care a portion of feces of about 1g in a tube containing 5 mL of Physiological Solution.
- Transfer 0.2 mL of homogenized sample into a vial of Inoculum Solution* contained in the kit.
- Shake and wait for 5 minutes before inoculating the system with this suspension **(Inoculum Suspension)**.

B) RECTAL SWAB

- Perform the rectal swab as reported in clinical protocols and methods.
- Dip the swab into a vial of Inoculum Solution contained in the kit.
- Leave the swab immersed for 5 minutes before inoculating the system with this suspension **(Inoculum Suspension)**.

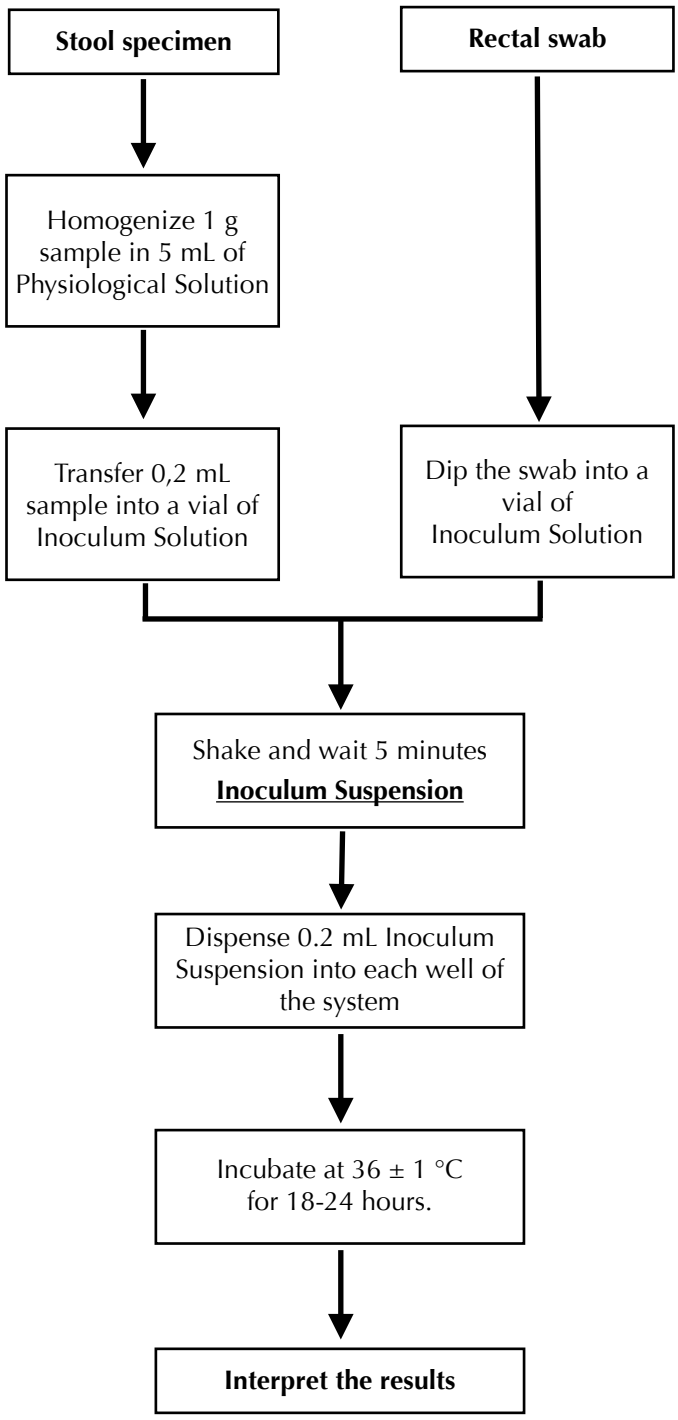
*Inoculum Solution (g/L):
Yeast extract 2.5g; Meat peptone 1.5g;
Glucose 2g; Distilled water 1000 mL; pH 6,8 ± 0,2

2) INOCULATION OF THE SYSTEM

- Take a system from its wrapper and bring it to room temperature.
- Write down the name of the patient and the date of the start of the examination.
- Dispense 0.2 mL **Inoculum Suspension** into each well of the system.
- Cover with one drop of VASELIN OIL the wells **1-LDC**, **2-H_2S** and **3-UR**.
- Cover the system with the lid provided and incubate at 36 ± 1 °C for 18-24 hours.
- After incubation, watch for the color change in the wells and interpret the results.

Note Each **COPRO SYSTEM** panel is configured to carry out two tests. In case of performance of one test only, cover the leftover half panel with the sealing film provided in the kit.

