

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

Lyophilized control	2°C-8°C. Do not freeze.
Reconstituted control	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.
Assay buffer	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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