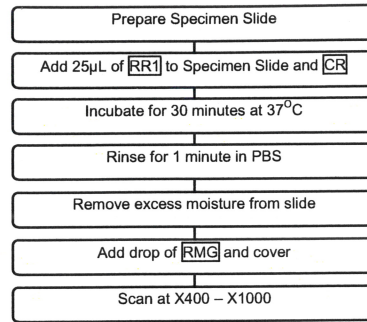




# CRYPTO CEL

English

FIGURE 1: CRYPTO CEL DIAGRAM FOR USE



## INTENDED USE AND PRINCIPLE OF THE TEST

The Crypto Cel IF Test is an in vitro direct immunofluorescence test for the detection of *Cryptosporidium* in faecal and environmental specimens. The fluorescein-labelled mouse monoclonal antibody reagent binds specifically to *Cryptosporidium* in the specimen. *Cryptosporidium* display bright green fluorescence with typical morphology.

## CONTENTS OF THE KIT

	RR1	CR	RMG	KR1 Demo	KR1 Standard	Bulk
	Crypto Cel Reagent	Positive Control Slide (Single Use only)	Mounting Fluid	0.25mL	1.25mL	5mL
				1	1	-
				2.5mL	2.5mL	-
				Tests	10	50
					200	200

Materials are supplied ready for use. Store at 2-8°C. Expiry dates are clearly marked on each kit component and on the box. Expiry dates do not change once opened.

## MATERIALS REQUIRED BUT NOT PROVIDED

Microscope slides with 6-8mm diameter wells; precision pipette for delivering 25µL; methanol for specimen fixation; humid chamber; wash bath; phosphate buffered saline (PBS) for washing step; cover slips; non-fluorescing immersion oil; and fluorescence microscope with filter system for FITC (maximum excitation wavelength 490nm, mean emission wavelength 530nm) and x400-x1000 magnification.

## PRECAUTIONS

For *in vitro* diagnostic use only. Do not use after the expiry date shown on the label. If protective packaging is damaged, contact your local distributor and ask for a replacement. Do not mix components from different kits. The Crypto Cel Reagent has been optimised for use with Cellabs Positive Control Slide and Mounting Fluid. Evans Blue dye contained in the test reagent is a possible carcinogen, therefore avoid contact with the skin. Patient specimens and the positive control slide should be handled as though potentially infectious. The detection of *Cryptosporidium* from water is dependent on the efficient filtration and recovery from large volumes of water (500-1000L). A Positive Control Slide must be run with each test run. Refer to Material Safety Data Sheet (MSDS) for further information.

## SPECIMEN PREPARATION

Stool specimens, either fresh or preserved in 10% formalin or SAF may be used (Specimens treated with other fixatives have not been tested). A procedure for processing fresh stool specimens is described below. If stool specimens are not processed immediately they may be stored at 2-8°C for 24-48 hours. Stools may be concentrated prior to processing using concentration kits. They may also be concentrated by the formalin-ether sedimentation method.

Prepare an approximate 1/10-1/50 dilution of stool. Dilute 50µL or 5mm diameter of stool in PBS with 0.1% sodium azide and mix thoroughly to disperse the specimen using an applicator stick and allow large stool particles to sediment.

## PREPARATION OF SLIDES

- Place 20µL of the faecal or concentrated specimen from water onto a microscope slide.
- Allow the specimen to completely air dry.
- Fix the slides for 5 minutes in methanol and allow to air dry.

## INSTRUCTIONS FOR USE

- Add 25µL of RR1 to the fixed specimen and CR covering well area.
- Incubate the slides at 37°C in a humid chamber for 30 minutes. Do not allow the slides to dry as this may cause non-specific binding.
- Rinse gently in a bath of PBS for one minute.
- Drain slide and remove excess moisture around well with tissue.
- Add a drop of RMG to the slide well. Place a coverslip on top of the drop and remove air bubbles.
- Scan the entire specimen using a fluorescence microscope initially at X400 magnification, then at X1000 for confirmation. Read immediately or store at 2-8°C in the dark for up to 24 hours.

## READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

*Cryptosporidium* oocysts are 2-6µm in size, round or oval in shape with bright green fluorescence. A fold or suture can be seen on the surface. This suture is less apparent in environmental samples. The test may be considered positive if one or more oocysts are present. The positive control slide should be used for comparison with the appearance and size of the oocysts. Negative specimens should have signs of faecal material containing debris such as undigested food particles, cells (counterstained red-brown), and possibly other organisms such as bacteria and protozoa, and should not show any organisms of characteristic green fluorescence and morphology. Non-specific fluorescence may occur in some specimens but this may be distinguished morphologically from the oocysts. When less than 5 oocysts are seen the test should be repeated with a lower dilution of specimen and subsequent specimens should also be tested. Algae may be present in environmental specimens and these fluoresce red-orange.

