# Verification Report for the ATI 100Xs Automated Filter Tester

## Introduction

The Biomaterials and Engineering Section (BiomE) has uses an ATI 100Xs Automated Filter Tester instrument to test the particulate filtration efficiency of medical respirators. The instrument achieves this by challenging filters with a dried aerosolised salt solution and measuring the percentage passing through the material. The test is carried out in strict accordance with an in-house developed procedure based on the National Institute for Occupational Safety and Health (NIOSH) TEB-APR-STP-0059 *Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air Purifying Respirators Standard testing Procedure (STP)*.

The purpose of this document is to demonstrate that the test instrument meets the performance expectations detailed in 42 CFR Part 84, Subpart 84.181, and to verify that the trained analysts (operators) using the apparatus can apply the method repeatedly obtaining the same outcomes as defined in the standard method.

## References

42 CFR Part 84 *Respiratory Protective Devices*.

NIOSH TEB-APR-STP-0059

NIOSH Modified Protocol - Assessment of Filter Penetration Performance for Non-NIOSH Approved Respirators – March 31, 2020 (withdrawn)

BiomE Particulate Penetration Efficiency Assessment – Rapid Screening – Standard Operating Procedure (SOP) D20-3958656

National Association of Testing Authorities (NATA), 2018, *General Accreditation Guidance – Validation and verification of quantitative and qualitative test methods*

ATI 100Xs Operators Manual

ATI 100Xs Performance Verification Sheet - D21-2824018

## Outline

The principle of filter particulate efficiency determination is that a quantity of dried salt aerosol of a known concentration, particle size and distribution challenges a filter at a specified flow rate and the particles passing through the filter are quantified as a penetration percentage.

The ATI 100Xs Automated Filter Tester is an all-in-one instrument that generates particles from a saline solution and precisely measures the penetration value. The particle size and distribution, aerosol concentration and flowrate are defined in standards (in this case 42 CFR 84) and the resultant penetration values are assessed in the context of medical device safety and fitness-for-purpose by determining whether respirator's meet claims of compliance with standards.

Pass/Fail testing criteria are specified in BiomE *Respirator PFE Decision Making Guide* D21-3056973

TEB-APR-STP-0059 is a published standard procedure used by NIOSH to certify respirators for compliance to 42 CFR 84. In response to COVID-19 to support the availability of respiratory protection to US healthcare workers, NIOSH developed a modified protocol based on TEB-APR-STP-0059. The purpose of the modified protocol was a means to efficiently quantify the filtration efficiency of a respirator approved by a foreign regulatory body based on a modified version of the NIOSH filter efficiency test (i.e. TEB-APR-STP-0059, Revision 3.2, December 13, 2019).

In response to COVID-19 in Australia, TGA using a similar type of automated filter tester as that specified in NIOSH procedures developed its own in-house testing procedure similar to the NIOSH modified protocol to rapidly assess the filtration efficiency of respirators used by Australian healthcare workers.

Given the breadth of detail provided in TEB-APR-STP-0059, method validation is not required. The purpose of this document is to outline the approach for test method verification. The guidance provided by NATA includes information on

parameters and control measures that should be considered for verification of quantitative/qualitative methods such as this one.

The following areas have been chosen to demonstrate that the required performance characteristics of the standard method can be met:

- Equipment
    - Test instrument – particle size distribution and charge, aerosol concentration, flow rate, pressure drop, temperature /humidity and penetration measurement
- Reagent
    - Salt solution– aerosol concentration
- Control
    - Particle generation –the relationship between size, distribution, charge, concentration, temperature, humidity on penetration
    - Aerosol flow rate - the relationship between flowrate and particle penetration
    - Pressure differential measurement - the relationship between filter mounting and sealing methods and the effect on breathing resistance values
    - Particle detection and quantification –the relationship between aerosol concentration and linearity of light scattering photometer to detect particles
    - Filter mounting and sealing- the relationship between filter mounting and sealing methods and the effect on penetration values
- Repeatability/reproducibility
    - Inter-analyst reliability – the level of agreement between different analysts
- Documentation
    - Worksheets – verification of formulas/values
    - Data transfer from instrument to computer

## Equipment

## Test Instrument ATI 100Xs

*Background:*

According to TEB-APR-STP-0059 (STP-0059), the test instrument should be a TSI Model 8130 or 8130A Automated Filter Tester or **equivalent** with an airflow control accuracy of 2% of full scale and pressure measurement accuracy of 2% of full scale. Penetrations can be measured to 0.001%, efficiencies to 99.999%. Testing requirements are:

- Specimen-holding test fixture
- Flowrate set to 85 ± 4.0 l/min
- Aerosol concentration not to exceed 200 mg/m³
- Particle size distribution will be 0.075 ± 0.020 micrometres with a geometric standard deviation not exceeding 1.86
- 2% sodium chloride solution in distilled water
- NaCl challenge aerosol 25 ± 5° C and RH 30 ± 10% that has been neutralised to the Boltzmann equilibrium state.

The test instrument used by BiomE is an ATI 100Xs Automated Filter Tester manufactured in 2020 with slightly better specifications than the TSI 8130/A and considered by industry a generation more advanced than the TSI 8130A.

**Accuracy specification for ATI 100Xs vs TSI 8130/A @ 85lpm**

| | Aerosol detection accuracy | Flow lpm | Pressure mmH20 | Particle detection | Sodium chloride in distilled water | Efficiency reading % |
|---|---|---|---|---|---|---|
| **ATI 100XS** | ± 1% of reading | ± 0.58 | ± 0.624 | photometer | 4%* | 99.9995 |
| **TSI 8130A** | Not specified | ± 1.7 | ± 2.5 | 2 photometers | 2% | 99.999 |
| **TSI 8130** | Not specified | ± 2 | ± 3 | 2 photometers | 2% | 99.999 |

* The ATI 100Xs uses 4% NaCl in distilled water to generate the particle characteristics required by 42 CFR 84 and STP0059.

### How the ATI 100Xs Operates

The test aerosol used to interrogate respirators is generated by a nebuliser nozzle suspended in an aqueous saline solution. The nebuliser air jet generates an aerosol mist that is passed through an impactor and controlled "drying" chamber to achieve the desired aerosol characteristics.

During testing, aerosol is drawn from the aerosol generator mixing manifold, through the respirator under test and a light scattering chamber (LSC). The LSC is used to measure the level of sodium chloride aerosol content that has succeeded in passing through the sample under test. This level of penetration is expressed as a percentage of the total available system aerosol or % penetration.

The sodium chloride aerosol is continuously generated at a known, reproducible concentration and particle size, while at the same time being dried, neutralised and maintained in a ready state for availability at a moment's notice when a test is initiated.

The forward light scattering chamber (also known as photometer) accurately provides a near real-time response to the sodium chloride aerosol.

