MycoTOOL Mycoplasma Real-Time PCR Test System

Revolutionize your mycoplasma QC testing
Building on more than a decade of mycoplasma testing innovation, Roche CustomBiotech offers the **MycoTOOL Mycoplasma Real-Time PCR Test System**, which empowers you to transform your mycoplasma QC strategy by replacing time-consuming culture methods with rapid, accurate PCR-based testing. The system combines optimized DNA purification with real-time PCR, offering you a reliable and versatile screening approach to confirm the absence of mycoplasma contamination with a single test – in hours instead of weeks.

**Go from sample to result in hours with real-time PCR**

1. **Sample preparation:** Manual or automated
2. **Real-Time PCR:** MycoTOOL Mycoplasma Real-Time PCR Kit
3. **Detection:** Result YES or NO

<5 hours

---

**Robust design**

- Universal primers enable broad detection of ~150 mycoplasma species
- TaqMan® probes and touchdown protocol provide sensitive, accurate detection
- Comprehensive control set included to provide high confidence in results
- All-inclusive kits with mycoplasma-free reagents reduce risk of contamination
- Useful for a variety of testing points such as raw materials and in-process testing
- Adaptable protocol offers flexibility for application needs

**Versatility**

- Multiple efficient sample preparation options that fit throughput needs
- Same-day results, with no culturing required, supports in-house testing
- Versatility to support your lab’s evolving needs

---

E.P. = European Pharmacopoeia; NAT = nucleic acid amplification techniques

**The MycoTOOL Mycoplasma Real-Time PCR Kit has been chosen by manufacturers for mycoplasma lot release test methods that they have validated and received acceptance by many regulatory agencies for select clinical or commercial products. Manufacturers are required to perform validation for the mycoplasma lot release test method for their product.**

The MycoTOOL Mycoplasma Real-Time PCR Kit has been chosen by manufacturers for mycoplasma lot release test methods that they have validated and received acceptance by many regulatory agencies for select clinical or commercial products. Manufacturers are required to perform validation for the mycoplasma lot release test method for their product.

Rapid, accurate, and reliable mycoplasma detection with a single test

Sample preparation options for your lab’s changing throughput needs

Roche offers a range of sample preparation solutions that easily integrate with the MycoTOOL Mycoplasma Real-Time PCR Kit, giving you the choice of manual DNA extraction for low-throughput workflows or automated extraction to increase efficiency for medium- and high-throughput workflows.

Proven technology to advance your QC testing strategy

- **Demonstrated sensitivity to ≤10 CFU/mL for common mycoplasma species**
- **Proven specificity avoids cross-reactivity with closely related bacterial species**
- **Validated according to E.P. 2.6.7 NAT validation guidelines**
- **Validated test methods accepted by regulatory agencies for lot release**

MagNA Pure 96 system
MagNA Pure 96 DNA and Viral Nucleic Acid Large Volume Kit

MagNA Pure 24 system
MagNA Pure 24 DNA and Viral Nucleic Acid Large Volume Kit

QC Sample Preparation Kit
<table>
<thead>
<tr>
<th>Application</th>
<th>Batch testing</th>
<th>Batch testing</th>
<th>Real Time PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flexible sample volume</td>
<td>Flexible sample volume</td>
<td></td>
</tr>
<tr>
<td>Instrument</td>
<td><strong>MagNA Pure 96 Instrument</strong></td>
<td><strong>MagNA Pure 24 Instrument</strong></td>
<td><strong>LightCycler® 480 Instrument II (96 well version)</strong></td>
</tr>
<tr>
<td>Catalog number</td>
<td>06 541 089 001</td>
<td>07 290 519 001</td>
<td>05 015 278 001 (96 well)</td>
</tr>
<tr>
<td>Kit</td>
<td>MagNA Pure 96 DNA and Viral NA Large Volume Kit</td>
<td>MagNA Pure 24 Total NA Isolation Kit</td>
<td>MycoTOOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)</td>
</tr>
<tr>
<td>Catalog number</td>
<td>06 374 891 001</td>
<td>07 658 036 001</td>
<td>06 495 605 001</td>
</tr>
</tbody>
</table>

**Ordering information**

**Product**

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>MycoTOOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)</td>
<td>06 495 605 001</td>
</tr>
</tbody>
</table>

**Related products**

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC Sample Preparation Kit</td>
<td>08 146 829 001</td>
</tr>
<tr>
<td>MycoTOOL Mycoplasma Detection Amplification Kit</td>
<td>05 184 240 001</td>
</tr>
</tbody>
</table>

**Regulatory disclaimer**

For use in quality control/manufacturing process only. LightCycler® 480 Instrument: for life science research only. Not for use in diagnostic procedures.

**Trademarks**

LIGHTCYCLER, MAGNA PURE, TAQMAN and MYCOTOOL are trademarks of Roche. All other product names and trademarks are the property of their respective owners.

**Please contact your local CustomBiotech representative**

**Europe, Middle East, Africa, Latin America**

Phone +49 621 759 8580  
Fax +49 621 759 6385  
mannheim.custombiotech@roche.com

**United States**

Phone +1 800 428 5433 (toll-free)  
Fax +1 317 521 4065  
custombiotech.ussales@roche.com

**Japan**

Phone +81 3 6634 1046  
Fax +81 3 5479 0585  
japan.custombiotech@roche.com

**Asia Pacific**

Phone +65 6371 6638  
Fax +65 6371 6601  
apac.custombiotech@roche.com

**Canada**

Phone +1 450 686 7050  
Fax +1 450 686 7012  
custombiotech.can@roche.com

**Published by**

Roche Diagnostics GmbH  
Sandhofer Straße 116  
68305 Mannheim  
Germany

© 2021 Roche Diagnostics GmbH
All rights reserved.

custombiotech.roche.com