

Mycoplasma genitalium* Macrolide Resistance Primers*Intended Use**

Analyte Specific Reagent (ASR). Analytical and performance characteristics are not established. This ASR is intended to be used as a component of a laboratory developed test (LDT) used exclusively by laboratories. Laboratories may develop their own LDTs using one or more ASRs and/or general laboratory reagents for in vitro diagnostic purposes.

Product Description

The *Mycoplasma genitalium* (MG) Macrolide (Mac) Resistance (Res) Primers ASR contains oligonucleotides designed to detect the mutations on 23S RNA (2058C, 2058G, 2058T, 2059C, and 2059G).

Materials Provided

MG Mac Res Primers (Cat. No. PRD-06107)

Component	Quantity	Description
Tube	1 x 0.53 mL	37.5 µM

Warnings and Limitations

- A. Analytical and performance characteristics are not established.
- B. Use routine laboratory precautions. Wear disposable, powderless gloves, protective eye wear, and laboratory coats when handling specimens and kit reagents. Wash hands thoroughly after handling reagents.
- C. Dispose of all materials that have come in contact with reagents according to local, state, and federal regulations.

Quality Control

This analyte specific reagent was manufactured and released in accordance with Hologic quality control and quality assurance procedures.

Storage and Handling

Upon receipt, store material at -15 to -25 °C. Multiple freeze/thaw cycles should be minimized by appropriate aliquoting and should not exceed 4 freeze/thaw cycles.

In silico Binding Affinity

The MG Mac Res Primers cover 100% of the aligned *Mycoplasma genitalium* macrolide resistance sequences available in the NCBI Database (as of January 2021). Additionally, the

Additionally, the MG Mac Res Primers did not show binding affinity for the organisms indicated in the table below or to human DNA.

<i>Acinetobacter lwoffii</i>	<i>Escherichia coli</i>	<i>Mycoplasma pneumoniae</i>
<i>Actinomyces israelii</i>	<i>Fusobacterium nucleatum</i>	<i>Neisseria gonorrhoeae</i>
<i>Alcaligenes faecalis</i>	<i>Gardnerella vaginalis</i>	<i>Peptostreptococcus magnus (Finegoldia magma)</i>
<i>Atopobium vaginae</i>	<i>Haemophilus ducreyi</i>	<i>Prevotella bivia</i>
<i>Bacteroides fragilis</i>	Herpes simplex virus type 1	<i>Propionibacterium acnes</i>
<i>Bifidobacterium adolescentis</i>	Herpes simplex virus type 2	<i>Proteus vulgaris</i>
<i>Campylobacter jejuni</i>	VIH-1 (IIIB)	<i>Pseudomonas aeruginosa</i>
<i>Candida albicans</i>	Human papillomavirus type 16	<i>Staphylococcus aureus</i>
<i>Chlamydia trachomatis</i>	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus epidermidis</i>
<i>Clostridium difficile</i>	<i>Lactobacillus acidophilus</i>	<i>Streptococcus agalactiae</i>
<i>Corynebacterium genitalium</i>	<i>Lactobacillus crispatus</i>	<i>Streptococcus pyogenes</i>
<i>Cryptococcus neoformans</i>	<i>Listeria monocytogenes</i>	<i>Trichomonas vaginalis</i>
Cytomegalovirus	<i>Mobiluncus curtisii</i>	<i>Ureaplasma parvum</i>
<i>Enterobacter cloacae</i>	<i>Mycoplasma hominis</i>	<i>Ureaplasma urealyticum</i>
<i>Enterococcus faecalis</i>	<i>Mycoplasma genitalium WT</i>	



Diagenode sa
Liège Science Park
Rue du Bois Saint Jean, 3
Seraing, Belgium

Customer Support: +1 800 442 9892
customersupport@hologic.com

Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

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