## WASTE DISPOSAL

Dispose of any unused components as biohazardous waste. Where the test reagent has been disposed of in the sink, ensure it is flushed with large quantities of water (as the sodium azide it contains may react with copper/lead plumbing systems). For more information, please refer to the MSDS.

## SENSITIVITY, SPECIFICITY, & OTHER DATA ON THE CRYPTO CEL

Refer to summary table at end of insert. All data on the Crypto Cel can be obtained in the product information sheet. Please ask your local distributor or contact Cellabs.

## INDEMNITY NOTICE

Modifications or changes made in the recommended procedure may affect the stated or implied claims. A positive or negative result does not preclude the presence of other underlying causative agents. Cellabs and its agents and distributors shall not be liable for damages under these circumstances.

TABLE 1: SENSITIVITY, SPECIFICITY, & OTHER DATA ON THE CRYPTO CEL

TABEAU 1: SENSIBILITÉ, SPÉCIFICITÉ ET AUTRES DONNÉES DU TEST CRYPTO CEL  
 TABELLA 1: SENSITIVITÄT, SPEZIFITÄT UND ANDERE DATEN ZUM CRYPTO CEL PN  
 TABELLA 1: SENSIBILITÀ, SPECIFICITÀ ED ALTRI DATI SULLA CRYPTO CEL  
 TABLA 1: SENSIBILIDAD, ESPECIFICIDAD Y OTROS DATOS DEL CRYPTO CEL  
 TABELA 1: SENSIBILIDADE, ESPECIFICIDADE, & OUTROS DADOS DO CRYPTO CEL

Trial Essai Versuch Prova Prueba Teste	Sensitivity Sensibilité Sensitivität Sensibilitá Sensibilidad Sensibilidade	Specificity Spécificité Spezifität Specificita Especificidad Especificidade	Repeatability Répétabilité Wiederholpräzision Ripetibilita Repetibilidad Repetição	Reproducibility Reproductibilité Reproduzierbarkeit Riproducibilita Reproducibilidad Reproduzibilidade
A	100%	100%	-	-
B	-	-	100% Correlation	100% Correlation
<p><b>Not cross reactive with / Pas de Réaction Croisée avec / Keine Kreuzreaktionen mit / Non mostra reazione crociata con / No muestra reacción cruzada con / Não apresenta reacções cruzadas com:</b>  <i>Eimeria tenella, Toxoplasma gondii, Giardia lamblia, Trichomonas hominis, Isospora belli, Microsporidium sp., Pneumocystis carinii, Candida sp., Aspergillus sp., Listeria sp., Legionella sp., Erysipelothrix sp., Escherichia sp., Lactobacillus sp., Streptococcus sp., Staphylococcus sp., Bacillus sp., Clostridium sp., Brochothrix sp., Corynebacterium sp.</i></p>				

## EXPLANATION OF SYMBOLS



Consult Instructions for Use  
Consulter le Mode d'Emploi  
Gebruiksaanwijzing  
Consultare le istruzioni per l'uso  
Consultar el manual de instrucciones  
Consultar o Folheto de Instruções



In Vitro Diagnostic Medical Device  
Produit Diagnostic Medical In Vitro  
In-vitro-Diagnostika  
Diagnostico in vitro Dispositivo medico  
Producto Sanitario para Diagnostico In Vitro  
Producto de Diagnostico Medico In vitro



Temperature Limitation  
Températures Limitées  
Temperaturbegrenzung  
Temperatura limite  
Limite de temperatura  
Temperatura Limitada



Biological Risks  
Risques Biologiques  
Biogefährdung  
Rischi biologici  
Riesgo biológico  
Riscos Biológicos



Authorised Representative in the EC  
Représentant Autorisé dans la EC  
Bevollmächtigter in der Europäischen Gemeinschaft  
Rappresentante Autorizzato nella EC  
Representante autorizado en la EC  
Representante Autorizado na CE

MDCI Ltd  
Arundel House, 1 Liverpool Gardens  
Worthing, West Sussex BN11 1SL  
United Kingdom



Manufacturer  
Fabricant  
Hersteller  
Fabbricante  
Fabricante  
Fabricante

Cellabs Pty Ltd  
Unit 7, 27 Dale Street (PO Box 421)  
Brookvale, NSW 2100 Australia  
Tel: +61 2 9905 0133 Fax: +61 2 9905 6426  
Web: http://www.cellabs.com.au  
Email: sales@cellabs.com.au

Insert Version  
Manuel Version  
Fassung der Packungsbeilage  
Versione Inserto  
Versión del manual de instrucciones  
Versão do folheto de instruções



LR1.11 - PDF  
28<sup>th</sup> November 2006