

Certificate – Faecal Pathogen Detection Kit

Product Number **EB 002**
 Lot Number **9002 A/B**
 Expiry Date **2012-01-01**
 Date of Issue **2009-02-26**

Kit Components: physical appearance

Component	Lot	Specification	Result	Pass / Fail
Molecular Biology Grade Water	FP90104	Clear liquid	Clear liquid	Pass
Test strips	FP90205	White, numbered membrane strips	White, numbered membrane strips	Pass
Denaturation Solution	FP90109	Clear liquid	Clear liquid	Pass
Probe Mix	FP90105	Clear liquid, lightly viscous	Clear liquid, lightly viscous	Pass
Wash Solution	FP90111	Clear liquid, foamy	Clear liquid, foamy	Pass
Substrate Buffer	FP90110	Clear liquid	Clear liquid	Pass
PCR tube	FP90207	Green, numbered tube strips á 8 tubes each, lyophilised pellet visible	Green, numbered tube strips á 8 tubes each, lyophilised pellet visible	Pass
Hybridisation Solution	FP90223	Opaque liquid	Opaque liquid	Pass
Substrate Solution I	FP90106	Clear, yellow liquid	Clear, yellow liquid	Pass
Substrate Solution II	FP90107	Clear, brownish liquid	Clear, brownish liquid	Pass
Positive Control	FP90108	Clear liquid	Clear liquid	Pass

QC Test of kit

Test	Specification	Result	Pass / Fail
Limit of detection (all targets in multiplex PCR)	10 ⁴ 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 ³ genome copies of target: Bluish or reddish-brown line visible for respective target and for internal positive control	confirms	Pass
Positive control DNA	10 ⁶ 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).

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