



# MicroBio Validation Kit

Operating Manual

# MicroBio Validation Kit

Model No. P0059

## Operating Manual



This work is licensed under a  
Creative Commons Attribution, Non-Commercial, ShareAlike 4.0  
International License

<https://creativecommons.org/licenses/by-nc-sa/4.0/>

Cantium Scientific Limited  
Clarendon Gardens  
Dartford  
Kent  
DA2 6EY  
United Kingdom

Tel: +44 (0) 1322 252000

[www.cantiumscientific.com](http://www.cantiumscientific.com)

February 2017 (Rev. 4)

Printed in England

*This page is left intentionally blank*

# Contents

Document Issue	5
Statement of Conformity	6
Warranty	7
Introduction	8
Kit Contents	9
Setting Up	10
Tube and head adaptor assembly	10
Preparing the air sampler	10
Validating the MB1 or MB2 bioaerosol sampler	11
Maintaining the Validation Kit	13
Additional Support	14
Calibration of the Validation Kit	15
Inspection Record	16

*This page is left intentionally blank*

## Document Issue

<b>Issue</b>	<b>Description</b>	<b>Date</b>	<b>Revision By</b>	<b>Approved</b>
1	First Issue.	06/05/2009	SNJP	DCP
2	Title modification. Web link update. Wording changes throughout document.	04/11/2010	SNJP	DCP
3	Updated to reflect new corporate logo.	06/02/2015	SNJP	DCP
4	Reformatting of manual.	03/02/2017	SNJP	DCP

## **Statement of Conformity**

We certify that this product complies with EEC DIRECTIVE 2002/95/EC the restriction of hazardous substances; commonly known as the RoHS directive. The validation kit is designed and manufactured under strict management systems compliant with ISO9001:2008 and calibration of the instruments is traceable to national standards.

## **Warranty**

The manufacturer warrants this product to be free from defects in materials and workmanship for **24 months** from the date of purchase.

If your product is found to be defective within that period, please contact Cantium Scientific Limited or your local distributor who will arrange for repair of the instrument, or if necessary a replacement.

This warranty does not cover accidental damage, wear and tear, consequential or incidental loss.

Damage caused by cleaning materials and methods not recommended by the manufacturer, use beyond the specification, use in wash down areas, or modifications without prior permission from the manufacturer will invalidate the warranty.

This warranty does not affect your statutory rights.



## Introduction

The MicroBio Validation Kit is the standard device used to validate standard 100 litre per minute MicroBio MB1 and MB2 bioaerosol samplers. It provides a simple and cost effective method to ensure the MicroBio samplers are working at peak performance, requiring the minimum of training to use.

This guide provides information needed to validate the MicroBio MB1 and MB2 bioaerosol samplers and maintain the kit. Instructional videos on how to use the equipment can also be found on our website by visiting <https://www.cantiumscientific.com/products/validation-kit/> or visit our YouTube channel at [www.youtube.com/cantiumscientific](http://www.youtube.com/cantiumscientific).

## Kit Contents

1. Calibrated flow tube (Part no. P0059M001)
2. Sampling head adaptor (Part no. 0059M002)
3. Contact plate
4. Petri dish
5. Trimmer screwdriver
6. Padded plastic carry case
7. User Guide (*not shown in picture*)
8. Factory calibration certificate (*not shown in picture*)

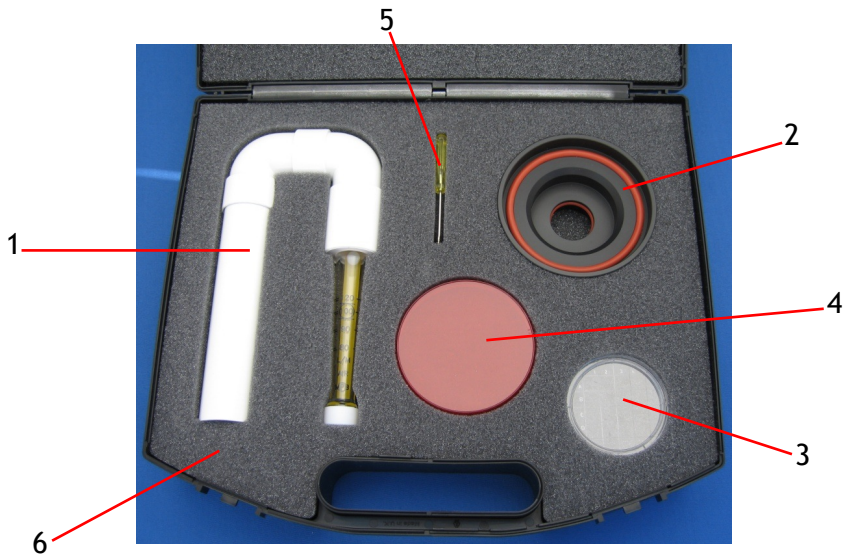


Figure 1: Kit Contents

## Setting Up

### Tube and head adaptor assembly

The first step is to insert the calibrated flow tube (1) into the head adaptor (2), as shown in figure 2. This forms the validation rig.



Figure 2: Tube and head adaptor assembly

### Preparing the air sampler

Fit the supplied Petri dish (4) or contact plate (3) into the MB1 or MB2 bioaerosol sampler to be validated and fit the sampling head. Then place the validation rig on top of the MB1 or MB2 sampling head as shown in figure 3.

