

## Introduction

Lithium is globally used to treat and prevent manic or depressive episodes in bipolar disorder. The drug has a small therapeutic window and is in potentiation a toxic substance. Since the difference between therapeutic window and a toxic concentration is small, close monitoring of the lithium concentration is necessary.

The Medimate Minilab<sup>®</sup> is intended to assess the lithium concentration in serum as well as fingerstick whole blood. The system is suitable for professional and self test use.

The Medimate Minilab<sup>®</sup> combines a measurement apparatus called the Multireader and a disposable cartridge called the lab-chip. A measurement is performed after applying the sample at the lab-chip and inserting the lab-chip into the Multireader. The device detects the lab-chip and performs the measurement. After 9 minutes the Multireader displays the measured lithium concentration, see Figure 1.

The objective of the study was to validate and compare the Medimate Minilab<sup>®</sup> with the Roche Modular Analytics<sup>®</sup> P800 module.

The results summarized here are published in detail by Wolthuis et. al. which report is published by Medimate.<sup>1</sup>



Figure 1: Photo of Medimate Minilab measurement steps. 1. Perform fingerstick, 2. Apply blood droplet, 3. Insert Cartridge, 4. Readout result

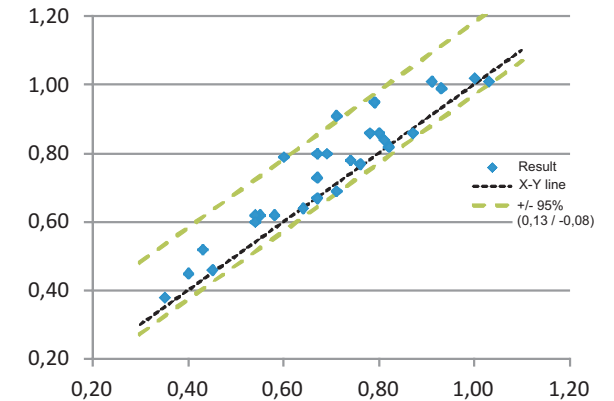


Figure 2: Lithium (mmol/l) method comparison results, X-Axis: Modular (plasma), Y-Axis: Minilab (fingerstick).

Person	Offset (mmol/l)	BIN boundary mmol/l				
		< 0.05	< 0.10	< 0.15	< 0.2	All
Specialist	0.058	61%	89%	100%	100%	100%

Table 1: Method comparison BIN results between Minilab and Modular.

## Acceptance criteria

Define if both methods are clinically equivalent and identify any offset between both methods

## Method

### Method comparison

The method comparison test includes 28 patients on lithium therapy. All experiments are performed at a standard blood collection point by trained personnel. To evaluate the lithium level on the Modular a venous puncture is taken according to standard protocol. At the same time a fingerstick is performed to measure the lithium on the Minilab.

### Linearity

The linearity is evaluated of the Infinity method (Thermo Fisher Scientific, New York, United States of America) applied on the P800 module of the Roche Modular Analytics (Roche Diagnostics GmbH, Mannheim, Germany) and the Medimate Minilab. To test the bias of each measurement extra measurements are performed on the reference method, Flame Photometer I1943 (Department of Clinical Pharmacy, Medical Spectrum Twente, Enschede). The test is evaluated for serum as well as plasma (Modular) and venous whole blood (Minilab).

Training precautions from the manufacturers are taken into account when working with the different methods.

## Results

### Method comparison

In Figure 2 the method comparison results are shown. Linearity analysis showed  $y = 0.952x + 0.091$  with  $R^2$  is 0.89. The  $R^2$  is lower than 0.95 indicating a too small measurement range, this is due to little availability of patients with large range differences in lithium. The linearity test indicates that the range is not a problem.

An offset of 0.06 mmol/l is measured between both methods.

95% measurement boundaries are at 0.13 and -0.08 mmol/l. Indicating that the results are within the claimed performance by Medimate. BIN results are shown in Table 1. These are offset corrected.

### Linearity

The applicable sample types for both methods are verified versus the reference method, see Figure 3. The Minilab has a bias of 3% resp 5% where the Modular has a bias of -4% respectively -6%.

Both methods are linear for both sample types in the measurement range 0.30 to 4.5 mmol/l. Both bias differences indicates a 9% difference between the Minilab and the Modular.

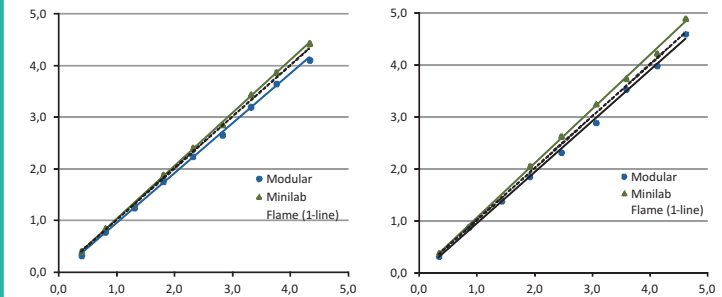


Figure 3: Lithium linearity results, X-Axis: Flame Photometer, Y-Axis: Lithium result on the Modular and on the Medimate Minilab. Left: serum vs serum. Right: plasma vs plasma (Modular) and venous whole blood (Minilab).

## Conclusions

The lithium results obtained with the Medimate Minilab can be interpreted in line with the results obtained by the Roche Modular Analytics.

Cumulative patient records can depict both routine lab as well as Medimate Minilab lithium results and a cumulative interpretation of the patient's lithium results can be made without distinguishing between both methods.

The measurement results indicate that the claimed performance of the Minilab is correct. No significant differences are found between the different sample types. The average difference between both methods is 6% to 9%.

1. Bram Reitsma, René Lont, Albert Wolthuis, Marloes Wielema, Jan Peter Yska, Mathijn Ungerer, Ellen Swart, Sybolt Okke de Vries, Validation (clinical use) and comparison of the first lithium analyser for Point-of-Care testing (Medimate Minilab) with the Infinity lithium analysis application on the Roche Modular Analytics P800 module. Date: March 27th, 2014. Internet published by Medimate BV

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