

Acceptance Check Post-calibration

ATI 100Xs Automated Filter Tester

DUT: LIMS 33211

Analytical balance 33203

Green line media lot #511576

NaCl solutions batch Nos 20210525/03 & 20201215/05

Masks LIMS 2106002509

Date: 3 August 2021

Time: 9:25 – 15:25

Location: FD 51

Checked by: S22

RESULT: Fit-for-purpose

Reference documents

The ALLICAT Flow meter certificate of calibration No: 352330 was scanned and filed in TRIM [D21-2921361](#).

The ATI 100Xs service documentation No: [210802] was filed in TRIM [D21-2927841](#).

The ATI 100Xs flow meter calibration documentation No: [352330] was filed in TRIM [D21-2921361](#).

Pressure sensor boards calibration reports in TRIM [D21-2931357](#)

Post calibration check raw data [D21-2925032](#)

ATI 100Xs Pre-Post Calibration PFE Results [D21-2925055](#)

ATI 100Xs Pre & Post Calibration Averaging Test Data [D21-2925102](#)

Note for File – ATI 100Xs Remote Calibration _ 3AUG21 [D21-2921476](#)

Purpose

The aim of this post calibration/service acceptance check was to confirm and document that the instrument specifications had not significantly deviated from last calibration and that the calibration carried out on 3rd August 2021 met TGA requirements.

Methodology

Various parameters of the ATI 100Xs instrument were recorded before re-calibration/service in addition to testing five very consistent masks to establish a “benchmark” for post calibration checking purposes. Post calibration checks involved testing five similar masks from the same batch and comparing test results as well as analysing post calibration test data. The flow meter and three pressure sensor boards calibration reports were reviewed to ensure results were within tolerance.

Pre calibration instrument verification

Prior to the remote onsite calibration/service involving replacing photometer, flowmeter and circuit boards as well as firmware upgrades, instrument performance was confirmed after 1-hour warm-up by WC conducting a gravimetric test to establish the aerosol concentration (18.4 ug/l). The LSC and pencil calibrations were carried out before verifying instrument performance using green line media [D21-2921504](#). See below for results plotted on the acceptance charts.

Prior to the onsite calibration, five 99.9% PFE masks (LIMS 2106002509) with very low variability were tested as the “control”. For relativity purposes masks were tested for 5 minutes (300 seconds) each. Data plotted every second does not conclusively indicate masks had reached maximum penetration. Masks with better than a 99% efficiency typically peak way after 5 minutes. After 300 seconds the average penetration and resistance for masks 1-5 was 0.04% and 20.20 mmH₂O respectively. The five masks PFE ranged from 99.96 to 99.97% and resistance 19.47 to 20.73 mmH₂O.

Post calibration verification

On completion of the remote calibration the LSC and pencil calibrations were carried out and the instrument's performance verified using green line media [D21-2921506](#). It is apparent from the results plotted on the green line media acceptance charts (see below) that penetration/resistance results very closely conform to the “red” average curve lines for all three tests.

Gravimetric testing was not performed because this had been carried out 30 minutes prior during the remote calibration process and the instrument had not been turned off.

It is noted that the aerosol concentration had dropped from 18.4 ug/l from the early morning to 17.4 ug/l later in the afternoon. This is mostly a result of the 0.9% replenishment pump topping up the salt generator however the level in the generator was within 1mm from start of day. ATI engineers have stated that concentration can vary by about 5% over the course of a day.

Aerosol concentration does not significantly effect a mask's penetration efficiency with the exception that higher or lower aerosol concentration influences when a mask will reach peak penetration. That is, if a mask reaches peak penetration when loaded with 8 mg of salt in five minutes; a weaker aerosol concentration will mean the mask takes longer to be loaded with the 8 mg therefore peak penetration will occur later in the test.