Penetration, filter resistance and flow rate data are transferred in near real time via USB cable to a nearby connected laptop running data acquisition program recording values and producing charted plots of resistance and penetration.

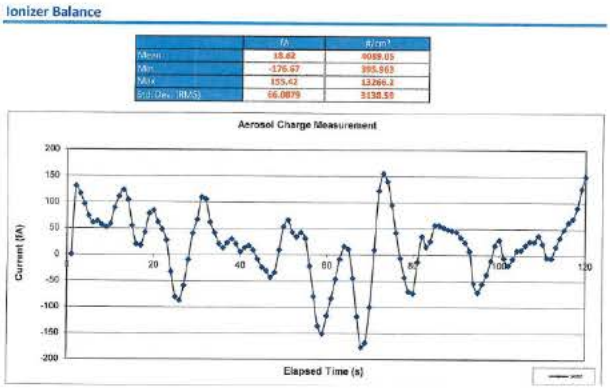
### Generator Replenishment Pump

The 100Xs is equipped with an integrated generator replenishment pump & reservoir. During operation, as 4% solution is consumed the generator replenishment pump automatically maintains the necessary liquid level in the main aerosol generator tank using the generator solution level sensor.

**Air Inlet Conditioning System**
Compressed air utilised within the 100Xs is conditioned by a series of regulators, dryers and heating elements, which provides for a consistent high quality source of aerosol.

**Aerosol Neutraliser**
An aerosol neutraliser reduces the electrical charge that builds up on the aerosol particles when the salt solution is atomised. This neutralisation technique enables the aerosol to reach the Boltzmann equilibrium.

The neutraliser consists of a high voltage power supply and an inline ionising air nozzle containing two tungsten needles. Pulsed high voltage applied to the needles ionises air passing through the nozzle that mixes with aerosol, effectively neutralising the aerosol particles.




**Dilution Air Heater**
Dilution air is required to adjust and maintain the desired aerosol concentration levels. An integrated heater standardises the dilution air temperature and provides a controlled drying environment for formation of the aerosol particles.

**Flow Controller**
The ALICAT mass flow controller sets and maintains a constant test flow rate regardless of varying test conditions. Test flow rates may be selected for display in either volumetric or mass lpm of flow. This allows for greater results repeatability as well as a significantly lower instrument monitoring burden to maintain flow during extended or load testing.

The manufacturer's accuracy specification is ± 0.4% of reading + 0.2% of full scale. Full scale range is 120 SLPM, therefore accuracy at 85 lpm is - 85 ± (0.34 + 0.24) = 0.58 lpm. ALICAT claims its calibrations are NIST Traceable but not ISO/IEC 17025.

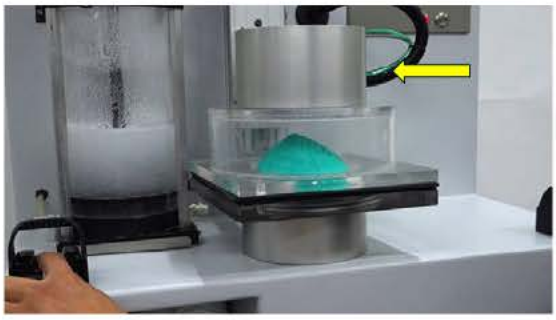
**Differential Pressure Transducer**
An integrated circuit based differential pressure sensor provides a real-time measurement of the pressure differential generated across the component under test. The manufacturer's specified accuracy is ± 2.5% of full scale reading. Full scale is 250 $mmH_2O$, therefore accuracy is ±0.625 $mmH_2O$.

The differential pressure sensor board is calibrated annually by the manufacturer at their ATI factory and sent to TGA for swap out. Most recent Calibration Test Report 0800207-061821-1821-0042/23 dated 18-Jun-2021. (not ISO 17025 but must be calibrated by ATI)

**Pressure Transducers**
The 100Xs incorporates a series of internal pressure transducers to monitor operating pressure levels. This allows systems messages and warnings to be presented when pressures fall outside of predetermined values necessary for consistent, accurate operation of the unit. Two pressure sensor boards are calibrated annually by the manufacturer ATI at their factory and sent to TGA for swap out. Most recent test reports are 0800207-061821-1821-0042/23 dated 18 JUN 2021.

**Test Fixture (Chuck)**

The test fixture, often referred to as the "chuck" is back mounted on a pneumatically driven linear actuator with a standard stroke length of 146 mm (5.75 inches). This allows incorporation of a variety of test adapters up to a diameter of 30.5 cm (12 inches) provided that a seal is maintained on the 13.9 cm (5.5 inch) OD upper and lower fixtures.



**Filter Test Adapters**
A variety of test adapters and inserts are used to mount, seal and enclose the respirator being tested. The test adapter is placed between the instrument upper and lower chuck.


**Photometer**
The near forward light scattering photometer analyses particles dispersed in a fluid. The design includes a cylindrical housing enclosing a pair of axially spaced, spherical surfaced, bi-convex lenses which provide axial focusing of the lamp image in an intermediate light scattering chamber through which the aerosol sample being analysed is passed.

The light scattering photometer is capable of measuring 0.0001 to 200 micrograms per litre with an accuracy of ± 1% of penetration reading. Measurement is accomplished by passing the entire sample through the optical detection window of the sampling chamber and measuring the resulting scattered light intensity. The scattered light intensity is directly proportional to the mass of the suspended particulate within the sample.

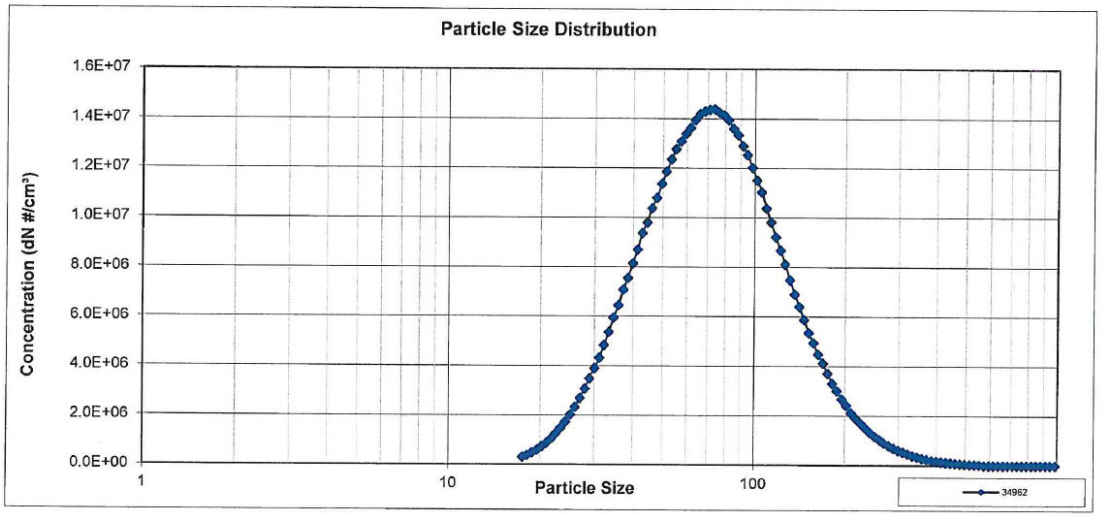
The photometer is replaced annually by the manufacturer (on exchange of the old one). The photometer does not undergo periodic calibration. It is a ratio measuring device optimised for salt particulates. Its linearity has been confirmed by passing through it different aerosol concentrations generated from 0.04, 0.2 and 4%, salt solutions then performing gravimetric weighing [D21-3205449].

