

Group A Strep Probe

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 Group A Strep (GAS) Probe ASR contains an oligonucleotide designed to detect the 16S gene of *Streptococcus pyogenes*. The oligonucleotide contains a 5' FAM label and a 3' BHQ-1 label.

Materials Provided

GAS Probe (Cat. No. PRD-05051)

| Component | Quantity | Concentration |
|-----------|-------------|---------------|
| Tubes | 1 x 0.53 mL | 25 µmol/L |

Warnings and Precautions

- Analytical and performance characteristics are not established.
- 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.
- 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 the Hologic quality control and quality assurance procedures.

Storage and Handling

Upon receipt, store material at -15 to -85 °C. Multiple freeze/thaw cycles should be minimized by appropriate aliquoting and should not exceed 3 freeze/thaw cycles.

***In silico* Binding Affinity**

The GAS probe covers 100% of the aligned *Streptococcus pyogenes* sequences available in the NCBI Database*.

Additionally, the GAS probe did not show binding affinity for the organisms indicated in the table below or to human DNA.

| | | |
|-------------------------------------|---|---|
| <i>Arcanobacterium haemolyticum</i> | Human Parainfluenza virus 3 | <i>Staphylococcus epidermidis</i> |
| <i>Bacillus cereus</i> | Human Parainfluenza virus 4 | <i>Stenotrophomonas maltophilia</i> |
| <i>Bordetella pertussis</i> | <i>Klebsiella spp.</i> | <i>Streptococcus agalactiae</i> |
| <i>Burkholderia cepacia</i> | <i>Lactobacillus acidophilus</i> | <i>Streptococcus anginosus</i> |
| <i>Corynebacterium diphtheriae</i> | <i>Lactococcus spp.</i> | <i>Streptococcus canis</i> |
| <i>Candida spp.</i> | <i>Legionella spp.</i> | <i>Streptococcus dysgalactiae subs. equisimilis</i> |
| <i>E. coli</i> | <i>Moraxella catarrhalis</i> | <i>Streptococcus gallolyticus</i> |
| <i>Enterococcus spp.</i> | <i>Mycoplasma pneumoniae</i> | <i>Streptococcus intermedius</i> |
| Influenza A | <i>Neisseria gonorrhoeae</i> | <i>Streptococcus mitis</i> |
| Influenza B | <i>Parvimonas micra</i> | <i>Streptococcus mutans</i> |
| <i>Fusobacterium necrophorum</i> | <i>Prevotella oralis</i> | <i>Streptococcus pneumoniae</i> |
| <i>Haemophilus influenzae</i> | <i>Pseudomonas spp.</i> | <i>Streptococcus salivarius</i> |
| Human Adenovirus | Rhinovirus | <i>Streptococcus sanguinus</i> |
| Human DNA | RSV | <i>Treponema denticola</i> |
| Human metapneumovirus | <i>Saccharomyces cerevisiae</i> | <i>Veillonella parvula</i> |
| Human Parainfluenza virus 1 | <i>Streptococcus constellatus subs. pharyngis</i> | |
| Human Parainfluenza virus 2 | <i>Staphylococcus aureus</i> | |

*As of May 2018



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