LIPSGENE® Bird Flu H5N1 Kit

Figure 1.2: Birds, like those geese, are potential carriers of the virus H5N1.

The LIPSGENE® Bird Flue (BF) H5N1 Kit is intended for qualitative detection of Bird Flu Virus (*H5N1*) RNA in cloacal swabs (animal samples), nasopharyngeal (human samples), serum or plasma samples. In 1997, 18 human cases of influenza A (*H5N1*) occurred in Hong Kong, coincident with outbreaks of highly pathogenic avian influenza A (*H5N1*) among domestic poultry. There was some evidence of very limited human-to-human transmission of this virus, but its efficiency was extremely low. However, human-to-human transmission of avian influenza may increase the chances of the emergence of a novel influenza virus with pandemic potential. On the 21st December 2009, the WHO announced a total of 447 human cases of H5N1 flu: the deaths reported were 263.

Kit contents

- ✓ Lyophilized oligonucleotide mix containing: *BF H5N1* and RNA control (RC) specific primers and probes, PCR vessels containing stabilized synthetic *BF H5N1* standard RNA (ready-to-use reference curves), sample PCR tubes, nucleic acids extraction tubes containing stabilized RC provided in a separate bag (shipped at room temperature).
- ✓ RT-PCR enzyme mix, reaction mix, Mg-sulfate solution, PCR grade water, 10x ROX, 10x BSA (shipped in a separate box on dry ice).
- ✓ Sufficient material to run either 120 or 60 tests.

Performance assessment

The LIPSGENE® Bird Flue H5N1 Kit was evaluated according to the requirements of the EU Directive 98/79/EC about *in vitro* diagnostic medical devices.

Assessment criterion	Sample type	Performance
Analytical sensitivity	Synthetic *BF H5N1* RNA	≥10 copies/run
	Cloacal swabs from chicken	1:10^8 dilution of *BF* virus sample
Linear range	Synthetic *BF* RNA	8 logs
Genotype recognition	Invalid	InfA *H5N1* (H5) specific
Analytical specificity	*BF* neg. pathogen samples	100%

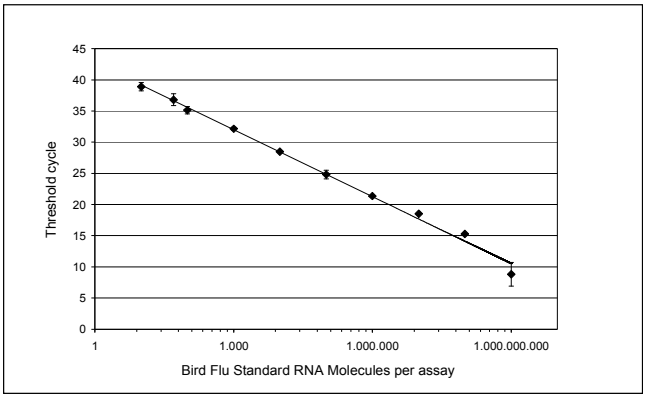

Figure 1.3: Linearity of Bird Flu H5N1 qualitative assay. The study was performed with synthetic BF RNA specimen and 2 replicates at each level on Rotor-Gene. The linear range of the LIPSGENE® Bird Flue H5N1 Kit was determined to cover at least 8 logs.

Typical run results

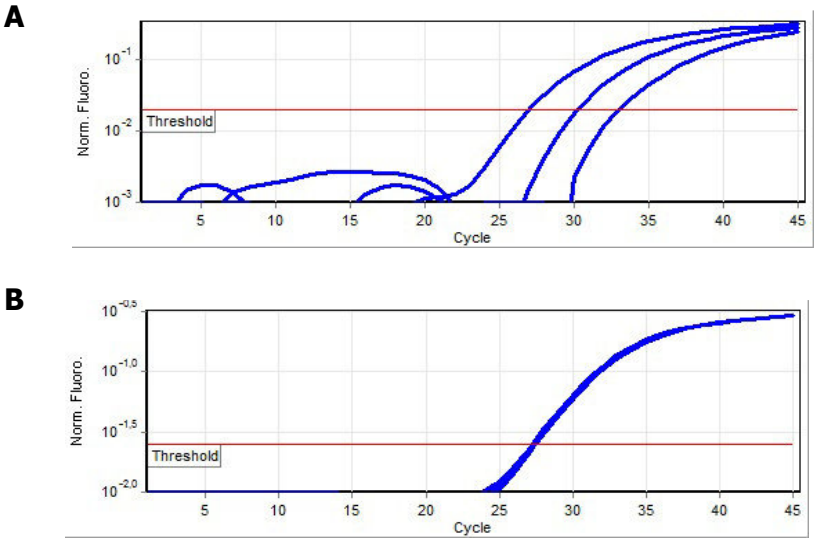

Figure 1.4: Typical run of simultaneous amplification of *BF* positive control tubes (10,000; 1000, and 100 copies) and Internal Control RNA (IC) using Rotor-Gene. The *BF* control amplicon was recorded in the FAM (A) channel and the RC signal in the VIC/JOE (B) channel.

Ordering information

Kit version	RP	ST	LP	LC	SC	SP	RS
IvD state	RUO	RUO	RUO	-	RUO	-	-
120 tests	1010009RP-120	1010009ST-120	1010009LP-120	-	1010009SC-120	-	-
60 tests	1010009RP-060	1010009ST-060	1010009LP-060	-	1010009SC-060	-	-

RP = 0.2 ml regular profile 8-well/strip PCR tubes and cap strips (e.g. ABI PRISM® 7000/7300/7700 SDS [Applied Biosystems/Life Technologies], iCycler IQ™; IQ5 [Bio-Rad], MX3000P, Mx3005P [Stratagene]; Mastercycler® ep realplex [Eppendorf]); **ST** = Singe 0.2 ml PCR Tube with attached cap (e.g. Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]; LineGene K [Bioer]); **LP** = 0.1 ml low profile 8-well/strip PCR tubes and cap strips (e.g. , 7500 Fast [Applied Biosystems/Life Technologies], MiniOpticon™, CFX-96 [Bio-Rad]; **LC** = 20 µl LightCycler glass capillaries (LightCycler 2.x, Roche); **SC** = 25 µl SmartCycler tubes (e.g. SmartCycler® [Cepheid]); **SP** = 20 µl DX-12 reaction tubes (Spartan Dx-12); **RS** = 0.1 ml 4-well tube/strips (Rotor-Gene™ 3000/6000, Rotor-Gene Q [Qiagen]).