**Particle Generation**
The 100Xs Salt Aerosol Automated Filter Tester was designed to meet the sodium chloride testing requirement of NIOSH 42 CFR Part 84. This testing specification requires a NaCl aerosol with a count median diameter (CMD) of 0.075 ± 0.020 µm with a particle distribution having a standard geometric deviation of less than 1.86. The aerosol produced is subjected to an ionized air stream to shift the electrically charged generated aerosol to a neutral state (Boltzmann Equilibrium) characteristic of naturally occurring aerosols.

Below is an excerpt from the ATI supplied initial calibration documentation (dated 22 July 2020) for TGA's ATI 100Xs delivered August 2020. At the time of testing (July 2020) the instrument generated an aerosol CMD of 0.0721 µm with a particle distribution standard geometric deviation of 1.71.

## SMPS Data Summary

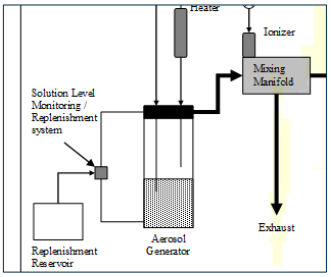
| | Number Particle Size | Diameter Particle Size | Surface Particle Size | Volume Particle Size | Mass Particle Size |
|---|---|---|---|---|---|
| median (nm) | 72.1 | 97.1 | 134.1 | 189.0 | 189.0 |
| mean (nm) | 84.5 | 115.3 | 158.8 | 214.0 | 214.0 |
| geo. mean (nm) | 72.9 | 98.4 | 135.4 | 185.6 | 185.6 |
| mode (nm) | 73.7 | 94.7 | 126.3 | 187.7 | 187.7 |
| geo. st. dev. | 1.71 | 1.75 | 1.76 | 1.73 | 1.73 |
| total conc. | 8.40e+06(#/cmÂ³) | 709.7(mm/cmÂ³) | 2.57e+11(nmÂ²/cmÂ³) | 6.80e+12(nmÂ³/cmÂ³) | 1.47e+04(Âµg/mÂ³) |




The above data characterising the particles generated by TGA's ATI 100Xs was measured by scanning mobility particle spectrometry (SMPS) at the ATI factory. TGA verifies particle size distribution (PSD) on a daily basis using green line filter media with known penetration and resistance characteristics and compares instrument readings with manufacturer provided graphs with upper and lower acceptance limits. The "Verifying Penetration Test Data" section below explains this in more detail.

**Aerosol Generation**

The 100Xs generates aerosol using a submerged nozzle nebulizer and regeneration technique. An air jet exiting the nozzle at high speed below the surface of the aerosol liquid generates bubbles that remain suspended within the liquid. When these bubbles reach the surface of the liquid they burst and generate airborne particles containing water and sodium chloride. As the airborne particles rise within the generator cylinder, the water is evaporated from the particle, forming the dry, sodium chloride aerosol necessary to perform efficiency testing.




Aerosol generation occurs at a level exceeding the maximum test flow capabilities of the 100Xs. The purpose of the excess aerosol is to maintain constant levels of aerosol regardless of the sample rate. Excess aerosol is exhausted from the 100Xs and captured in the ATI Self-Contained Exhaust Module.

**Sodium Chloride Solutions**

The 100Xs is designed to operate using a 4% mixture of sodium chloride by weight in the main aerosol generator reservoir. To achieve a 4% solution by weight, 40 ± 0.001 grams of reagent grade NaCl is mixed with 1000 ml of distilled water. TGA Media Preparation Unit creates the 4% NaCl solution in accordance with the *Sodium Chloride 4%* method in Biocompatibility Media Manual MP6 using NATA calibrated balance LIMS 33090 accurate to 0.0001 g. [D20-3997450]

A separate replenishment reservoir contains the 0.9% solution. The 0.9% solution by weight is achieved by mixing 9 ± 0.001 grams of reagent grade NaCl with 1000 ml of distilled water. TGA Media Preparation Unit creates the 0.9% NaCl

solution in accordance with the *Sodium Chloride 0.9% (Non Sterile)* method in Biocompatibility Media Manual MP6 using NATA calibrated balance LIMS 33090 with a resolution of 0.0001 g.

NaCl solutions are normally made in 5 or 10 litre quantities at a time. Media Prep Unit performs quality control checks including documenting batch records before delivering the 1-litre solutions in 2-litre sealed Schott bottles to the PFE laboratory. All Schott bottles arrive with clearly marked concentration and batch numbers before being segregated to avoid any mix-ups.

Solutions are stored until used which is usually within a couple of months. Advice from the instrument manufacturer ATI suggests storage will not detrimentally effect the solution provided the bottles are sealed.

Prior to each day's testing, one litre of 4% NaCl is poured into the main aerosol generator. The replenishment 0.9% reservoir is checked at instrument start-up and topped when needed. Batch numbers of both solutions are recorded on the test specimen's Results Test Sheet D20-3377358.

| ATI Salt Aerosol Automated Filter Tester 100XS | 33211 |
|---|---|
| Analytical balance LIMS No. | 33203 |
| NaCl 4% batch No. | 20210712/05 |
| NaCl 0.9% batch No. | 20201215/05 |
| Reference filter media sheet batch No. | 511576 |

**Verifying Penetration Test Data**

The 100Xs Salt Aerosol Automated Filter Tester incorporates a means for validating key system parameters. The validation procedure is designed to test many aspects of the instrument, one of which is verifying the particle size, by performing filter penetration measurements using filters (green line) with a known aerosol penetration level and analysing the results.

This technique is used to qualify the following:

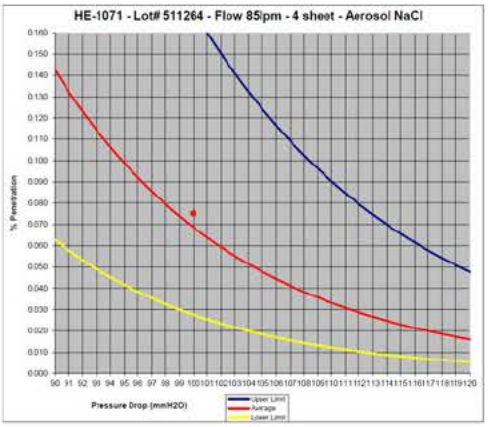
- challenge aerosol size distribution
- filter test flow measurement
- filter pressure drop measurement
- proper photometer operation
- general system operation

The validation technique uses filter media sheets with a known penetration range. The filter media are the glass fibre type, in 15 cm disks, part number 5500175. Supplied by ATI, the disks are accompanied by data sheets that list the expected penetration range for the specific media. The theory underlying the use of penetration data to verify system performance is as follows:


The aerosol penetration through a filter is a function of four test parameters: aerosol size, distribution, filter flow rate and the filter or media being tested.

