

DSQ Alert™ HT Pneumocystis jirovecii RUO Detection Reagent

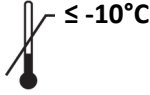
For Research Use Only. Not for use in diagnostic procedures.

**SPIN TUBES
PRIOR TO
OPENING**



ELITechGroup MDx LLC
21720 23rd Dr SE, Suite 150
Bothell, WA 98021 USA
Telephone: 1-800-453-2725

REF M400923



Intended Use

The DSQ Alert HT Pneumocystis jirovecii RUO Detection Reagent is intended for use in a nucleic acid amplification test, to detect human *Pneumocystis jirovecii* DNA in a nucleic acid sample. This product is intended for use with the cobas® 5800, 6800, or 8800 System (Roche Diagnostics).

Assay Principle

The DSQ Alert HT Pneumocystis jirovecii RUO Detection Reagent is a single plex real-time PCR reagent designed with DSQ hydrolysis probe chemistry, the next generation of MGB hydrolysis probes, to detect DNA from *Pneumocystis jirovecii*. The reagent contains a primer set and probe, labeled with a fluorophore and a duplex stabilizing quencher (DSQ), to generate a fluorescent signal during PCR. During each cycle of PCR, the primers and probe anneal to their target template, if present, and DNA is synthesized from the primers by a polymerase. During synthesis, the polymerase encounters the probe annealed to the template downstream of the primer, and the exonuclease activity of the polymerase hydrolyzes the probe, releasing the fluorophore from the proximity of the DSQ and allowing fluorescence emission. The PCR cycles result in exponential amplification of the target DNA and fluorescence levels.

Product Description

The DSQ Alert HT Pneumocystis jirovecii RUO Detection Reagent is a ready-to-use 61.2X mix of primer and probe sets specific to the DNA of the target pathogens. Probes are labeled with FAM and a DSQ that serves as a combined fluorescence quencher and DNA double helix stabilizer. No internal control (IC) primers or probes are included in the product.

Target Template	DSQ Probe Fluorophore	cobas Optical Channel [Excitation / Emission]	Recommended RFI Setting
<i>Pneumocystis jirovecii</i> large subunit ribosomal RNA gene	FAM	2 [495 nm / 521 nm]	2.5

The DSQ Alert HT Pneumocystis jirovecii RUO Detection Reagent is provided in a single tube at a volume of 600 µL (192 reactions) and designed to be added directly to the omni Utility Channel Reagent Kit, 192-reactions (Roche, REF 09052011190). The 61.2X concentration is relative to the optimal final concentration of the primers and probes in the PCR. The reagent cartridge should be prepared according to the cobas omni Utility Channel User Assistance documentation (Roche).

Recommended Materials Not Provided

Table 2. Additional materials recommended for real-time PCR not provided in the DSQ Alert HT *Pneumocystis jirovecii* RUO Detection Reagent.

Material	Use	Vendor	Part Number
cobas omni Utility Channel Reagent Kit	Contains DNA polymerase with reverse transcription and exonuclease activity, buffers, dNTPs, components for PCR and primers and probes for IC amplification and detection	Roche	09052011190
Negative Control Kit	Negative Control	Roche	07002238190
Positive Control	Positive Control DNA for each pathogen target primer/probe set	NA	NA

Recommended Reaction Setup

For optimal performance, protect all reagents from light, store them at $\leq -10^{\circ}\text{C}$ while not in use, and limit the number of freeze-thaw cycles.

The following is an example of how to set up a real-time PCR using the DSQ Alert HT *Pneumocystis jirovecii* RUO Detection Reagent for a cobas 5800, 6800, or 8800 System.

1. Prepare cobas omni Utility Channel Reagent Cassette and cobas omni Utility Channel Master Mix Reagent 2 (UC MMx-R2) as described in the cobas omni Utility Channel User Assistance documentation, in an area separate from preparation of samples and controls.
2. Add 600 μL DSQ Alert HT RUO Detection Reagent to the UC MMx-R2 for 192 reactions, to make the prepared master mix reagent 2.
3. Fill the reagent cassette with the prepared master mix reagent 2 and proceed with performing and viewing tests as described in the cobas omni Utility Channel User Assistance documentation.

Table 3. Recommended thermal cycling conditions. Default cobas thermocycling conditions include the reverse transcription (RT) stages required for the cobas Utility Channel IC. Refer to the instrument manual to set up the real-time PCR.

Program	Number of Cycles	Step	Step Description	Temperature ($^{\circ}\text{C}$)	Hold Time (s)	Acquisition
Pre-PCR step	1	1	UNG activation	50	120	None
		2	UNG deactivation	94	5	None
		3	RT stage 1	55	120	None
		4	RT stage 2	60	360	None
		5	RT stage 3	65	240	None
1 st measurement	5	1	Initial PCR Cycling	95	5	None
		2*		55	30	Single
2 nd measurement	45	1	PCR Cycling	91	5	None
		2*		58	25	Single

* Read fluorescence

Warnings and Precautions

- This product is for Research Use Only, and not for use in diagnostic procedures.
- Use of this product requires personnel trained in molecular biology techniques.
- This product should be protected from light and stored at $\leq -10^{\circ}\text{C}$ while not in use.
- This product should not be used after its expiration date.
- This product should be used in accordance with local, state, and federal regulations or accreditation requirements.
- Disposal of all waste material should be done in accordance with local, state, and federal regulations or accreditation requirements.

Technical Support

For technical support, call the ELITechGroup MDx (EG MDx) Technical Support Center: 1.800.453.2725 or email mdx@elitechgroup.com, or contact your EG MDx Field Applications Specialist.

Legal Notices

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Symbols

The following symbols are used within ELITechGroup MDx DSQ Alert labeling.

 REF	Catalog number	 LOT	Lot or Batch Code
	Expiration Date YYYY-MM-DD		Contains sufficient material for <n> tests
	Keep away from sunlight		Upper limit of temperature
	Manufacturer		