

## Certificate – Faecal Pathogen Detection Kit

Product Number           EB 002  
 Lot Number                1107  
 Expiry Date               2014-02-30  
 Date of Issue              2011-12-02

### Kit Components: physical appearance

Component	Lot	Specification	Result	Pass / Fail
Molecular Biology Grade Water	EB 111106	Clear liquid	Clear liquid	Pass
Test strips	EB 111104	White, numbered membrane strips	White, numbered membrane strips	Pass
Denaturation Solution	EB 111108	Clear liquid	Clear liquid	Pass
Probe Mix	E 2110706	Clear liquid, lightly viscous	Clear liquid, lightly viscous	Pass
Wash Solution	E 2110708	Clear liquid, foamy	Clear liquid, foamy	Pass
Substrate Buffer	E 2110707	Clear liquid	Clear liquid	Pass
PCR tube	EB 111112	Green, numbered tube strips 8 tubes each, lyophilised pellet visible	Green, numbered tube strips á 8 tubes each, lyophilised pellet visible	Pass
Hybridisation Solution	EB 111103	Opaque liquid	Opaque liquid	Pass
Substrate Solution I	E 2110611	Clear, yellow liquid	Clear, yellow liquid	Pass
Substrate Solution II	E 2110612	Clear, brownish liquid	Clear, brownish liquid	Pass
Positive Control	EB 111116	Clear liquid	Clear liquid	Pass

### QC Test of kit

Test	Specification	Result	Pass / Fail
Limit of detection (all targets in multiplex PCR)	10 <sup>4</sup> genome copies of each target: Bluish or reddish-brown line visible for all targets and (optionally) for internal positive control	confirms	Pass
Limit of detection (single targets)	10 <sup>3</sup> genome copies of target: Bluish or reddish-brown line visible for respective target and for internal positive control	confirms	Pass
Positive control DNA	10 <sup>6</sup> genome copies of each target: Bluish or reddish-brown line visible for all targets and (optionally) for internal positive control	confirms	Pass
Negative controls (water)	Bluish or reddish-brown line visible for internal positive control only	confirms	Pass

*Notes: Quality controls are performed according to SOPs QS-QA-2095-xx (Production of EntericBio Kits – Testing of mastermix for lack of contamination – PCR), QS-QA-2097-xx (Production of EntericBio Kits – Testing of mastermix for lack of contamination – Hybridisation) (for liquid mastermix) and according to SOPs QS-QA-2098-xx (Production of EntericBio Kits – Final Quality Control – PCR) and QS-QA-2099-xx (Production of EntericBio Kits – Final Quality Control – Hybridisation) (for lyophilised mastermix).*

*Tom Russell.*