

Attachment 3 – rRT-PCR Swine Flu Panel Labeling Examples

rRT-PCR Swine Flu Panel Package Insert

*****DO NOT DISCARD: Important product-specific information *****

Swine Influenza Virus Real-time RT-PCR Detection Panel with the AgPath-ID™ One-Step RT-PCR Kit in Additional Respiratory Specimens

CATALOG: FLUSW01

LOT: 904251

EXPIRATION DATE: 04/25/2011

INTENDED USE:

The rRT-PCR Swine Flu Panel is intended for use in Real-time RT-PCR assays on an ABI 7500 Fast Real-time PCR instrument in conjunction with clinical and epidemiological information:

- to identify patients who may be infected with swine influenza virus (A/H1N1) to allow public health authorities to respond to and limit transmission the virus during this public health emergency,
- for the qualitative detection of influenza virus type A in symptomatic patients from viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates specimens,
- for presumptive identification of virus in patients who may be infected with swine influenza A subtype A/H1N1 from viral RNA from nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, dual naso-pharyngeal/throat swabs, and isolates specimens in conjunction with clinical and epidemiological risk factors, and
- to provide epidemiologic information for surveillance for swine influenza viruses.

Testing with the swine influenza swInfA and swH1 primer and probe sets should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens. The definitive identification of swine influenza A/H1N1 either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

The definitive identification of swine Influenza A (H1N1) virus from patient specimens requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.

All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed training provided by CDC instructors or designees.

Use is limited to designated public health laboratories and other laboratories qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) K080570

REAGENTS

COMPONENT	PART NUMBER	LOT NUMBER	QUANTITY PER/VIAL	REHYDRATION VOLUME	STATE
InfA-F	MR-023	904251	20.0 nmol	0.5 ml	Lyophilized
InfA-R	MR-024	904251	20.0 nmol	0.5 ml	Lyophilized
InfA-P	MR-025	904251	5.0 nmol	0.5 ml	Lyophilized
SwInfA-F	MR-029	904251	20.0 nmol	0.5 ml	Lyophilized
SwInfA -R	MR-030	904251	20.0 nmol	0.5 ml	Lyophilized
SwInfA -P	MR-031	904251	5.0 nmol	0.5 ml	Lyophilized
SwH1-F	MR-026	904251	20.0 nmol	0.5 ml	Lyophilized
SwH1-R	MR-027	904251	20.0 nmol	0.5 ml	Lyophilized
SwH1-P	MR-028	904251	5.0 nmol	0.5 ml	Lyophilized
RP-F	MR-032	904251	20.0 nmol	0.5 ml	Lyophilized
RP-R	MR-033	904251	20.0 nmol	0.5 ml	Lyophilized
RP -P	MR-034	904251	5.0 nmol	0.5 ml	Lyophilized

Probe contains 6-FAM reporter and BHQ1 quencher. Approximate number of tests per kit: 1,000.

PRECAUTIONS:

Reagents are for use under emergency authorization only. Performance characteristics have not been established.

REHYDRATION

Rehydrate each tube with 0.5 ml (500 µl) of 10 mM Tris, pH 7.4 to 8.2 or PCR water. Dispense into aliquots.

STORAGE INSTRUCTIONS:

Prior to rehydration, store kits at 2-8°C. Store rehydrated aliquots of primers and probes at -20°C or below. Do not store in frost-free freezers. Rehydrated primers and probes may be stored frozen for up to 12 months. Thawed aliquots of probes and primers may be stored in the dark up to 6 months at 2-8°C. Do not use any product (refrigerated or frozen) past the expiration date.

PROCEDURE/INTERPRETATION/LIMITATIONS/EXPECTED VALUES:

Refer to CDC Influenza rRT-PCR Panel Flu (IVD) for instruction on using the Swine Influenza Virus Real-time RT-PCR Detection Panel provided by CDC Influenza Division. The procedure may be requested by sending email to FluSupport@cdc.gov

REAGENT COMPLAINTS/QUESTIONS:

Please send comments by email to FluSupport@cdc.gov

DISTRIBUTED BY:

Centers for Disease Control and Prevention, Influenza Division, 1600 Clifton Road, Atlanta, Georgia, 30333 USA