WORKFLOW



INTERPRETATION OF THE RESULTS

- At the end of the incubation, watch for the color change of the wells and interpret the results using the table 1.
- The presence of ***Salmonella* spp**. is indicated by the color change of the well **1-LDC** from yellow to red, by the color change of the well **2-H_2S** from yellow to black and by the yellow color of the well **3-UR**.
- The presence of ***Citrobacter* spp**. is indicated by the yellow color of the well **1-LDC**, by the color change of the well **2-H_2S** from yellow to black and by the yellow color of the well **3-UR**.
- The presence of ***Proteus* spp**./***Providencia* spp**. is indicated by the yellow color of the well **1-LDC**, by the color change of the well **2-H_2S** from yellow to black and by color change of well **3-UR** from yellow to red-fuchsia. Confirmation of *Proteus* spp./*Providencia* spp. is indicated by the color change of the well **4-PRO** from yellow to brown-black.
- The presence of ***Pseudomonas* spp**. is indicated by the color change of the well **5-PSE** from yellow to turbid green. The identification of *Pseudomonas* spp. should be confirmed with oxidase test using OXIDASE TEST STICK.
- The presence of ***Escherichia coli*** strains is indicated by the color change of the well **6-ESC** from red to blue. The identification of *E. coli* is confirmed with indole test on the well **7-IND**. The presence of enterohaemorrhagic ***E. coli* serotype O157** is confirmed with the agglutination test from the well **6-ESC** using E.COLI O157 LATEX KIT
- The presence of microorganisms of **KES** Group (Klebsiella spp., Enterobacter spp., Serratia spp.) is indicated by the color change of the well **8-KES** from violet to yellow. The identification of the various microorganisms should be confirmed by culturing onto selective media for enterobacteria and performing biochemical tests.
- The presence of ***Shigella* spp**. is detected by directly performing the agglutination test from the well **9-SHI** with SHIGELLA ANTISERUM.
- The presence of ***Yersinia enterocolitica*** is indicated by the color change of the well **3-UR** from yellow to red-fuchsia and confirmed with the agglutination test directly performed from the well **10-YER** using YERSINIA ENTEROCOLITICA ANTISERUM.
- The presence of ***Campylobacter jejunii*** is detected by directly performing the agglutination test from the well **11-CAM** with CAMPYLOBACTER LATEX KIT.
- The presence of ***Candida* spp**. is indicated by the color change of the well **12-CAN** from green to turbid yellow. Confirm *Candida* spp. by taking a drop of liquid from the well and examining at the microscope (400X) for chlamydospores and fungal hyphae.
- Note the results on the TEST RESULTS FORM included as appendix.

Table 1.

Well	BIOCHEMICAL REACTIONS FOR IDENTIFICATION	Well color		Biochemical reactions results per microorganism			
		Positive reaction	Negative reaction	*Salmonella*	*Citrobacter*	*Proteus/ Providencia*	*Yersinia*
1-LDC	Lysine decarboxylation	red	yellow	+	–	–	–
2-H_2S	Sulphur hydrogen production	black	yellow	+	+	+	–
3-UR	Urea hydrolysis	red-fuchsia	yellow	–	–	+	+

Well	IDENTIFICATION	Well color	
		Positive reaction	Negative reaction
4-PRO	*Proteus* spp./*Providencia* spp.	brown-black	yellow
5-PSE	*Pseudomonas* spp.	turbid green	yellow
6-ESC	*Escherichia coli*	blue	gray-red
	Immunoserological test for confirming *E.coli* O157	agglutination	no agglutination
7-IND	Indole test for confirming *Escherichia coli*	pink-red ring	colorless
8-KES	KES Group (*Klebsiella* spp., *Enterobacter* spp., *Serratia* spp.)	yellow	violet
9-SHI	Immunoserological test for confirming *Shigella* spp.	agglutination	no agglutination
10-YER	Immunoserological test for confirming *Yersinia enterocolitica*	agglutination	no agglutination
11-CAM	Immunoserological test for confirming *Campylobacter jejunii*	agglutination	no agglutination
12-CAN	*Candida* spp.	yellow	green

QUALITY CONTROL

Each batch of **COPRO SYSTEM** is subjected to quality control using the following reference strains of bacteria at concentrations of 10^4, 10^5, 10^6 CFU/ mL:
Salmonella typhimurium ATCC® 14028, *Citrobacter freundii* ATCC® 8090, *Proteus mirabilis* ATCC® 25933, *Pseudomonas aeruginosa* ATCC® 27853, *Escherichia coli* ATCC® 25922, *Escherichia coli* O157 ATCC® 35150, *Klebsiella pneumoniae* ATCC® 13883, *Shigella flexneri* ATCC® 12022, *Yersinia enterocolitica* ATCC® 9610, *Campylobacter jejunii* ATCC® 33291, *Candida albicans* ATCC® 10231.

FACTORS THAT MAY INVALIDATE THE RESULTS

Poor standardisation of the inoculum; clinical material unsuitable; use of expired systems or expired supplementary reagents; non compliance with temperatures and times of incubation.

LIMITS AND WARNINGS

For definitive identification of the micro-organisms, it is necessary to make use of biochemical confirmation tests.

PRECAUTIONS

The product, **COPRO SYSTEM**, is not classified as hazardous under current legislation, nor does it contain harmful substances in concentrations ≥1%. It therefore does not require a Safety Data Sheet to be available.
COPRO SYSTEM is a disposable device to be used only for diagnostic use *in vitro*. It is intended for use in a professional environment and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

CONSERVATION

Store at 2-8 °C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions the product will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After use, **COPRO SYSTEM** and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

PRESENTATION

Product	Ref.	Packaging
COPRO SYSTEM	71670	40 tests
COPRO SYSTEM	79670	8 tests

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Use by	See Instruction For Use	**LOT** Batch code

CE IVD