Aerosol penetration reaches a maximum at the most penetrating particle size and then decreases for larger and smaller particles. Penetration also typically increases with increasing filter flow rates.

The effect aerosol size distribution has on aerosol penetration decreases with increasing width in the size distribution. The width of the size distribution is generally measured and referred to as the geometric standard deviation (GSD). A poly-disperse aerosol is one with a GSD greater than 1.6.




In addition to verifying a consistent challenge aerosol, the filter media penetration method also ensures the filter tester is operating properly. This technique indirectly tests the photometer output and also verifies the pressure drop measured across the filter is within specifications.

Since the photometer is the device used to measure particulate penetration, a malfunctioning photometer would be instantly identified.

Likewise, if the photometer is not purging correctly between tests, the results would indicate a problem.

Filter pressure drop is also tested. If the pressure drop is measured incorrectly, the verification test would clearly indicate this parameter is out of specification.

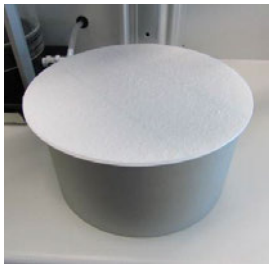
The filter media test method of system performance verification is the same as that used by NIOSH and Nelson Laboratories in USA who are both ISO/IEC 17025 accredited and is a precise and easy-to implement means of ensuring proper filter tester operation post installation. The technique verifies not only the correct challenge aerosol but also tests the entire system as a whole.

**Software**

The 100Xs Salt Aerosol Automated Filter Tester uses a software program contained in a Flash memory mounted on a custom PCBA (Printed Circuit Board Assembly) board. The software controls all aspects of the filter test, including reading the forward light scattering photometer, pressure transducers, controlling the test fixture, turning on and directing the aerosol flow, and outputting test data on the touch screen display.

**NIOSH TEB-APR-STP-0059-058 (STP-0059)**

STP-0059, paragraph 5.1.5. states "The NaCl particle size distribution shall be verified using "green line" filter discs supplied by TSI with a known penetration range. Graphs of penetration vs. resistance for two sheets and five sheets of stacked filter discs are supplied with each lot of standard filters, with a central line and upper and lower lines representing the expected penetration range at a given resistance. The test data should fall within an acceptance zone having boundaries defined by the upper and lower curves on the graphs. The standard filter test using both the 2 sheets and 5 sheets will be run at least once in each 8 hour test period to verify that the aerosol distribution is within the acceptance zone".



TGA carries out the green line media test prior to any testing on a daily basis and after eight hours of testing to verify NaCl particle size distribution and confirm instrument performance is within specifications. The test is performed in accordance with the instructions in the manufacturer's operator's manual and TGA's *Particulate Penetration Efficiency Assessment – Rapid Screening* – Standard Operating Procedure D20-3958656 . The green line graphs are accessible to the test analyst both as a laminated hardcopy in a folder and as a softcopy D21-2422561.

NIOSH STP-0059 specifies 2 and 5 green line sheets but TGA uses 2, 3, & 4 sheets which to align with the instrument's calibration data.

Test analysts record the green line filter media penetration and resistance values in the ATI 100Xs Performance Validation Sheet D21-2824018, confirming the instrument is within limits then file the document in TRIM E20-354732.

| | | Penetration | Resistance | Flow | Lot Number |
|---|---|---|---|---|---|
| # of filter sheets | 4 | 0.0725 | 109.7 | 85.2 | 511576 |
| | 3 | 0.2210 | 82.0 | 85.2 | 511576 |
| | 2 | 1.1520 | 54.8 | 85.2 | 511576 |
| Performance within limits (Y/N) | | | | Y | |

| GREENLINE VERIFICATION TEST RESULTS (As Left) | | | | | |
|---|---|---|---|---|---|
| Load time (secs) | 8 | Sample Time (secs) | 2 | Flow Rate (LPM) | 85 |
| | | | | | |
| # of filter sheets | Test | Lot Number | % Penetration | Resistance (Choose) | Flow (LPM) |
| 2 | Test # 1 | 511576 | 1.0649 | 56.3 | 85.2 |
| | Test # 2 | 511576 | 0.9729 | 56.3 | 85.1 |
| | Average | | | | |
| 3 | Test # 1 | 511576 | 0.1874 | 84.3 | 85.1 |
| | Test # 2 | 511576 | 0.1744 | 85.0 | 85.2 |
| | Average | | | | |
| 4 | Test # 1 | 511576 | 0.0505 | 112.1 | 85.2 |
| | Test # 2 | 511576 | 0.0413 | 112.1 | 85.2 |
| | Average | | | | |

ATI engineer confirmed in an email "verification curves are meant to verify the particle size distribution (PSD) of the challenge aerosol as described in the NIOSH protocol. For a given PSD, the relationship between resistance and penetration / efficiency can be modelled mathematically to construct the curves, the intrinsic variation in the media that we test leads to variations in resistance and penetration efficiency, and hence the acceptance zone bracketed by the upper and lower limits in each graph".

On January 31, 2021, NIOSH / National Personal Protective Technology Laboratory (NPPTL) were accredited by A2LA to ISO/IEC 17025 for *Determination of Particulate Filter Efficiency Level for N95 Series Filters against Solid Particles for Non-Powered, Air-Purifying Respirators STP TEB-APR-STP-0059* (including 11 other NIOSH STPs)

On 16 February, 2021 the TGA PFE Team Leader spoke with NPPTL Physical Scientist s22 about their ISO/IEC 17025 accreditation using the TSI Automated Filter Tester 8130A. During this discussion s22 mentioned that NPPTL do not detail UoM on reports except for their own internal use however their UoM with PFE testing was around 0.48%

NIOSH's green line filter media verification was realised by A2LA as an acceptable validation method of generated particle size and distribution. NIOSH greenline charts are produced by TSI Certitest (manufacturer of TSI 8130A instruments used by NIOSH). NIOSH have TSI service their instruments onsite every three months. D21-2223519

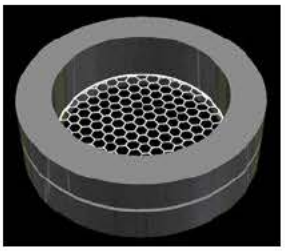
Nelson Laboratories, Salt Lake City, were ANAB accredited to ISO/IEC 17025:2017 on 16 March 2021, to test procedure *TEB-APR-STP-0059. [TRIM* D21-3203858]

