



Product Information Document

Product Number:	BF-40-01
Product Family:	SSPGo [™]
Product Name:	HLA Wipe Test Kit
Product Description:	Wipe test for contamination of surfaces, solutions and equipment where the contamination originates from the use of Biofortuna SSPGo Kits. Also detects contamination from genomic DNA.
Controls:	Integral PCR reactions designed to accommodate negative and positive control reactions as well as inhibition controls.
Product Packaging:	8 reaction strips, packed within individual foil pouch. 12 pouches per kit Each 8 reaction strip tests three wipe zones Each kit contains 36 sterile swabs Each Kit contains 12 PCR strip caps
Tests per Kit:	36 wipe zones
Stability:	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

The Biofortuna SSPGo HLA Wipe Test is intended to be used to monitor laboratory areas and equipment for PCR amplicon contamination that may be generated by Biofortuna SSPGo products. It can also be used to detect genomic DNA contamination of surfaces, solutions and equipment.

PCR is a sensitive technique that is susceptible to contamination with DNA amplicon from a previous PCR. Contamination can lead to false positive amplification in subsequent PCRs, which can lead to incorrect genotyping. PCR amplicon can contaminate reagents and samples, as well as laboratory equipment such as pipettes. Reagents and equipment should be monitored regularly for signs of contamination.

Each SSPGo HLA Wipe Test consists of a strip of eight PCR reactions containing freeze dried PCR buffer, polymerase and primers specific for the HLA-DRA gene and will produce a 187bp amplicon from human genomic DNA. Since all SSPGo kits utilise a DRA amplicon as an internal control, any contamination from the use of SSPGo kits will have an amplification of the DRA gene and will be detected by the wipe test primers.

Each strip of eight reactions tests up to three wipe test zones for contamination. Each strip has integral positive and negative control reactions, as well as inhibition control reactions for each wipe test zones. To test an area for contamination it is first wiped with a swab which is then soaked in water. This water is used as a template in the wipe test, and as a 50:50 mixture with genomic DNA as a PCR inhibition test.

It is recommended to test for contamination on a regular basis. Typical areas to be tested include DNA preparation area, PCR setup area and post-amplification area. Typical items to be tested include work benches, pipettes, centrifuges, refrigerator and freezer handles, door knobs and racks. Typical solutions to be tested include DNA preparation buffers and DNA diluents. Multi-use shared reagents such as PCR buffers and Taq polymerase are particularly susceptible to contamination but these do not affect Biofortuna kits since Biofortuna products are complete and only require the addition of DNA.

Sensitivity: PCR amplicon from a Biofortuna Kit was allowed to dry on a solid surface. The wipe test was performed on the amplicon undiluted and then in dilutions from 1×10^1 to 1×10^{15} . The amplicon was detected in dilutions up to and including 1×10^{15} .

Genomic DNA was allowed to dry on a solid surface. The wipe test was performed on gDNA at $100 \text{ ng}/\mu\text{l}$ and then in dilutions from 1×10^1 to 1×10^{15} . The DNA was detected in dilutions up to 1×10^3 .

Version numbers: All Biofortuna kits have a version number.

Version changes between kits: V1 Current 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 wipe test 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 $10 \mu\text{l}$ volumes and requires a $10 \mu\text{l}$ 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 $10 \mu\text{l}$ of dry solid in the base of each well; this is the complete freeze-dried PCR reaction.

Assay Format: 12 strips of 8 PCR wells, each containing $10 \mu\text{l}$ pre-dispensed freeze dried primers, polymerase, dNTPs and buffer. Each foil packed strip is intended for testing three areas of contamination. The eight reaction strip format is shown below.

Reaction	Dye	Use
1	Red	Positive Control: DNA
2	Purple	Negative Control: water used to wet swab
3	Blue	Zone 1 Inhibition Test: 50% DNA, 50% wipe water
4	Purple	Zone 1 Wipe Test
5	Blue	Zone 2 Inhibition Test: 50% DNA, 50% wipe water
6	Purple	Zone 2 Wipe Test
7	Blue	Zone 3 Inhibition Test: 50% DNA, 50% wipe water
8	Purple	Zone 3 Wipe Test

Interpretation: No interpretation sheets and software are required for the interpretation of this kit. Refer to the HLA Wipe Test Kit IFU for interpretation.

Validation: This is a CE marked product. All 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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Holdsworth et al. The HLA dictionary 2008: a summary of HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1 alleles and their association with serologically defined HLA-A, -B, -C, -DR, and -DQ antigens. *Tissue Antigens* 73, 95–170 (2009).

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.

Revision history.

This document is version 2. Dated 1-November-11