

EasyPC[™] is UK DWI (United Kingdom Drinking Water Inspectorate) approved for use as an IFA positive control. It is not approved for the seeding of water samples for quality assurance purposes.

BTF's *EasySeed*[™] is UK DWI approved for use as a precise seeding (spiking) material for the quality control of *Cryptosporidium* testing.

1. Background

Laboratories testing water for the presence of *Cryptosporidium* are required to maintain an adequate system of quality control and quality assurance. UK DWI regulations on the Quality Control of *Cryptosporidium* testing¹, require the staining and microscopy stages to be quality controlled via the use of a positive control sample.

EasyPC[™] provides a positive control sample from which laboratories following the UK DWI regulated *Cryptosporidium* testing method can easily and efficiently perform this Quality Control function. *EasyPC*[™] replaces the need to formulate and maintain oocyst suspensions for quality control purposes.

The use of live oocysts in a routine laboratory is hazardous. Inactivated oocysts are preferable. Gamma irradiated oocysts are an excellent alternative, as provided in all BTF C&G products.

EasyPC[™] provides a positive control sample that is sterilised via gamma irradiation providing a safe, efficient and reliable oocyst suspension, for positive control purposes.

2. Product description

EasyPC[™] is a 5mL tube containing irradiated flow cytometry enumerated *Cryptosporidium* oocysts for use as a daily IFA positive control.

EasyPC[™] tubes are sealed, sterilized and are stable unopened for 4 months when stored between 2–8°C.

Once opened an *EasyPC*[™] tube is stable for 7 days when kept refrigerated between 2–8°C.

EasyPC[™] is supplied in a kit containing 4 tubes, product insert and a Certificate of Analysis.

3. Product quality control information

Each batch of *EasyPC*[™] is quality controlled by testing 3% of batches <1000. For batches >1000 the QC batch size is $3 \times 3\sqrt{n}$.

EasyPC[™] is supplied with a Certificate of Analysis. This document provides a mean count and standard deviation of *Cryptosporidium* for each batch, as well as stock information.

Tubes spaced evenly throughout the batch are selected, stained with FITC labelled antibodies and enumerated using flow cytometry². The total number of oocysts in each tube is recorded as well as the number of full oocysts, the number of empty oocysts and the number of partially empty oocysts. DAPI staining is performed and the percentage of oocysts that stain with DAPI is recorded.

Each tube of *EasyPC*[™] is individually weighed.

Each batch of *EasyPC*[™] must meet the following standards:

% Standard deviation	<2.5%
% of oocysts/cysts that stain with DAPI	>95%
Variation in weight	<0.10g

4. Establishing the volume of *EasyPC*[™] to be used for IFA positive control in accordance with UK DWI methods

Each laboratory is responsible for determining the volume of *EasyPC*[™] pipetted to obtain the required 80 to 120 oocysts for the IFA positive control, as described in the UK Drinking Water Inspectorate regulations¹.

Determination of the volume required should follow the guidelines as stipulated in the DWI standard Operating Protocol for the monitoring of *Cryptosporidium*¹, Appendix D.2.

5. Use of EasyPC™ as an IFA Positive Control

It is recommended that IFA positive controls are prepared outside the area used for preparing sample slides to prevent the risk of cross contamination.

1. Vortex EasyPC™ tube for 15 seconds.
2. Pipette desired volume onto the centre of a slide well. Ensure the sample does not spread beyond the non-coated area of the well.
3. Ensure the Positive Control slide is labelled.
4. Incubate slides until the evaporation step is complete. Do not incubate at a temperature above 42°C.
5. Apply 50µl of absolute methanol (standard reagent grade) to each slide well and allow to air dry for 3–5 minutes.
6. Then follow DWI guidelines for IFA staining, microscopy and enumeration.

6. Technical assistance

Technical assistance with regard to the use of any BTF products is available at:

E-mail: contact@btfbio.com

Fax: +61 2 8877 9101

Phone: +61 2 8877 9150

or by contacting your local distributor.

7. References

1. Standard Operating Protocols for the Monitoring of *Cryptosporidium* Oocysts in Treated Water Supplies to Satisfy Water Supply (Water Quality) Amendment Regulations 2000 SI No 3184. UK Drinking Water Inspectorate.
2. Bennett JW. Gauci MR. Le Moenic S. Schaefer FW. Lindquist HDA. A comparison of enumeration techniques for *Cryptosporidium parvum* oocysts. Journal of Parasitology. 85(6):1165-1168, 1999.

Warranty

The products are warranted to the original purchaser only to conform to the quantity and contents stated on the product labels for the duration of the stated shelf life. BTF's obligation and the purchaser's exclusive remedy under this warranty is limited either to replacement, at BTF's expense, of any products which shall be defective in manufacture, and which shall be returned to BTF, transportation prepaid, or at BTF's option, refund of the purchase price.

Claims for merchandise damaged in transit must be submitted to the carrier.

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BTF Pty Ltd

PO Box 599 North Ryde BC NSW 1670 Australia

Telephone +61 2 8877 9150 Facsimile +61 2 8877 9101

contact@btfbio.com <http://www.btfbio.com>