

## *Sensitivity and Specificity of Rapid Helicoscreen*

Helicoscreen is a rapid antigen test for the detection of *Helicobacter pylori* antigen in faeces. This report shows results obtained when sensitivity and specificity were extensively evaluated.

### **Sensitivity**

#### **Method:**

*H. pylori* strains were serially diluted in dilution buffer starting at  $1.0 \times 10^4$ ,  $5.0 \times 10^4$ ,  $1.0 \times 10^5$ ,  $5.0 \times 10^5$  and  $1.0 \times 10^6$  CFU/ml. The dilution were directly added to the sample well of the tests. The Helicoscreen strips were read and rated at the recommended time.

#### **Result:**

Samples Lot#	Buffer	$1 \times 10^4$ CFU/ml	$5 \times 10^4$ CFU/ml	$1 \times 10^5$ CFU/ml	$5 \times 10^5$ CFU/ml	$1 \times 10^6$ CFU/ml
1	Negative	Negative	Positive	Positive	Positive	Positive
2	Negative	Negative	Positive	Positive	Positive	Positive
3	Negative	Negative	Positive	Positive	Positive	Positive

#### **Conclusion:**

From the above data, we can find the lowest detectable concentration of Helicoscreen is  $5.0 \times 10^4$  CFU/ml.

### **Specificity**

#### **Cross Reactivity**

The suspension of organisms listed below were directly added to the sample well of the test in duplicate. The devices were rated as either positive or negative at the read time.

**Results:**

Analyte	Buffer	Analyte	Buffer
Adenovirus Type 2	Negative	Adenovirus Type 40	Negative
Coxsackie Type B1	Negative	Coxsackie Type B6	Negative
Echovirus Type 22	Negative	Feline calicivirus	Negative
Rotavirus	Negative	Borrelia burgdorferi	Negative
Aeromonas hydrophila	Negative	Campylobacter coli	Negative
Campylobacter jejuni	Negative	Candida albicans	Negative
Citrobacter freundii	Negative	Clostridium perfringens	Negative
Clostridium difficile (2)	Negative	Enterobacter cloacae	Negative
Enterococcus faecalis (2)	Negative	E. coli (2)	Negative
E. coli O157:H7 (2)	Negative	E. fergusonii	Negative
Staphylococcus aureus (Cowan I)	Negative	Staphylococcus epidermidis	Negative
Shigella boydii	Negative	Shigella dysenteriae	Negative
Shigella sonnei	Negative	Yersinia enterocolitica	Negative
Helicobacter felis	Negative	Salmonella hilversum	Negative
Klebsiella pneumoniae	Negative	Salmonella minnesota	Negative
Proteus vulgaris	Negative	Salmonella typhimurium	Negative
Pseudomonas aeruginosa	Negative	Staphylococcus aureus	Negative
Salmonella dublin	Negative	Serratia liquefaciens	Negative
Salmonella (Group B)	Negative	Shigella flexneri	Negative

**Conclusion:**

The result show that all non-target organisms have no cross reactions with Helicoscreen at a concentration of  $1.0 \times 10^7$  org/ml.

**Interfering substances****Method:**

The suspension of interfering substance was spiked into *H. pylori* positive and negative control and the controls were directly added to the sample well of the test in duplicate. The devices were recorded as either positive or negative at the read time.

Analyte	Concentration	Analyte	Concentration
Whole Blood	50%	Leukocytes	50%
Mucin	3.4%	Stearic acid/palmitic acid (fecal fat)	4%
Hemoglobin(tarry stool)	12.5%		

**Result:**

Analyte	Buffer	$5 \times 10^5$ CFU/ml
Whole Blood	Negative	Positive
Mucin	Negative	Positive
Hemoglobin(tarry stool)	Negative	Positive
Barium sulfate	Negative	Positive
Leukocytes	Negative	Positive
Stearic acid/palmitic acid (fecal fat)	Negative	Positive

**Conclusion:**

The results show that the above interfering substances have no effect on the result of *H. pylori* positivity at the level indicated.