

## MycoAlert™ Assay Control Set Instructions for Use

### Intended Use

The MycoAlert™ Assay Control Set is intended for use with **MycoAlert™ PLUS Mycoplasma Detection Kits** (LT07-701, LT07-703, LT07-705 and LT07-710) and with the first generation **MycoAlert™ Mycoplasma Detection Kits** (LT07-118, LT07-218, LT07-318 and LT07-41) as control for assay performance. The MycoAlert™ Assay Control Set will provide a positive and negative control ratio when used with the kits. The MycoAlert™ Assay Control Set **DOES NOT** contain live mycoplasma and is not suited for quantification of mycoplasma contamination.

Care should be taken to avoid cross contamination of reagents with the MycoAlert™ Assay Control. Employ good laboratory practice at all times.

### Kit Contents & Storage

LT07-518	10 tests
MycoAlert™ Assay Control	1 x 1 ml (LT27-235)
MycoAlert™ Assay Buffer	1 x 2 ml (LT27-236)

### MycoAlert™ Assay Control Reconstitution

1. Add 1 ml of MycoAlert™ Assay Buffer into the vial containing the lyophilized MycoAlert™ Assay Control. Keep the remaining 1 ml of MycoAlert™ Assay Buffer for use as a **negative ratio control**.
2. Replace the red screw cap and mix gently.
3. Allow the control to equilibrate for 15 minutes at room temperature before use.

### Storage Conditions

<b>Lyophilized control</b>	2°C-8°C. Do not freeze.
<b>Reconstituted control</b>	Keep on ice when not in use and use within 5 hours.  If prolonged storage is required the assay control can be aliquoted into polypropylene tubes and stored at -80°C for up to six months. Once thawed, the assay control must not be refrozen and should be allowed to reach room temperature before use without the aid of artificial heat.
<b>Assay buffer</b>	This is provided ready for use. Store at 2°C-8°C when not in use.

See kit label for expiration date of the whole kit. See bottle labels for expiry dates of individual components.

### Protocol

#### Standard Controls in a MycoAlert™ PLUS and standard MycoAlert™ Mycoplasma Detection Kit Assay

- Positive control: To produce a positive ratio when using the MycoAlert™ PLUS and standard MycoAlert™ Mycoplasma Detection Kit Assay, use 100 µl of reconstituted MycoAlert™ Assay Control in place of a sample.
- Negative control: To produce a negative ratio when using the MycoAlert™ PLUS and standard MycoAlert™ Mycoplasma Detection Kit Assay, use 100 µl of MycoAlert™ Assay Buffer in place of a sample.
- Proceed with the MycoAlert™ Assay according to the instructions in the MycoAlert™ PLUS

Mycoplasma Detection Kit or standard MycoAlert™ Mycoplasma Detection Kit Assay respectively.

## Testing the Sensitivity of Luminometers

The MycoAlert™ Assay Control Set can be used for testing the suitability of a luminometer model for the MycoAlert™ PLUS and standard MycoAlert™ Mycoplasma Detection Kit Assay.

- Prepare following samples according to the table below (in triplicate).
- The 100 µl samples should be assayed according to the MycoAlert™ PLUS or standard MycoAlert™ Mycoplasma Detection Kit Assay instructions respectively.

### a) Samples to be tested when using MycoAlert™ PLUS Assay

Sample Name	MycoAlert™ Assay Control	MycoAlert™ Assay Buffer
Neat MycoAlert™ Assay Control	100 µl	-
1:10 MycoAlert™ Assay Control	10 µl of neat control	90 µl
1:100 MycoAlert™ Assay Control	10 µl of 1:10 dilution	90 µl
1:1000 MycoAlert™ Assay Control	10 µl of 1:100 dilution	90 µl
1:10000 MycoAlert™ Assay Control	10 µl of 1:1000 dilution	90 µl
MycoAlert™ Negative Control	-	100 µl

- The negative control should produce a ratio of < 1.0.
- The MycoAlert™ Assay Control samples should produce definite positive results (ratios > 1.0) for dilutions of at least **1:1000**.

If the data produced is not this clearly defined, it is probable that the chosen luminometer model may lack sensitivity. In this case, please contact Scientific Support.

### b) Samples to be tested when using MycoAlert™ Assay

Sample Name	MycoAlert™ Assay Control	MycoAlert™ Assay Buffer
Neat MycoAlert™ Assay Control	100 µl	-
1:2 MycoAlert™ Assay Control	50 µl	50 µl
1:4 MycoAlert™ Assay Control	25 µl	75 µl
1:8 MycoAlert™ Assay Control	12.5 µl	87.5 µl
1:16 MycoAlert™ Assay Control	6.25 µl	93.75 µl
MycoAlert™ Negative Control	-	100 µl

- The negative control should produce a ratio of < 0.9.
- The MycoAlert™ Assay Control samples should produce definite positive results (ratios > 1.0) for dilutions of at least **1:8**.

If the data produced is not this clearly defined, it is probable that the chosen luminometer model may lack sensitivity. In this case, please contact Scientific Support.

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