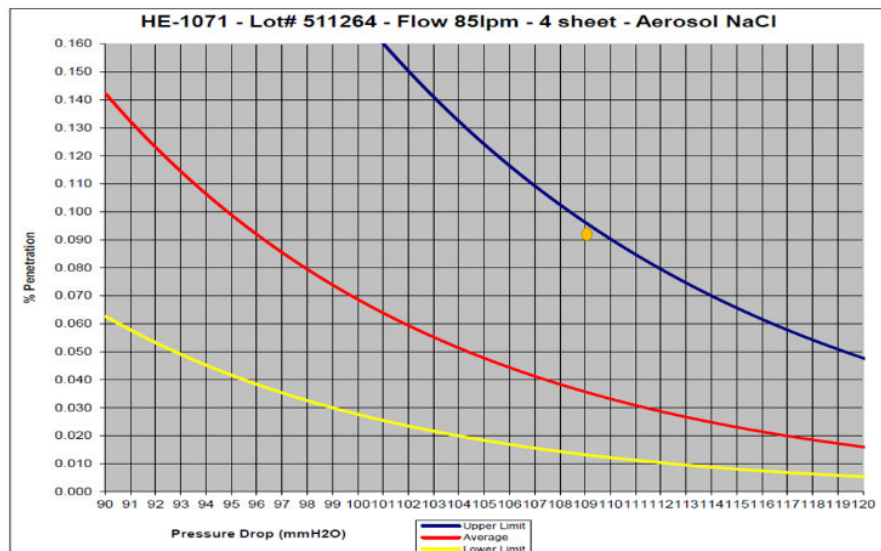
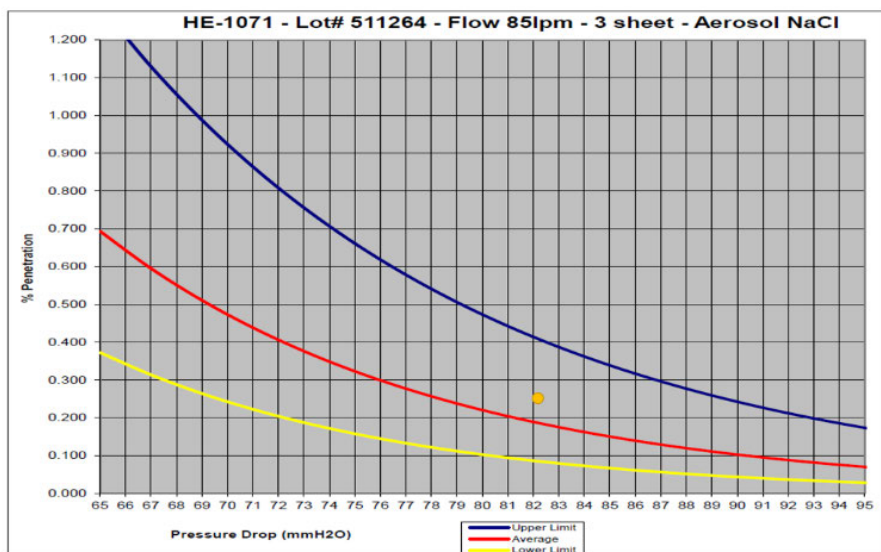
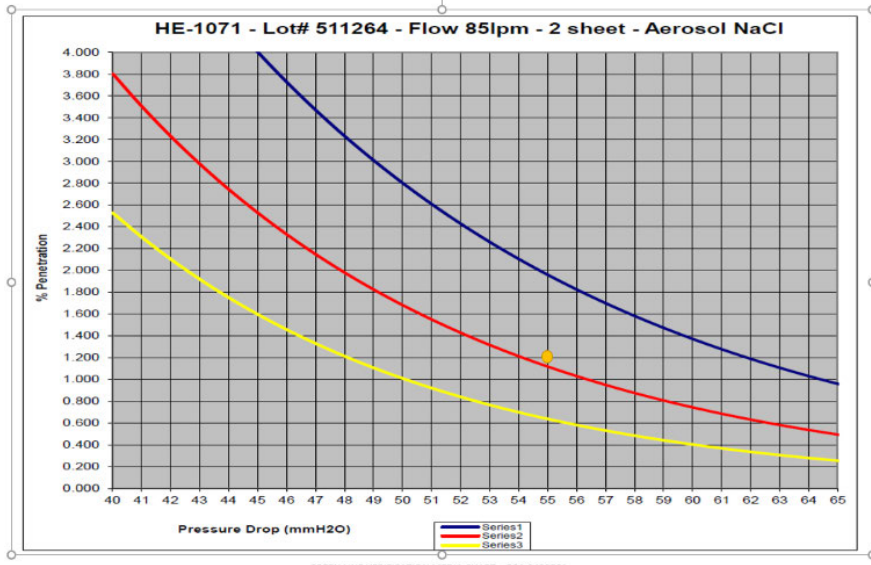
The same testing methodology for the pre-calibration verification was carried out for post cal checking. After 300 seconds the average penetration and resistance for masks 6-10 resulted in an average penetration and resistance of 0.01% and 20.86 mmH2O respectively. The five mask's PFE ranged from 99.97 to 99.99% and resistance 20.01 to 21.40 mmH2O.

	Pre-cal masks 1-5	Post cal masks 6-10
Pen Ave	0.04%	0.01%
Res Ave	20.20 mmH2O	20.86 mmH2O
Pen Range	99.96 - 99.97%	99.97 - 99.99%
Res Range	19.47 - 20.73 mmH2O	20.01 - 21.10 mmH2O

Instrument pressure differential accuracy ± 0.625 mmH2O, (e.g. 20 ± 0.625 mmH2O)

Instrument photometer aerosol detection accuracy $\pm 1\%$ of penetration reading. (e.g. $0.03\% \pm 0.00003$) or $(10\% \pm 0.1)$

Average initial penetrations for masks 6-10 (taken after the 12-second mark) indicate about a 0.03% lower value thereby ruling out any significant influence the reduced concentration may have had during each five-minute test. Notwithstanding, the difference between the pre and post mask tests of 0.03% is deemed insignificant for TGA screening purposes and the instrument is assessed as fit-for purpose.



Post-cal verification [D21-2921506](#)