**Determining Aerosol Mass Concentration**

The aerosol mass concentration of the 100Xs Salt Aerosol Automated Filter Tester is determined by performing a gravimetric test similar to NIOSH *TEB-APR-STP-0059.*

Immediately upon start-up the 100Xs prompts for a gravimetric test. TGA performs a gravimetric test in the following way:

- A gravimetric filter media is weighed on the analytical balance accurate to 0.0001 grams – LIMS Instrument No. 33203.
- GRAVIMETRIC TEST is selected from the "Test Mode" menu on instrument display and the initial mass of the filter media on the balance display is entered.
- The gravimetric filter media is inserted into the special gravimetric filter test adapter which is placed on the instrument lower chuck and the test started.
- Testing continues for 10 minutes then the filter is removed from the gravimetric test adapter and reweighed on the balance.
- The final mass of the filter media is then entered into the 100Xs software and the concentration value is automatically calculated and stored by the instrument.



The calculated aerosol concentration is also recorded daily on the ATI 100Xs Performance Validation Sheet D21-2824018.


**Analytical balance**

NIOSH STP-0059 and TGA SOP require the use of an analytical balance accurate to 0.0001 grams for gravimetric weighing. TGA uses a current Mettler Toledo ME104T/00 with a measurement range up to 120 g and a readability of 0.1 mg.

This balance is calibrated onsite every three years with a NATA endorsed report. The most recent report is No. 2005932 dated 07 Aug 2020 and filed in E20-313316. A laboratory coordinator carries out monthly and 6-monthly checks in accordance with the laboratory ISO/IEC 17025 quality management system and records of these checks are filed in E20-313316.

**Verifying Flow rate**

NIOSH STP-0059 specifies a flow rate of 85 l/min ± 4 l/min. The ATI 100Xs mass flow controller sets and maintains a constant test flow rate of 85 l/min. Flow rate stability is not presented in the manufacturer's specifications but raw data records show 85 ± 0.3 l/min The mass flowmeter is calibrated by the US manufacturer ALICAT Scientific yearly. Most recent Certificate of Calibration 352330 dated 2021-06-16. (not ISO 17025 but must be calibrated by ALICAT).

| | | | | | |
|---|---|---|---|---|---|
| 31 | 225 | 224 | 0.07951 | 18.7 | 85 |
| 32 | 226 | 225 | 0.082055 | 18.7 | 84.9 |
| 33 | 227 | 226 | 0.082227 | 18.6 | 85.1 |
| 34 | 228 | 227 | 0.082914 | 18.6 | 85.1 |

Evidence of the flow rate showing its stability is recorded as raw data and transferred to the laptop when testing filters as shown in the example. Every filter tested has its penetration, resistance and flow rate raw data documented at one-second intervals.

The current mass flow controller is a brand new item supplied by the ATI in July 21 with manufacturer's ALICAT cal report. The previous mass flow controller was swapped out at the same time however a few months before it was sent to VIPAC for calibration with NATA endorsed report. The NATA report is filed in TRIM D21-2602345 and showed the device remained well within its accuracy specifications of ± 0.4% of reading + ± 0.2% of full scale (i.e. 120 SLPM) and had not drifted.

**Test Results**

| Average Indicated Flow Rate | Accepted True Flow Rate |
|---|---|
| SLPM | standard L/min |
| 25.00 | 25.01 |
| 50.03 | 50.02 |
| 75.01 | 74.96 |
| 100.07 | 99.06 |
| 120.05 | 119.79 |

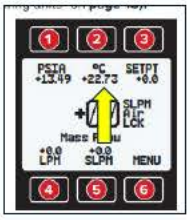
Table 1

**Uncertainty of Test**

The uncertainty of the reported values of Accepted True Flow Rate in Table 1 is: ± 0.18 % of flow

Flow rate is indirectly checked during the daily green line filter media check. Flowrate outside expectations will breach the upper and lower acceptance curves on the green line media graphs.

**Verifying aerosol temperature and humidity**




NIOSH STP-0059 states respirators are to be challenged by a NaCl aerosol at 25 ± 5° C and a relative humidity of 30 ± 10%. The filter tester flow controller diagnostic screen allows the operator to view aerosol flow temperature, as detected by the ALICAT flow controller. ALICAT's stated temperature accuracy is ± 0.75° C however it is not calibrated.

The instrument manufacturer presented a temperature/humidity table in the instruments' July 2020 initial calibration report but there is no temperature or humidity information in the latest calibration report (performed remotely at TGA via video link to ATI USA in July 2021).

**Aerosol Conditioning**

| | Measured | Nominal | Tolerance | Units |
|---|---|---|---|---|
| Temperature | 22 | 25.0 | 5.0 | °C |
| Humidity | 34.9 | 30.0 | 10.0 | %RH |

Correspondence with the ATI 100Xs engineers revealed that aerosol temperature and humidity can be measured and confirmed by placing a probe between the instrument aerosol mixing manifold and exhaust port.

TGA recently participated in an inter-laboratory comparison program run by INSPEC UK on 26 July, 2021 testing three P2 respirators to EN 13274-7 standard. Aerosol temperature and humidity had to be reported so a NATA calibrated Vaisala HMT 331 probe was placed into the aerosol mixer reading a temperature of 22° C and 22.7 to 24.6% RH. Taking into account the UoM of the Vaisala's most recent NATA calibration report [D21-2307088 ] the condition of the aerosol remained within the ATI manufacturer's claimed specification.

The ATI 100Xs instrument continuously monitors current dilution air temperature and the alarm set-point. Dilution air is required to adjust and maintain the desired aerosol concentration levels.

An integrated heater is used to standardise the dilution air temperature and provide a controlled drying environment for the formation of the aerosol particles. If the temperature exceeds the temperature limit, the instrument will automatically power off to prevent damage to the heating system.

## DOCUMENTATION

Data Reader Program Version 1.1.0

Data is retrieved from the 100Xs instrument via the instrument USB communications port to a stand-alone laptop running ATI-dataReader software customised by TGA. The software records the raw testing data of penetration level (%), resistance ($mmH_20$) and flow rate (L/min) from the ATI 100Xs Automatic Filter Tester (LIMS No. 33211) during the filtration efficiency test. It plots real-time penetration and penetration measurement curves. The test data is recorded at 1 Hz frequency by default.

The program notifies the user with an alarm five minutes after the penetration level has peaked or when ten minutes have elapsed.

After the user manually stops the recording by ceasing the test, it saves the final results, graphs the penetration and resistance time history for each specimen and calculates the initial resistance and max penetration for each specimen.

On completion of testing a batch of specimens (the sample) a summary table is produced of max penetration, minimum filtration and initial resistance for each specimen.

