Australian Government
Department of Health
Therapeutic Goods Administration

Laboratories Branch

Procedure	Assessment Results - Particulate Penetration Efficiency - Rapid Screening
Written	s22 & s22
Authorised	s22
Date Issued	23/07/2021
Revision	6

PFE RAPID SCREENING ASSESSMENT RESULTS

Summary:

In response to the COVID-19 pandemic, the Therapeutic Goods Administration (TGA) is undertaking a post-market review of all face masks included in the Australian Register of Therapeutic Goods (ARTG) to ensure the quality and effectiveness of face masks supplied in Australia, including that they meet the legislative requirements for medical devices and perform as intended.

Testing was performed in accordance with the TGA in-house Rapid Screening standard operating procedure D20-3958656 (SOP) to assess the particulate filter efficiency of TGA registered respirators claiming compliance with standards used in other countries.

The post-market rapid assessment program was specifically developed to expeditiously quantify the filtration efficiency of respirators. The in-house rapid screening test methodology is based on a modified version of the 42 CFR Part 84 Approval of Respiratory Protective Devices.

Whilst most of the test parameters listed in the SOP are consistent with NIOSH Standard Test Procedure TEB-APR-STP-0059 (STP-0059), this modified test differs for respirator pre-conditioning, test duration and respirator mass loading. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059. The values reported are only to provide an indication of filter efficiency to ensure masks perform as intended.

Respirator filters were tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The aerosol was dried, charge neutralised and passed through the test article at a flow rate of 85 ± 4 litres per minute. Each respirator was tested for five minutes after maximum penetration was reached or ten minutes and the findings recorded.

This assessment used convenience sampling, a non-probability sampling technique whereby samples were drawn from a population based on their availability. Respirator filter specimens were then selected at random from the sample provided.

Prior to penetration testing, specimens underwent a visual inspection to qualitatively assess build and marking quality. The initial inhalation resistance and maximum particle penetration (%) for each individual respirator was then determined.

An ATI 100Xs Salt Aerosol Automated Filter Tester was used capable of efficiency measurements of up to 99.9995%. The tester produces a particle size distribution with a count median diameter of 0.075 ± 0.02 um and a geometric standard deviation <1.86. The mass median diameter is approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size.

Unless stated otherwise, specimens were tested under normal laboratory environmental conditions in the condition received. Data relating to the initial resistance does not take into account any bias due to specific mounting fixture used for testing.

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Sample Details

LIMS No.	2101000400-R3
ARTG No	s22 [redacted]
Label name	N95 Health Care Particulate Respirator Surgical Face Masks
Certification claimed	N95
Batch No.	202011001
Expiry date	04 Nov 2023

Equipment Used

ATI Salt Aerosol Automated Filter Tester 100XS	33211
Analytical balance LIMS No.	33203
NaCl 4% batch No.	20210712/04
NaCl 0.9% batch No.	20201215/05
Reference filter media sheet batch No.	511576
Test method used	D20-3958656 - Particulate Penetration Efficiency Assessment -Rapid Screening

Testing

Operator	s22 [redacted]	**Test date**	5/08/2021
Room Temp/RH	21.37/30.19	**Probe LIMS**	33215

Sample Conditioning

Enclosure LIMS	N/A	**Probe LIMS**	
Date/Time IN		**Temp/RH IN**	
Date/Time OUT		**Temp/RH OUT**	

Particulate Penetration Efficiency Assessment Results

Rapid Screening

The minimum filter efficiency requirement for respirators must be greater than or equal to the certification standard claimed for each item tested. Test data indicate the minimum and maximum filter efficiency for the sample batch was as follows:

Minimum Filter Efficiency =	95.85%	Masks Tested =	10
Maximum Filter Efficiency =	99.61%	Total Fails =	0
Maximum Initial Resistance =	27.4	Certification claimed = N95	

Filter No	Initial Airflow Resistance (mmH_2O)	Max Particle Penetration (%)	Filtration Efficiency (%)	Test Result
1	22.9	3.50	96.50	Pass
2	22.5	2.73	97.27	Pass
3	27.4	2.89	97.11	Pass
4	21.1	1.17	98.83	Pass
5	23.9	4.15	95.85	Pass
6	26.4	0.39	99.61	Pass
7	21.7	0.69	99.31	Pass
8	20.9	1.45	98.55	Pass
9	22.8	2.11	97.89	Pass
10	21.7	1.11	98.89	Pass
11			not tested	not tested
12			not tested	not tested
13			not tested	not tested
14			not tested	not tested
15			not tested	not tested
16			not tested	not tested
17			not tested	not tested
18			not tested	not tested
19			not tested	not tested
20			not tested	not tested

File Name = *2101000400-R3_Rapid_N95_PFE_Results_05-08-2021*

Comments & observations: Ambient temperature/RH probe LIMS #32223 used in lieu of LIMS 33215 - Refer to TRIM D21-292986. PENCAL'd after warm-up & #5.

LIMS Number	2101000400-R3

SAMPLE_ID	LAB_RESPONS	ST_NAME
2101000400-R3	350633	N95 Health Care Particulate Respirator Surgical Face Masks

TEXT7	DATE1
202011001	4/11/2023 8:23