CAMPYLOBACTER RAPID LATEX TEST KIT

For professional *in Vitro* **diagnostic use only**

Latex slide agglutination test for the confirmatory identification of presumptive *Campylobacter* colonies

INTENDED USE
Campylobacter Rapid Latex Test Kit is a rapid latex agglutination test intended for confirmatory identification of enteropathogenic thermophilic campylobacters cultured on selective solid media from faecal samples from patients with suspected bacterial enteritis.

PRINCIPLE OF THE TEST
Latex particles are coated with rabbit immunoglobulins raised against antigen preparations from selected *Campylobacter jejuni* serotypes. When the sensitised latex particles are mixed with a solution containing thermophilic *Campylobacter* antigens, a sensitive and specific immunochemical reaction takes place causing the finely dispersed latex particles to agglutinate into aggregates that are easily visible to the unaided eye.

REAGENTS AND MATERIALS PROVIDED
REAG TEST C1: Test Latex Reagent: 2.5mL - Latex particles coated with rabbit antibodies to Campylobacter antigens. Preserved with 0.099% sodium azide. (**red** cap)
REAG CONTROL: Control Latex Reagent: 2.5mL - Latex particles coated with non-specific rabbit immunoglobulins. Preserved with 0.099% sodium azide. (**green** cap)
CONTROL +: Positive Control: 1.0mL - Suspension of inactivated *Campylobacter* antigens reactive with Test Latex Reagent and non-reactive with Control Latex Reagent. Preserved with 0.099% sodium azide. (**white** cap)
SAMPLE DILUENT: 5.0 mL - 0.9% Saline preserved with 0.095% sodium azide (**black** cap).
Disposable agglutination cards : 20 cards, each with 6 black agglutination areas
Mixing Sticks : 100 disposable mixing sticks
DISPOSABLE PIPETTE: 1 disposable transfer pipette
Instructions for Use

MATERIALS REQUIRED BUT NOT SUPPLIED
Bacteriological loops; Campylobacter culture plates (e.g CCDA Bolton REF 541113); Disposable plastic specimen tubes (capacity 1mL); Gas jars for maintaining microaerophilic culture conditions; 42°C incubator (if not available, a 37°C incubator is acceptable)

WARNINGS AND PRECAUTIONS
Safety:
- The reagents supplied in this kit are for in vitro diagnostic use only
- The kit is intended for professional laboratory use only.
- Sodium azide, which is used as a preservative in the kit reagents can react with lead or copper plumbing to form potentially explosive metal azides. Dispose by flushing with a large volume of water to prevent azide build-up.
- Appropriate precautions should be taken when handling or disposing of potential pathogens. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30 minutes. Liquid waste containing acid must be neutralised before treatment.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Procedural:
- Campylobacter Rapid Latex Test Kit should be used according to the kit instructions.
- Allow all reagents to reach room temperature before use.
- Do not dilute any of the kit reagents
- Do not intermix reagents from different batches of kits.
- Do not freeze any of the kit reagents
- Do not allow the latex reagent dropper to touch the positive control or bacterial samples.
- Ensure the agglutination slide is clean and dry prior to use.

STORAGE AND SHELF LIFE
Campylobacter Rapid Latex Test Kit should be stored at 2-8°C when not in use. The kit should not be used after the expiry date printed on the carton label.

SPECIMENS
Faecal samples should be inoculated on to blood-free selective agar plates (e.g. CCDA Bolton,, REF 541113) at a concentration of 0.2-0.3g sample per plate. Plates should be incubated in a micro-aerophilic atmosphere at 42°C for 48 hours.
Colonies with morphology resembling *Campylobacter* are removed for testing with Campylobacter Rapid Latex Test Kit

TECHNIQUE
Quality Control:
The following check with the Positive Control should be performed each time the kit is used to confirm that the reagents are functioning correctly:
A single 50µL drop of **CONTROL+** should be dispensed on to two adjacent areas on the test slide.
These should be tested with the **REAG TEST C1** Test and **REAG CONTROL** as described in "Test Procedure" below.
Deterioration of a reagent should be suspected if:
I. There is no reaction between the Test Latex Reagent and the Positive Control or the reaction shows a significant loss of strength with time.
II. The REAG CONTROL reacts with the CONTROL+
III. A latex reagent becomes discoloured or forms lumps which do not disperse with gentle shaking.