The in-house software is controlled and documented by the QMS system [2016/032315]. Software is developed in accordance with BiomE - SOP - *Use and development of in-house software [*D17-525636]. Changes to the software validated before use. The purpose of the validation testing is to ensure all requirements pertaining to the assessment and release of in-house software are completed. The validation procedures include instructions for data preparation, validating results, changing sampling interval and early stopping times.

Program updates such as cease testing time alarm and sample interval plots are formally validated in accordance with BiomE In-house software procedure "Validation and Verification Plan and Procedures" [D20-3978973].

**Rapid Assessment Standard Operating Procedure**

The Standard Operating Procedure (SOP) - *Particulate Penetration Efficiency Assessment – Rapid Screening* assists operators and analysts in efficiently quantifying the filtration efficiency of respirators included in the Australian Register of Therapeutic Goods.

The purpose of the SOP is to outline the "rapid screening" method for assessing the particle filtration efficiency (PFE) of respirators using the Salt Aerosol Automated Filter Tester ATI 100Xs located in the Biomaterials and Engineering (BIOME) laboratory.

The TGA laboratories' in-house developed rapid screening method (SOP) for assessing respirators is an abbreviated version of the National Institute for Occupational Safety and Health's (NIOSH) published filter efficiency test TEB-APR-STP-0059, Revision 3.2, December 13, 2019.

Standard Testing Procedure TEB-APR-STP-0059 (STP-0059) was specifically designed to meet the requirements set forth in United States 42 CFR, Part 84, Subpart K, 84.1811 for **certifying** N95 respirators.

TGA as part of its Post market review in response to COVID-19 developed the "modified" protocol – *Particulate Filter Efficiency Penetration Assessment – Rapid Screening* to **rapidly assess** the filtration efficiency of respirators in the Australian Register of Therapeutic Goods (ARTG) listed, distributed to or used by Australian healthcare workers.

The test method and principles prescribed in the SOP

- Clause 3.1.1 Instead of a TSI 8130 Automated Filter Tester, BIOME uses a Salt Aerosol Automated Filter Tester ATI 100Xs that has equivalent or better specifications.
- Clause 3.1.5 Instead of a 2% salt aerosol solution, the ATI100Xs uses a 4% salt aerosol solution producing the same particle size and distribution.
- Clause 5.1.1 The $mg/m^3$ NaCl aerosol concentration is determined by gravimetric weighing and recorded prior to testing, however, the rapid assessment protocol **does not** load respirator filter units with 200 mg over a typical two hour period. Instead, the primary purpose of the rapid assessment is to identify respirator peak penetration during a shorter 5-10 minute test where filters are usually loaded with around 8 to 18 mg NaCl.

- Clause 5.1.4 Verification of NaCl particle size distribution (PSD) **is not** determined using **2** and **5** stacked "greenline" filter discs run at least once in each 8-hour test period as per the NIOSH STP-0059. Instead, NaCl PSD is verified using **4**, **3** & **2** stacked "greenline" filter discs.
- Clause 5.2 Respirators **are not** pre-conditioned at 85 ± 5% relative humidity and 38 ± 2.5 °C for 25 ± 1 hours then sealed in a gas-tight container and used within 10 hours. Instead, respirators are exposed to and tested under normal laboratory environmental conditions.
- Clause 5.4 The first three of 20 filters **are not** mass loaded with 200 ± mg of NaCl to determine the method for testing the remaining 17 filters. Instead, for each filter, testing is manually stopped 5 minutes after peak penetration has been reached or 10 minutes has expired (whichever is sooner). Penetration, flow and resistance data are automatically captured and transferred by USB cable to a computer every 1 second then recorded and plotted on a chart in near real time during testing.
- Respirators **are not** sealed with heated bees wax on a flat metal plate inside a test fixture. Instead, they are mounted in a purpose designed adapter and sealed by compressing the mask between clear rigid plastic and EVA foam fixtures. If seal integrity cannot be established with the fixtures then masks are mounted using mounting putty and/or hot melt glue.

The current SOP is version 8 [D20-3958656]. Minor edits and changes occur every few months. Before the SOP is approved in the quality management system (QMS) it is first vetted and authorised by the BIOME Section Director. As soon as the new version is approved in the QMS an email is sent to all analysts/operators highlighting the changes.

**Rapid PFE Results Sheet**

Test data is read by ATI_dataReader software on the laptop connected to the ATI 100Xs instrument and as soon as each mask is tested the initial resistance and maximum penetration is displayed on the screen. The operator reads this information from the laptop screen and manually transcribes it to the *Rapid PFE Results* spreadsheet [D20-3377358] on an adjacent corporate networked connected desktop computer. Note: Instrument software is generally not allowed to directly download to the corporate network for security reasons.

The *Rapid PFE Results Template* is an Excel spreadsheet that is semi-populating and automatically calculates particle filtration efficiency based on penetration values input, the number of masks tested and failed. The spreadsheet also documents the ambient environmental conditions and reagents used at time of test.

On completion of testing the *Rapid PFE Results spreadsheet* displays the following information for the batch of samples tested:

a. minimum filter efficiency (%)
b. maximum filter efficiency (%)
c. maximum intial resistance
d. number of masks tested
e. total fails

The analyst / operator files the spreadsheet in TRIM then manually transcribes the a. to e. data into QLIMS.

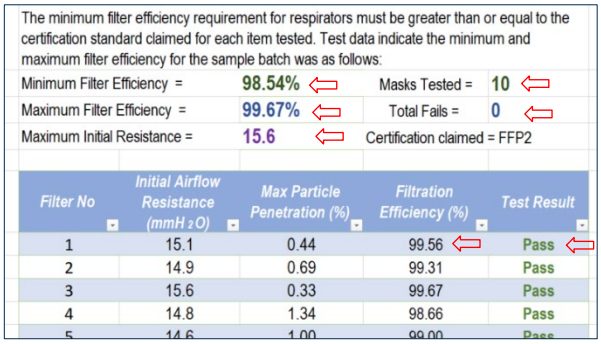
Upon opening up the blank *Rapid PFE Results spreadsheet* the analyst / operator manually enters the specific information in the table below causing some fields to automatically populate.

| Sample Details | Equipment Details | Each Specimen's Assessment Results |
|---|---|---|
| TGA sample number | room temp/RH reading | maximum penetration % |
| certification claimed | green line filter media sheets # | initial airflow resistance $mmH_2O$ |
| | NaCl 0.9% & 4% batch Nos | |

Calculations automatically performed by the spreadsheet include:

- converting each specimen's max penetration reading (max P) to a filtration efficiency (FE) that is 100% - max P = FE %
- comparing each specimen's max penetration reading to its certification (standard) to define a test result (Pass/Fail)
- listing the highest filtration efficiency value of all specimens tested (Maximum Filter Efficiency)
- listing the lowest filtration efficiency value of all specimens tested (Minimum Filter Efficiency)
- comparing each specimen's initial airflow resistance and presenting the highest value within the sample batch (Maximum Initial Resistance)
- calculating the number of all the specimens tested (Masks Tested)
- calculating the number of specimens that failed (Total Fails)

