



## Product Information Document

<b>Product Number:</b>	BF-40-02
<b>Product Family:</b>	SSPGo™
<b>Product Name:</b>	HLA No template Control Kit
<b>Product Description:</b>	Single PCR-SSP reaction to identify contamination in external reagents used by customers.
<b>Product Packaging:</b>	8 reaction strips, packed within individual foil pouch. 12 pouches per kit
<b>Test per Kit</b>	96
<b>No template control:</b>	Not applicable.
<b>Control amplification:</b>	Not applicable.
<b>Stability:</b>	16 Months from manufacture. See pack details for date. Store between 4-30°C. Once a foil pouch is opened use within 3 hours.

### Product specifications:

**BF-40-02** is designed to amplify an internal section of the DRA control gene used in SSPGo kits. This can be used to identify if there is PCR contamination originating from use of SSPGo kits as all SSPGo kits utilise either 700bp, 1000bp or 1400bp control amplifications from the DRA gene.

If there is PCR contamination from a SSPGo kit present in either the DNA diluents, DNA preparation reagents or pipettes used then the NTC will amplify a 187bp section of the control, regardless of whether it is the 700, 1000 or 1400bp control amplicon. In some cases extra bands may be apparent depending on the level of contamination. The NTC will detect PCR contamination to at least  $1 \times 10^{15}$ .

The NTC will also detect genomic DNA added to the the NTC. In this case the NTC will also amplify a 187bp section of the control, regardless of whether it is the 700, 1000 or 1400bp control amplicon. The NTC can detect DNA contamination to at least 0.01ng/ $\mu$ l.

**Version numbers:** All Biofortuna kits have a version number. The No Template Control Test version number should match the test instructions for use.

**Version changes:** V1 First version: no previous version.

**General description:** SSPGo kits including this wipe test are unique freeze-dried assays where complete hot-start PCR reactions are pre-dispensed into 0.2ml PCR tubes. Each NTC reaction in the kit contains a freeze-dried PCR solution consisting of primers specific for the HLA-DRA gene and will produce a 187bp amplicon from human genomic DNA. All the PCR ingredients include Taq polymerase, buffer, dNTPs, Magnesium Chloride, dyes and loading buffer. The hot start dNTPs are provided under license from Trilink. The PCR reaction is dispensed in 10 $\mu$ l volumes and requires a 10 $\mu$ l sample to rehydrate the primers prior to PCR.

**Contents:** Each assay is contained within a foil pouch also containing a disposable desiccant bag. The assay strips are sealed with PCR strip caps that should be removed and discarded prior to adding sample. The PCR vessels should contain 10µl of dry solid in the base of each well; this is the complete freeze-dried PCR reaction.

**Assay Format:** 12 strips of 8 PCR reactions, each containing 10µl pre-dispensed freeze dried primers, polymerase, dNTPs\* and buffer. The eight reaction strip format is shown below.

Reaction	Dye	Use
1	Red	No Template Control: Sample 1
2	Purple	No Template Control: Sample 2
3	Purple	No Template Control: Sample 3
4	Purple	No Template Control: Sample 4
5	Purple	No Template Control: Sample 5
6	Purple	No Template Control: Sample 6
7	Purple	No Template Control: Sample 7
8	Purple	No Template Control: Sample 8

**Interpretation:** No interpretation sheets and software are required for the interpretation of this kit. Refer to the No Template Control Kit IFU for interpretation.

**Allele updates:** Not applicable for this kit.

**Primer information:** The 3' base of the primers used are located at positions 401 & 542 of the DRA1 gene. This position is internal to all Biofortuna SSPGo control amplification amplicons and generates a 187bp amplicon. The primer location position is taken from the official alignments at <http://www.ebi.ac.uk/imgt/hla/align.html>.

**Validation:** All Biofortuna SSPGo kits are validated against at least 48 well characterised DNA samples.

**Licenses:** CleanAmp™ dNTPs are licensed from Trilink Biotechnologies Inc for use in Biofortuna SSPGo products. No license to perform PCR is required to use Biofortuna SSPGo kits.

## References:

- Bunce et al.** Phototyping: comprehensive DNA typing for HLA-A, B, C, DRB1, DRB3, DRB4, DRB5 & DQB1 by PCR with 144 primer mixes utilizing sequence-specific primers (PCR-SSP). *Tissue Antigens*. 1995 Nov;46(5):355-67.
- Bunce et al.** Rapid HLA-DQB typing by eight polymerase chain reaction amplifications with sequence-specific primers (PCR-SSP). *Hum Immunol*.1993 Aug;37(4):201-6.
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- Hovhannisyan et al.** The role of HLA-DQ8  $\beta$ 57 polymorphism in the anti-gluten T-cell response in coeliac disease. *Nature* 456, 534-538 (2008).
- Liu et al.** Genomewide linkage analysis of celiac disease in Finnish families. *Am. J. Hum. Genet.* 70: 51-59, (2002).
- Olerup & Zetterquist.** HLA-DRB1\*01 subtyping by allele-specific PCR amplification: a sensitive, specific and rapid technique. *H. Tissue Antigens*. 1991 May;37(5):197-204.
- Pearce et al.** Use of the anti-endomysial antibody test to diagnose coeliac disease in clinical practice. *Clin Lab*. 2002;48(5-6):319-25 (2002).
- Sollid LM.** Coeliac disease: dissecting a complex inflammatory disorder. *Nat Rev Immunol*. 2002 Sep;2(9):647-55.

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## Revision history.

This document is version 1. Dated 1-June-11