

Australian Government

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Department of Health Therapeutic Goods Administration

Note for file

Date and time	3/8/21
Type of event (e.g. meeting/ telephone conversation)	Maintenance Activity
Торіс	ATI 100Xs PFE instrument onsite calibration/service via remote hook-up
Participants	^{\$22} & ^{\$22} under guidance of ATI USA engineer

Key points	ATI 100Xs PFE instrument was programmed for service / re-calibration 22 July 21, however delayed by ATI. Instrument offline since 26 July 21 refer note to file <u>D21-2893174</u> . Instrument was serviced and re-calibrated in-house under direction of ATI engineer 3 Aug 21, and back online 5 Aug 21.
	Service report filed in TRIM <u>D21-2927841</u> .
Decision	ATI 100Xs LIMS 33211 successfully serviced and passed both calibration and performance verification checks before being deemed suitable to resume PFE testing.
	Note for File - Post service/calibration acceptance check <u>D21-2925594</u>
Author details	Signed: <mark>\$22</mark>

On 3 August 2021, the PFE instrument ATI 100Xs LIMS 3322 underwent onsite annual service. The light scattering photometer, ALICAT flow meter and three circuit boards were replaced with items provided some weeks earlier by ATI [D21-2921411].

(assisted by ^{\$22} and) removed the old components and installed the various new items under the watchful guise and advice from ATI engineer using video hook-up and handheld video camera.

The process started at 11am and was completed at 3:15 pm.

The following servicing steps were completed in order:

- The ATI engineer checked the instrument outside condition, exhaust filters and internal areas via remote camera video. Checks included looking for salt water leaks and pulling various cables to ensure they remained secure. Normally the instrument o-rings, seals, hoses and filters would be replaced at the same time (est. 4 hours), however WC had already performed this maintenance activity 21 April 2021 [D21-2564501]. After a comprehensive inspection the instrument was powered on.
- The instrument system variables data file was transmitted via laptop PUTTY software on the instrument laptop and transferred to USB. The file was immediately emailed to ATI as an "as found" snapshot of the instrument settings [D21-2921400].

- 3. A gravimetric calibration was performed to establish the aerosol concentration.
- 4. The LSC and penetration calibrations were then performed.
- 5. Instrument performance was verified by performing (twice) the 4,3,& 2 greenline media tests. The ATI engineer was shown close-ups of the instrument display so that he could document results.
- 6. ATI engineer emailed the updated software (.hex) files. Note: **S22** forwarded these emails to **S22** personal bigpond email so he could transfer them from personal laptop to a USB for downloading onto the ATI 100Xs connected laptop. This workaround was required because files cannot be removed from Health Dept. networked computers.
- 7. The instrument main control board was reflashed using the MPLAB PICKit 4 debugger with the latest .hex version.
- 8. The LSC photometer control board did not need firmware updating as ³²² had done this earlier in the new year.
- 9. The miscellaneous control board was firmware updated.
- 10. The differential pressure sensor board was replaced
- 11. The two pressure sensor boards were replaced.
- 12. The light scattering photometer was replaced.
- 13. The ALICAT flow meter was replaced. Note: The instrument would not boot-up due to ATI not having programmed the ALICAT. About 20 minutes was spent trying to reprogram the flow meter.
- 14. On completion of the calibrations and installation of new components a gravimetric, LSC, Pencal and (2 x 4,3,2) green line tests were performed.
- 15. The instrument system variables file was downloaded to laptop and immediately emailed to ATI [D21-2921385].

After reviewing the information the ATI engineer confirmed the instrument was within specification and stated he would send the instrument calibration documentation to TGA in the next few days as well as some instructions for returning the removed components. The remote calibration ceased at 15:15 (1am US time).

Notes:

 The newly inserted ALICAT flowmeter certificate of calibration [D21-2921361] is not ISO 17025 endorsed. The ATI engineer said that if this was required in future the flow meter would have to be sent to ALICAT who would send to a 3rd party. Flowtech Scientific will advise TGA on the way forward in the coming month. They are also developing a maintenance/recalibration program so that TGA will not have to do the calibrations themselves.