

DSQ Alert™ HT Parvovirus B19 RUO Detection Reagent
For Research Use Only. Not for use in diagnostic procedures.

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PRIOR TO
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M400857



Intended Use

The **DSQ Alert™ HT Parvovirus B19 RUO Detection Reagent** is intended for use in a nucleic acid amplification to detect parvovirus B19 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 Parvovirus B19 RUO Detection Reagent** is a real-time PCR reagent designed with DSQ hydrolysis probe chemistry, the next generation of MGB hydrolysis probes, to detect **parvovirus B19 DNA**. 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 Parvovirus B19 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 (Table 1) 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.

Table 1. DSQ Alert HT Parvovirus B19 RUO Detection Reagent components description. Recommended Relative Fluorescence Index (RFI) settings are included for cobas systems.

Target template	DSQ probe fluorophore	cobas optical channel [excitation / emission]	Recommended RFI setting
Parvovirus B19 VP1u gene	FAM	2 [495 nm / 521 nm]	2

The DSQ Alert HT Parvovirus B19 RUO Detection Reagent is provided at a volume of 600 µL (25 µL overfill), and designed to be added directly to the omni Utility Channel Reagent Kit, 192-reactions (Roche, mat. no. 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 Parvovirus B19 RUO Detection Reagent.

Material	Use	Vendor	Part Number
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 controls	Positive control DNA for each pathogen target primer/probe set	NA	NA

Recommended Reaction Setup

For optimal performance, protect all reagents from light, store 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 Parvovirus B19 RUO Detection Reagent for cobas 5800, 6800, or 8800.

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. Refer to the instrument manual to set up the real-time PCR.

Stage		Temperature	Time (seconds)
UNG activation	Hold	50°C	120
UNG deactivation	Hold	94°C	5
RT stage 1	Hold	55°C	120
RT stage 2	Hold	60°C	360
RT stage 3	Hold	65°C	240
Initial PCR (5 cycles)	Denaturation	95°C	5
	Annealing and extension	55°C	30
PCR (45 cycles)	Denaturation	91°C	5
	Annealing and extension*	58°C	25

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

Legal Notices

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EG MDx warrants that this product will meet the specifications stated above. If any component of this product does not conform to these specifications, EG MDx will, at its sole discretion, as its sole and exclusive liability and as the users' sole and exclusive remedy, replace the product at no charge or refund the cost of the product; provided that notice of non-conformance is given to EG MDx within sixty (60) days of receipt of the product.

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DSQ Alert detection reagents are covered by one or more of U.S. Patents Numbers 6972339, 7319022, 7348146, 7381818, 7541454, 7582739, 7601851, 7671218, 7718374, 7723038, 7759126, 7767834, 7851606, 8008522, 8067177, 8163910, 8389745, 8569516, 8969003, 9056887, 9085800, 9169256, 9328384, 10677728, 10738346, 10890529, and 11320376 as well as applications that are currently pending.

This limited license permits the person or legal entity to which this product has been provided to use the product, and the data generated by use of the product, only for internal RUO assay validation purposes involving hybridization-based analysis of nucleic acids as defined and restricted by the U.S. Food and Drug Administration

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DSQ Alert is a trademark of ELITechGroup BV.

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Symbols

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

	Catalog number		Lot or Batch Code
	Expiration Date YYYY-MM-DD		Upper limit of temperature
	Manufacturer		Keep away from sunlight