Shown is a typical example of a *Rapid PFE Results spreadsheet.* (Auto-populating ⇨)



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 = 98.54% ⇦ Masks Tested = 10 ⇦

Maximum Filter Efficiency = 99.67% ⇦ Total Fails = 0 ⇦

Maximum Initial Resistance = 15.6 ⇦ Certification claimed = FFP2

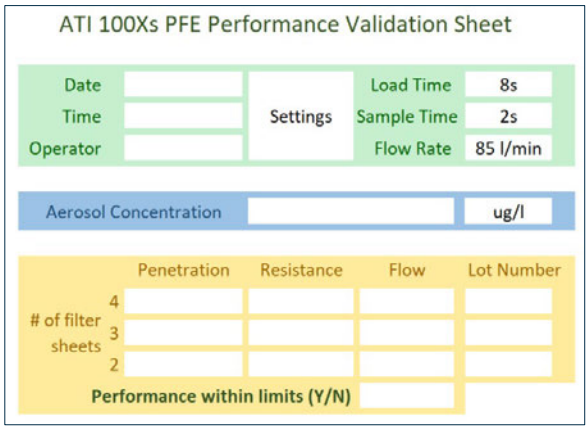
| Filter No | Initial Airflow Resistance (mmH 2O) | Max Particle Penetration (%) | Filtration Efficiency (%) | Test Result |
|---|---|---|---|---|
| 1 | 15.1 | 0.44 | 99.56 ⇦ | Pass ⇦ |
| 2 | 14.9 | 0.69 | 99.31 | Pass |
| 3 | 15.6 | 0.33 | 99.67 | Pass |
| 4 | 14.8 | 1.34 | 98.66 | Pass |
| 5 | 14.6 | 1.00 | 99.00 | Pass |

Calculations are relatively uncomplicated and any inconsistencies or errors would be obvious to the person entering the data. As an additional safeguard, each entry in the *Rapid PFE Results spreadsheet* is cross-checked by a validator on completion of testing comparing the raw data captured by the laptop in-conjunction with each specimen's penetration and resistance chart plot.

The Rapid PFE Results spreadsheet is locked but when it is edited or modified it undergoes a formal spreadsheet validation process before being approved and authorised for use in accordance with TGA QMS. The most recent spreadsheet validation is filed in D21-2673504.

**Performance Verification Sheet**

The *Performance Verification Sheet* [D21-28247018] is used daily to record the penetration, resistance and flow rate values achieved when carrying out the green line filter media test.



ATI 100Xs PFE Performance Validation Sheet

| | | | | |
|---|---|---|---|---|
| Date | | Settings | Load Time | 8s |
| Time | | | Sample Time | 2s |
| Operator | | | Flow Rate | 85 l/min |

| | | | | |
|---|---|---|---|---|
| Aerosol Concentration | | | | ug/l |

| | | Penetration | Resistance | Flow | Lot Number |
|---|---|---|---|---|---|
| # of filter sheets | 4 | | | | |
| | 3 | | | | |
| | 2 | | | | |
| Performance within limits (Y/N) | | | | | |

The sheet documents both the aerosol concentration and the 4, 3, & 2 media filter results and is documented confirmation that the instrument performance is within specification prior to testing.

The green line media test is conducted in sequence after the gravimetric, light scattering photometer (LSC) and penetration (pencal) calibrations have been carried out. It is the final verification step ensuring that the instrument is operating within specification and is an indirect method for qualifying:

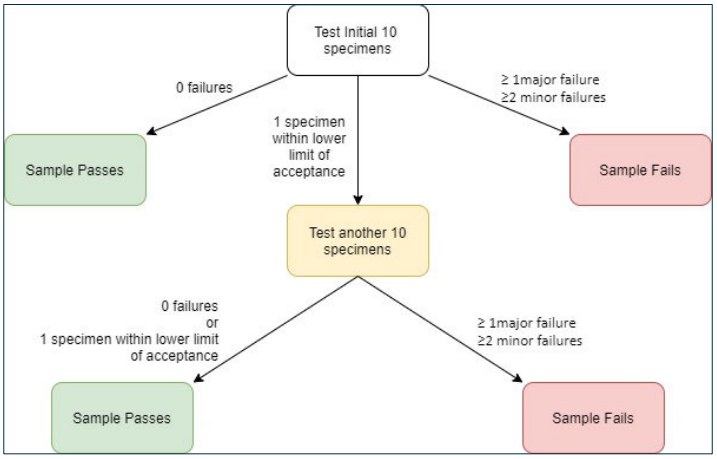
- challenge aerosol size distribution
- filter test flow measurement
- filter pressure drop measurement
- proper photometer operation
- general system operation

As stipulated in the SOP, filter testing does not commence until the *Performance Verification Sheet* has been successfully completed. The operator / analyst first starting up the instrument records that day's *Performance Verification Sheet* in TRIM E20-354732. As part of the QLIMS validation process, the person validating test results checks to ensure this sheet has been properly filled out at start of each day's testing; if it has not, all test results are deemed invalid and samples are retested.

Although it is an Excel template, the sheet does not perform any calculations. It is a quality controlled document therefore revisions and updates still require the usual authorisation by the BiomE Section Director before approval in the quality system and use.

### Decision Rule

The *Respirator Decision Rule Making Guide* is used by analysts and operators during testing to help them determine how many masks they should test when presented with specimens that fail the claimed PFE level.




The decision process takes into account contextual information about the samples and is an objective way of defining the level of Pass and Fail acceptance for health regulatory purposes.

Depending on the number of failures, analysts / operators will either test ten or twenty masks, which can take between 1.5 to 4 hours. The Decision Rules for PFE testing are filed in TRIM D21-3056973 & D21-3053847.

## Repeatability / Reproducibility

Inter-analyst reliability

*Aim:* The purpose of this test is to investigate the variation in test results between different analysts.

*Method:* Two lots of 10 specimens (D21-2877778 & D21-2865697) from the same batch/bag were tested independently by two different operators on 20th & 23rd Aug 2021 using the same instrument, reagents, procedure and test fixtures (i.e. same conditions).

The samples were chosen because they had presented low variability during previous testing however, they are not considered reference standards. Variation of testing results includes the actual variation between masks themselves but this has not been quantified. D21-3032263.

