

Concent.	Measurement	M/D	Interpol.	Concent.	Measurement	M/D	Interpo
0 %	2.106 OD/mn		0 %	0 %	2.077 OD/mn		-2 %
35 %	1.660 OD/mn		34 %	35 %	1.577 OD/mn		36 %
69 %	1.210 OD/mn		70 %	69 %	1.104 OD/mn		72 %
104 %	0.756 OD/mn		105 %	104 %	0.641 OD/mn		107 %
139 %	0.341 OD/mn		138 %	139 %	0.283 OD/mn		134 %

This is two calibration curves for ATIII The left is Stago Max and the right is Maxine.

These are from July 2019.

Note:

The r<sup>2</sup> are 1.000 and 0.998 respectively Stago Max OD range 2.106 to 0.341 Stago Maxine OD range 2.077 to 0.283

The predicted calibration levels (Concent) and the calculated levels (Interpol) are quite close.

These appear to be good calibration curves. Max is slightly better than Maxine



This is two calibration curves for ATIII The left is Stago Max and the right is Maxine.

These are from Nov 2019 on a new batch of ATIII

- The r<sup>2</sup> are 0.999 and 0.985 respectively
- Stago Max OD range 1.766 to 0.099
- Stago Maxine OD range 2.024 to 0.216

The predicted calibration levels (Concent) and the calculated levels (Interpol) are quite close on Max.

The predicted calibration levels (Concent) and the calculated levels (Interpol) are not close on Maxine.

The calibration "worked" on Max but then didn't on Maxine. This is highly unusual.

Further review shows a significant difference in OD ranges between Max and Maxine today.

There is also a significant change in OD's from the previous batch – this is unusual.



Concent.	Measurement	M/D	Interpol.	Concent.	Measurement	M/D	Interpol.
0%	2.063 OD/mn		-1 %	0 %	2.137 OD/mn		-2 %
34 %	1.603 OD/mn		35 %	34 %	1.628 OD/mn		35 %
67 %	1.182 OD/mn		68 %	67 %	1.168 OD/mn		69 %
101 %	0.745 OD/mn		102 %	101 %	0.732 OD/mn		101 %
135 %	0.336 OD/mn		134 %	135 %	0.289 OD/mn		133 %

This is two calibration curves for ATIII The left is Stago Max and the right is Maxine. These are from Nov 2019 from new batch of ATIII A new reagent set has been made up.

- The r<sup>2</sup> are 1.000 and 1.000 respectively
- Stago Max OD range 2.063 to 0.336
- Stago Maxine OD range 2.137 to 0.289

The predicted calibration levels (Concent) and the calculated levels (Interpol) are quite close on both analysers. The 0% OD's have increased from 1.766 and 2.024 respectively. The 135% OD's have increased from 0.099 and 0.216 respectively.

## The reagent was only reconstituted for 30 minutes – not 1 hr

- 1) This coincided with a lot number change dual changes
- 2) Always compare previous calibration times/OD's for changes.
- 3) Always be familiar with reconstitution requirements
- 4) The difference in OD's between Max and Maxine (slide 2) reflected the 2.5 hr delay in calibration between analysers and was a hint to what was going on The reagent was reconstituting during the calibration process.
- 5) New vials needed to be made as reagent had been removed from the vials during calibration. If the vials had just been remixed then the calibrations would be wrong