DSQ Alert[™] GUD-1 HSV 1&2, T. pallidum 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 M400872



Intended Use

The **DSQ Alert GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent** is intended for use in a nucleic acid amplification test, to detect and distinguish DNA from herpes simplex viruses 1 & 2 (HSV-1 & 2) and *Treponema pallidum* in a nucleic acid sample. This product is intended for use with a real-time PCR system with appropriate optical specifications.

Assay Principle

The **DSQ Alert GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent** is a multiplex real-time PCR reagent designed with DSQ hydrolysis probe chemistry, the next generation of MGB hydrolysis probes, to detect and distinguish **HSV-1, HSV-2, and** *T. pallidum* **DNA**. For each target in the multiplex, 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 GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent** is a ready-to-use 20X mix of primer and probe sets specific to the DNA of each of the target pathogens, and to a synthetic sequence that serves as an internal control (IC) to monitor assay performance. (The IC DNA template is sold separately, see below.) Probes are labeled with FAM or an AquaPhluor[®] (AP) fluorophore (Table 1), and a DSQ that serves as a combined fluorescence quencher and DNA double helix stabilizer.

Table 1. DSQ Alert GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent components description. Each number in the AP fluorophore name indicates its peak excitation wavelength.

Target template	DSQ probe fluorophore	Analogous fluorophore (for optical channel selection)
HSV-1 glycoprotein D gene	AP593	ROX, Texas Red
HSV-2 glycoprotein G gene	AP639	Cy5, Quasar 670
T. pallidum 16S rRNA gene	FAM	FAM
Internal control IC2	AP525	VIC, JOE, HEX

The **DSQ Alert GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent** is provided at a volume of 120 μ L, and designed to be combined with a master mix containing the necessary components for PCR (not provided). The 20X concentration is relative to the optimal final concentration of the primers and probes in the PCR.

For optimal performance, protect all reagents from light, store at \leq -10°C while not in use, and limit the number of freeze-thaw cycles.

Recommended Materials Not Provided

Table 2. Additional materials recommended for real-time PCR not provided in the DSQ Alert GUD-1 HSV 1&2, T.pallidum RUO Detection Reagent.

Material	Use	Vendor	Part Number
Internal Control IC2 DNA	Internal control DNA template to monitor nucleic acid extraction and PCR performance	ELITechGroup	M800737
MGB Alert® ELITaq Master Mix (2X)	Contains DNA polymerase with exonuclease activity, buffers, dNTPs, components for PCR	ELITechGroup	M800809, 48 reactions M800810, 480 reactions
Molecular biology grade water	Reaction mix preparation, negative controls	NA	NA
Positive controls	Positive control DNA for each pathogen target primer/probe set if available	NA	NA

Recommended Reaction Setup

The following is an example of how to set up a real-time PCR using the DSQ Alert GUD-1 HSV 1&2, T. pallidum RUO Detection Reagent for 50 μ L reactions. Preparation of the reaction mix should be done in an area separate from preparation and addition of samples and controls.

Table 3. Example recipe for real-time PCR reaction mix.

Reagent	Stock concentration	Volume per reaction (μL)
PCR master mix	2X	25
Molecular biology grade water		12.5
DSQ Alert RUO Detection Reagent	20X	2.5
Total reaction mix		40.0
Sample/control template		10.0

1. Prepare reaction mix as above (Table 3), or adjust volumes per reaction based on PCR master mix stock concentration and final reaction volume, multiplying the volumes per reaction by the number of samples + controls being run and an appropriate overage to add the needed dead volume.

2. Array 40 µL of the reaction mix into the wells of an optical plate or tubes.

- 3. Prepare positive and negative controls as appropriate.
- 4. Pipette 10 µL of sample or control into the appropriate well or PCR tube containing reaction mix.
- 5. Seal the plate with optical adhesive film or cap PCR tubes.
- 6. Load the plate or tubes onto the real-time PCR instrument and program the thermal cycling as below (Table 4). Start the run.

Table 4. Recommended thermal cycling conditions. Adjustments may be required to optimize the PCR for various real-time PCR instruments. Refer to the instrument manual to set up the real-time PCR.

Stage		Temperature	Time
Denaturation	Hold	95°C	5 min
PCR (45 cycles)	Denaturation	95°C	10 sec
	Annealing and extension*	63°C	45 sec

* 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 shall not be used after its expiration date.
- This product shall be used in accordance with local, state, and federal regulations or accreditation requirements.
- Disposal of all waste material shall 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

Limited Product Warranty

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.

This warranty limits EG MDx's liability to the replacement of this product or refund of the cost of the product. NO OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, ARE PROVIDED BY ELITECH GROUP INC. EG MDx shall have no liability for any direct, indirect, consequential or incidental damages arising out of the use, the results of use or the inability to use this product and its components.

In no event shall EG MDx be liable for claims for any other damages, whether direct, incidental, foreseeable, consequential, or special (including but not limited to loss of use, revenue or profit), whether based upon warranty, contract, tort (including negligence) or strict liability arising in connection with the sale or use or the failure of EG MDx products to perform in accordance with the stated specifications.

Licensing and Legal Notice

Some components of nucleic acid analysis, such as specific methods and compositions for manipulating or visualizing nucleic acids for analysis, may be covered by one or more patents owned by other parties. Similarly, nucleic acids containing specific nucleotides sequences may be patented. Making, using, offering for sale, or selling such components or nucleic acids may require one or more licenses. Nothing in this document should be construed as an authorization or implicit license to make, use or sell any so covered component or nucleic acid under any such patents.

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 in 21 CFR 864.4020 and 21 CFR 809.30. Neither EG MDx nor any of its licensors grants any other licenses, whether express or implied, for any other purposes.

Although patents covering the basic polymerase chain reaction (PCR) have expired, patents covering the use of certain enzymes and other uses of the PCR process owned by Hoffman-LaRoche and others remain in effect and may require a license. Purchase of this product does not include or provide a license with respect to these patents. EG MDx does not encourage or support the unauthorized or unlicensed use of the PCR process. Use of this product is recommended for persons that either have the license to perform PCR or are not required to obtain a license. No license under the patents to use the PCR process is conveyed expressly or by implication to the purchaser by the purchase of this product. Nothing herein is to be construed as recommending any practice or any products in violation of any patent or in violation of any law or regulation.

Trademarks

ELITechGroup and ELITe InGenius are trademarks of ELITechGroup SAS.

DSQ Alert and AquaPhluor are trademarks of and ELITechGroup BV.

Symbols

		ار	
REF	Catalog number		Upper limit of temperature
LOT	Lot or Batch Code	52	Expiration Date
	Lot of Baton Codo		YYYY-MM-DD
	Manufacturer	×	Keep away from sunlight
	Contains sufficient for <n> tests</n>		

The following symbols are used within ELITechGroup MDx DSQ Alert labeling