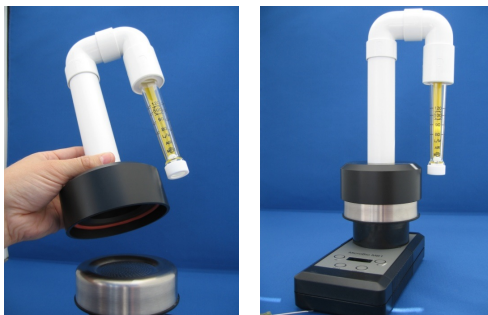


Figure 3: Fitting validation rig to the MB1/MB2 bioaerosol sampler

## Validating the MB1 or MB2 bioaerosol sampler

Calibration and validation should be carried out in a controlled environment and on a level surface. Air movement around the calibration zone should be eliminated and ideally carried out in normal atmospheric pressure of 1013 mbar at 20°C.

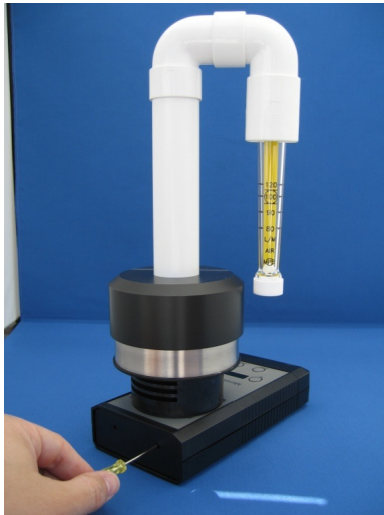


Figure 4: Location of adjustment screw hole

Switch on the air sampler and set to take a volume of 400 litres. This will allow sufficient operating time for validation/calibration to be performed. Now start the sampler.

**NOTE:** *MB2 users will need to initiate sampling operation before fitting the validation rig to the MB2 sampler.*

The float will rise in the validation rig. Hold the validation rig down firmly onto the MicroBio sampling head or alternatively use quick grip clamps (not supplied) to hold in place. The float should centre on the circle printed on the glass tube indicating a flow rate of 100 litres per minute. Approximately 20 seconds should be allowed for the float to stabilise.

**NOTE:** *It is important not to obstruct the exhaust vents of the MB1 or MB2 sampler or the bottom of the glass tube of the flow rig during the validation test.*

If the validation kit does not indicate correct flow, first check the rig is held firmly down and repeat the test. If the test fails a second time, the sampler should be returned to Cantium Scientific Limited or your local distributor for calibration. It is possible for users to adjust the flow if required by turning the adjustment screw, located as shown in figure 4, using the screwdriver supplied (5). The adjustments should always be made slowly. Self adjusting will invalidate the calibration certificate provided with the sampler.

Once adjusted, allow approximately 1 minute and observe that the float remains predominantly within the 100 litres per minute circle. There may be some occasional fluctuation of the float. The air sampler can now be considered validated.

If it is not possible to increase or decrease the flow rate to 100 litres per minute, this may indicate a fault in the air sampler. For service, contact Cantium Scientific Limited or your local distributor.

## **Maintaining the Validation Kit**

Due to the nature of variable area flow meters, as used in the validation kit and the product being manufactured to precise standards, annual calibration is not required. Regular inspection is needed. It is recommended that the validation kit is returned to Cantium Scientific Limited or an appointed re-seller for full factory inspection every five years.

When not in use, the kit should always be stored in the padded carry case and kept in a clean dry environment. The kit should be cleaned with a soft dry cloth. Inspection should include the following checks:

1. Ensure the orange coloured seals in the head adaptor (2) are clean, secure and level.
2. The calibrated flow tube (1) fits securely into the adaptor head (2).
3. Looking into the bottom of the glass tube check the white PTFE stopper is in-line with the direction of the tube and not at an angle restricting flow. If not, this can be moved into position using small pliers or tweezers.
4. The glass tube is parallel with the longer white plastic tube. If not, this can be moved into position by hand, as the silicone rubber fitting does allow a small degree of movement.
5. The glass tube is firmly fitted into the silicone rubber fitting.

If required, the kit can be returned to Cantium Scientific Limited or your local distributor for independent verification.

## **Additional Support**

Further support for using the validation kit and the MicroBio MB1 and MB2 bioaerosol samplers can be obtained from Cantium Scientific Limited or your local distributor.

Documentation to support IQ/OQ/PQ for use within pharmaceutical and related industries is available upon request by contacting Cantium Scientific Limited or your local distributor. Or visit our website at <https://www.cantiumscientific.com/support/information>

## **Calibration of the Validation Kit**

Calibration of the validation kit shall only be undertaken by Cantium Scientific Limited. It is recommended this is done at five yearly intervals.

Variable area flow meters impose a restriction on air flow. This will cause a reduction in the normal flow of air through the MB1 and MB2 bioaerosol samplers. Through experimentation during development, this restriction is known at various set-points on the tube scale and is compensated for on the flow markings on the tube.

The exact printing position on each tube is adjusted to take into account the equivalent true flow based on the known restrictions. Once printed, the tube is calibrated for life and no further adjustments are necessary.

Five year inspections will check the scale against the known restrictions using the same flow meter rig used during manufacture. This rig is a calibrated secondary standard held by the glass flow-tube manufacturer.

For calibration, please arrange through your local distributor or directly with Cantium Scientific Limited.



## Inspection Record

Year	Date	By	Seal Check	Head/ Tube Fit OK	PTFE Stoppers OK	Glass Tube Fit OK
1						
2						
3						
4						
5		RETURN FOR 5 YEAR CALIBRATION				
6						
7						
8						
9						
10		RETURN FOR 5 YEAR CALIBRATION				
11						
12						
13						
14						
15		RETURN FOR 5 YEAR CALIBRATION				
16						
17						
18						
19						
20		RETURN FOR 5 YEAR CALIBRATION				

Cantium Scientific Limited  
**MicroBio Validation Kit Operating Manual**  
[www.cantiumscientific.com](http://www.cantiumscientific.com)

February 2017 (Rev. 4)

**Article #A-00133**