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### **Australian Government**

### Department of Health

Therapeutic Goods Administration

Laboratories Branch

Operations	Biomaterials & Engineering - Forms	
Procedure	Training Record – Face Mask Testing	
Written	s22.	
Authorised	s22	
Date issued	08/01/2021	
Revision #	1	

### Training Record – Face Mask Testing

- Visual Inspection of Particle Filtering Respirators and Medical masks
- Respirator Filter Particulate Penetration Performance Assessment
- Medical face masks Resistance against penetration by synthetic blood ISO 22609

Trainee:



### To be signed off the following must be done:

- a) The training tasks sheet below must be signed and completed by the training coordinator.
- b) Competency is maintained when an officer has performed the operation satisfactorily within the last 18-month period. Verification of competency shall be achieved by referring to the date the procedure was last performed by the operator (LIMS, calibration record sheet, test results, etc.).
- c) If the operation is not performed within the 18 month period retraining/re-familiarisation is required.

### Responsibility

The Senior Testing Manager is responsible for the maintenance of this procedure and general compliance with its requirements.

#### **WHS Requirements**

As per each SOP

#### **Training**

For the purposes of the following SOPs, training comprises the following:

- 1. The trainee observes a test being performed by an instructor.
- 2. The trainee demonstrates the processes under close supervision of the instructor.
- The trainee then completes a test on a sample on their own.
- 4. The instructor verifies the trainee has correctly performed the test.

The instructor shall be a person with qualifications or experience relevant to the test method

### Visual Inspection of Particle Filtering Respirators and Medical masks

#### Reference

Document title: <QPulse\_DocTitle>
Active Date: <QPulse\_DocActiveDate>
Print Date: 14/10/2021 10:26

• BIOME - SOP - Visual Inspection of Particle Filtering Respirators and Medical masks

## Visual Inspection of Particle Filtering Respirators and Medical masks

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## Resistance against penetration by synthetic blood

### Reference

BIOME - SOP - Medical Face Masks

## Resistance against penetration by synthetic blood

Procedure	Date Performed	Trainee/Supervisor Initial	Trainer to Sign & Date when Competent
Sampling			
Sample Conditioning			
Equipment Setup	18/6/21	s22	- Digitally signed in TRIM 19/6/21
Equipment Setup Verification	18/6/21	s22	- Digitally signed in TRIM 19/6/21
Testing	18/6/21	s22	- Digitally signed in TRIM 19/6/21
Completion of Testing	18/6/21	s22	- Digitally signed in TRIM 19/6/21
Document Management	18/6/21	s22	- Digitally signed in TRIM 19/6/21

### **Respirator Filter Particulate Penetration Performance Assessment**

### Reference

• BIOME - SOP - Assessment of Filter Penetration Efficiency - 42-CFR-84

### **Respirator Filter Particulate Penetration Performance Assessment**

Procedure	Date Performed	Trainee/Supervisor Initial	Trainer to Sign & Date when Competent
ANALYST/OPERATOR - Primary purpo	se - test respirators		er de la
Demonstrate safe work practices	8—11 Jun 21	s22	Workflowed 11/6/21 Competency assessment D21- 273255. TRNG 2103001159-R3
Replenish Instrument NaCl	8—11 Jun 21	s22	- Workflowed 11/6/21
Set up instrument and perform calibrations	8—11 Jun 21	s22	Workflowed 11/6/21
Verify instrument setup with reference media sheets	8—11 Jun 21	s22	- Workflowed 11/6/21
Test respirators IAW SOPs	8—11 Jun 21	s22	- Workflowed 11/6/21
Document results and observations online templates and TRIM	8—11 Jun 21	s22	Workflowed 11/6/21
Equipment Shutdown	8—11 Jun 21	s22	- Workflowed 11/6/21
Clean instrument at end of shift	8—11 Jun 21	s22	- Workflowed 11/6/21
TEAM LEADER - Primary purpose – Ma	anage and oversee i	ntegrity of testing and	l safety
Coordinate samples – issue respirators for testing based on priority, precondition as required			
Maintain sufficient stocks of NaCl and consumables			
Troubleshoot instrument problems			
Review test results			
Validate QLIMS			

### **Measurement of Cannulas**

### Reference

• BIOME - SOP - Medical Face Masks - Measurement of Cannulas

### Measurement of Cannulas Performance Assessment

Procedure	Date Performed	Trainee/Supervisor Initial	Trainer to Sign & Date when Competent
Equipment Setup			
Cannula Measurement			

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Verification			
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