### Penetration (%)

| | Penetration mean (%) | Variance (%) | RPT UNC | RPD UNC |
|---|---|---|---|---|
| **Operator 1** | 0.572 | 0.014107 | 0.116 | 0.0007 |
| **Operator 2** | 0.571 | 0.012832 | | |

| D21-2877778 | Cody | D21-2865697 | Mabel |
|---|---|---|---|
| | 0.60 | | 0.54 |
| | 0.42 | | 0.62 |
| | 0.50 | | 0.45 |
| | 0.52 | | 0.51 |
| | 0.64 | | 0.54 |
| | 0.57 | | 0.81 |
| | 0.84 | | 0.6 |
| | 0.63 | | 0.4 |
| | 0.55 | | 0.6 |
| | 0.45 | | 0.64 |
| **SD** | **0.119** | **SD of MEAN** | **0.113** |
| **MEAN** | 0.572 | 0.001 | 0.571 |
| PFE MIN | **99.20%** | | **99.20%** |
| PFE MAX | **99.60%** | | **99.60%** |

Anova: Single Factor

SUMMARY

| *Groups* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| Column 1 | 10 | 5.72 | 0.572 | 0.014107 |
| Column 2 | 10 | 5.71 | 0.571 | 0.012832 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Between Groups | 5E-06 | 1 | 5E-06 | 0.000371 | 0.98484 | 4.413873 |
| Within Groups | 0.24245 | 18 | 0.013469 | | | |
| Total | 0.242455 | 19 | | | | |

**Initial resistance values**

| | **Initial Resistance** ($mmH_2O$) | **Variance** (%) |
|---|---|---|
| **Operator 1** | 16.58 | 0.124 |
| **Operator 2** | 16.66 | 0.416 |

| | Init Res | | Init res |
|---|---|---|---|
| | 16.8 | | 16.2 |
| | 16.6 | | 16.9 |
| | 16.3 | | 15.8 |
| | 17.2 | | 15.9 |
| | 16.2 | | 17.3 |
| | 16.5 | | 16.8 |
| | 16.7 | | 16.6 |
| | 16 | | 17.9 |
| | 16.6 | | 16.9 |
| | 16.9 | | 16.3 |
| **SD** | **0.352** | **SD of MEAN** | **0.645** |
| **MEAN** | 16.580 | 0.057 | 16.660 |
| RES MIN | **16** | | **15.8** |
| RES MAX | **17.2** | | **17.9** |

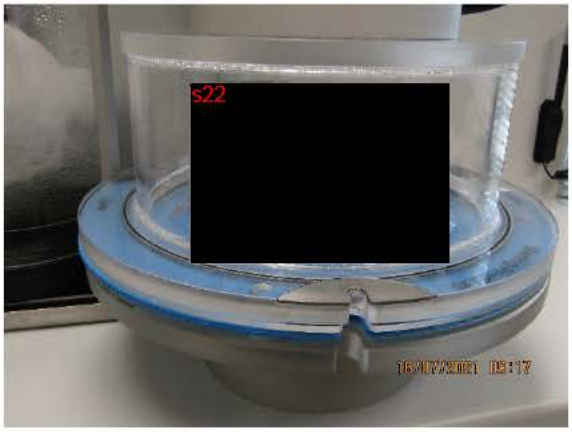
| A | B | C | D | E | F | G |
|---|---|---|---|---|---|---|
| Anova: Single Factor | | | | | | |
| | | | | | | |
| SUMMARY | | | | | | |
| *Groups* | *Count* | *Sum* | *Average* | *Variance* | | |
| Column 1 | 10 | 165.8 | 16.58 | 0.124 | | |
| Column 2 | 10 | 166.6 | 16.66 | 0.416 | | |
| | | | | | | |
| | | | | | | |
| ANOVA | | | | | | |
| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
| Between Groups | 0.032 | 1 | 0.032 | 0.118519 | 0.734636 | 4.413873 |
| Within Groups | 4.86 | 18 | 0.27 | | | |
| | | | | | | |
| Total | 4.892 | 19 | | | | |

Finding filter specimens with low variability is quite difficult; however, it is of paramount importance when evaluating reproducibility between operators. Most specimens possess an intrinsic variability within the batch making it very hard to discern between random error of measurement, system bias or operator error. The testing results in the above examples demonstrate (in this instance) acceptable repeatability and reproducibility between the two operators.

**Repeatability**

The three main sources of measurement uncertainty (UoM) associated with testing a batch of samples are:

- The characteristic (accuracy) of measuring instruments. Uncertainty is evaluated using data provided by calibration certificates.
- Variability due to repeatability and reproducibility of the test method. Factors affecting this variability depend on the method. In most cases, it is not possible to assess the effect of an individual factor on uncertainty and it is common to use the Type A evaluation of standard uncertainty from the statistical distribution of the values obtained from a series of measurements.
- Variability due to the tested product and its inhomogeneity. The repeatability of the test item is not dependent on the laboratory but on the type of product and its production process.




| Tested by CLANWA 16/07/2021. 2106002509-R3 | | |
|---|---|---|
| | PEN (%) | RES mmH2O |
| | 0.099 | 19.9 |
| | 0.060 | 18.7 |
| | 0.048 | 19.3 |
| | 0.052 | 19.0 |
| | 0.042 | 19.7 |
| | 0.079 | 19.3 |
| | 0.057 | 19.2 |
| | 0.080 | 19.8 |
| | 0.057 | 19.2 |
| | 0.046 | 20.2 |
| MEAN | 0.062 | 19.43 |
| **SD** | **0.018** | **0.457** |
| VARIANCE | 0.000334 | 0.209 |

To calculate repeatability, ten very efficient (99.9 %) specimens were tested on 16/07/2021 by operator s22 using a Sterling test fixture with a **KN95** compression insert. (D21-2852004). The operator started the instrument and completed all required performance checks and calibrations prior to testing (D21-2851921).

The above table shows after taking into consideration the three main sources of UoM the sample batch presented a penetration repeatability of 0.018 % with an initial resistance repeatability of 0.457 $mmH_2O$. The masks tested were from 99.90 to 99.96 % PFE, which is a range of 0.06 %.

In another example, operator s22 on 27Jan21 tested ten FFP3 specimens using the Sterling test fixture with this time a **N95** compression insert. The table below shows that the penetration repeatability within the sample batch was 0.034 %. The masks tested were from 99.89 to 99.93 % PFE, which is a range of 0.04%. [D21-3210143]

| Tested by CLANW 27JAN21 - 2011004481 | | |
|---|---|---|
| | PEN % | PFE |
| 1 | 0.081 | 99.92 |
| 2 | 0.111 | 99.89 |
| 3 | 0.106 | 99.89 |
| 4 | 0.105 | 99.89 |
| 5 | 0.189 | 99.81 |
| 6 | 0.077 | 99.92 |
| 7 | 0.088 | 99.91 |
| 8 | 0.091 | 99.91 |
| 9 | 0.094 | 99.91 |
| 10 | 0.067 | 99.93 |
| | | |
| **MEAN** | **0.101** | 99.899 |
| **SD** | **0.034** | 0.034 |
| **Variance** | **0.001** | 0.001 |


Because there are no such thing a "filter" reference standard with a known or certified value, it is difficult to assign or quantify the exact causes or sources of variability when a mask is being tested.