

Certificate – Faecal Pathogen Kit (Panel II) *Salmonella, Shigella, Campylobacter, S LT 1, SLT 2.*

Product Number **EB 006**
 Lot Number **1202**
 Expiry Date **2013-06-30**
 Date of Issue **2012-01-10**

Kit Components: physical appearance

Component	Lot	Specification	Result	Pass / Fail
Molecular Biology Grade Water	EB 110409	Clear liquid	Clear liquid	Pass
Test strips	EB 2110410	White, numbered membrane strips	White, numbered membrane strips	Pass
Denaturation Solution	EB 110415	Clear liquid	Clear liquid	Pass
Probe Mix	EB 2110412	Clear liquid, lightly viscous	Clear liquid, lightly viscous	Pass
Wash Solution	EB 2110411	Clear liquid, foamy	Clear liquid, foamy	Pass
Substrate Buffer	EB 110408	Clear liquid	Clear liquid	Pass
PCR tube	EB 2110414	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	EB 2120101	Opaque liquid	Opaque liquid	Pass
Substrate Solution I	EB 110406	Clear, yellow liquid	Clear, yellow liquid	Pass
Substrate Solution II	EB 110407	Clear, brownish liquid	Clear, brownish liquid	Pass
Positive Control	EB 2100619	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(s) and for internal positive control	confirms	Pass
Positive control DNA	10 ⁴ 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

**SDS Wash Solution may form crystals at ambient temperature that will dissolve at 37°C*

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.