Test Procedure:
1. Bring all reagents to room temperature. Gently shake the latex reagents to ensure a homogeneous suspension.
2. Dispense 50µL of **SAMPLE DILUENT** on to each of two ovals of the agglutination slide.
3. Use an inoculating loop to remove several colonies with *Campylobacter*-like morphology. If evidence of microbial growth is sparse, take a broad sweep of the agar surface. Mix the bacteria into each of the two drops of **SAMPLE DILUENT** on the slide to form even suspensions.
4. Add 1 drop (50µL) of **REAG CONTROL** to one of the bacterial suspensions on the slide. Similarly dispense 1 drop (50µL) of **REAG TEST C1** to the other bacterial suspension.
5. Mix the bacterial suspensions with the latex reagents using a mixing stick, starting with the REAG CONTROL. Spread the mixtures to the edges of the oval areas.

6. Gently rock the slide, to keep the fluid suspensions in constant movement, for 2 minutes. Observe for agglutination.
7. Read the test results (see INTERPRETATION below)
8. Discard the used mixing sticks and slides into a suitable disinfectant.

INTERPRETATION

An agglutination reaction is indicated by visible aggregation of the latex particles. The strength of the reaction may vary, and can be assessed according to the following guidelines.

\+ reaction : fine, but readily discernible granularity against a milky background.
++ reaction : coarse granularity against a milky background.
+++ reaction : heavy clumping of particles around the periphery of the test oval, against a clear background.

Campylobacter Rapid Latex Test Kit results should be interpreted as follows:

Reaction with REAG TEST C1	Reaction with REAG CONTROL	Interpretation
+	-	Campylobacter present
-	-	Campylobacter not present in sufficient numbers to be detected by the test
+	+	Non-specific agglutination. Inconclusive result*

*A specimen that causes the Control Latex reagent to agglutinate cannot be tested by Campylobacter Rapid Latex Test Kit .

LIMITATIONS OF USE

1. Results should be interpreted by the clinician in the context of all available clinical and laboratory information.
2. Non-specific agglutination of the Control Latex reagent does not preclude the presence of Campylobacters but the result has to be reported as inconclusive. The sample should be tested by an alternative method.
3. Very low numbers of Campylobacters may result in a negative test result. 48-hour cultures should be used to maximise growth of the bacteria.

PERFORMANCE CHARACTERISTICS

Campylobacter Rapid Latex Test Kit has been evaluated as a culture confirmation test at two independent external centres and in-house. In total, 527 faecal specimens were cultured on selective agar plates for 48 hours and colonies tested by Campylobacter Rapid Latex Test Kit

		Campylobacter Rapid Latex Test Kit		
		Positive	Negative	Total
Reference Methods	Positive	143	2	145
	Negative	1	381	382
Total		144	383	527

Sensitivity: 143/145 = 98.6%
Specificity: 381/382 = 99.7%
Efficiency: 524/527 = 99.4%

The specificity of Campylobacter Rapid Latex Test Kit has been confirmed by testing a wide variety of cultured microorganisms-
All thermophilic Campylobacters tested were reactive with Campylobacter Rapid Latex Test Kit. Non-thermophilic campylobacters were non-reactive although 3 of the 11 strains tested showed weak non-specific agglutination.
Of a group of closely related bacteria, 2 *Helicobacter pylori* isolates (of 12) were weakly reactive in the test and 2 isolates of *Helicobacter cinaedi* cross-reacted.
A wide range of other non-related bacteria was also tested. None were reactive in the test although one isolate of *Acinetobacter baumanii* exhibited strong non-specific agglutination. Complete results available on request.

REPRODUCIBILITY

Intra-batch reproducibility was established by testing sensitivity of 1 batch of product against serial dilutions of reference and kit positive control antigens on 3 separate occasions. End-point titres obtained with reference/control antigens were identical in the three assays.
Inter-batch reproducibility was examined by testing sensitivity of 3 batches of product against serial dilutions of reference and kit positive control antigens. No significant differences in end-point titres were seen across the three batches.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (50 tests) **REF 271020**

REAG TEST C1:	2.5 mL (dropper red cap)
REAG CONTROL	2.5 mL (dropper green cap)
CONTROL +:	1.0 mL (dropper white cap)
SAMPLE DILUENT	5.0 mL (black cap)
DISPOSABLE AGGL. CARDS (SLIDE)	20 cards with 6 wells each
MIXING STICKS:	4x25 disposable mixing sticks
DISPOSABLE PIPETTE:	1 disposable transfer pipette
INSTRUCTIONS FOR USE	1 item

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