Gardnerella vaginalis Amplification Non-T7 Oligo

Analyte Specific Reagent (ASR).
Analytical and performance characteristics are not established.

Intended Use

Analyte Specific Reagent. Analytical and performance characteristics are not established. This analyte specific reagent is intended to be used as a component of a Lab Developed Test (LDT) used exclusively by laboratories. Laboratories can develop their own LDTs using one or more Analyte Specific Reagents and/or general laboratory reagents and/or general laboratory instruments for in vitro diagnostic purposes.

Materials Provided

Gardnerella vaginalis Amplification Non-T7 Oligo (Cat No. PRD-03861)

<table>
<thead>
<tr>
<th>Component</th>
<th>Volume</th>
<th>Concentration</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube</td>
<td>1 x 0.28 mL</td>
<td>14.8 nmol/mL solution</td>
<td>DNA oligonucleotide primer for Gardnerella vaginalis 16S rRNA</td>
</tr>
</tbody>
</table>

Warnings and Precautions

• For Laboratory Use only. 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.

Product Specifications

Quality Control

This analyte specific reagent was manufactured and released in accordance with the Hologic quality control and quality assurance procedures. This reagent has been analytically tested to verify oligonucleotide mass and concentration. However, it is the responsibility of each laboratory to develop and validate their own tests for clinical diagnostic purposes.

Storage and Stability

Please refer to product labels for information on storage and stability.