

# Evaluation of the QMS<sup>®</sup> Lamotrigine Immunoassay from Thermo Fisher Scientific on the Abbott ARCHITECT<sup>®</sup> c8000 Clinical Chemistry Analyzer by Comparison to HPLC

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## Introduction

Lamotrigine is a widely used anticonvulsant drug for the treatment of epilepsy and bipolar disorders [1]. Due to its large inter-patient variability and potential interactions with co-administered drugs, a routine assessment of blood levels continues to be recommended [2]. This approach has traditionally encompassed relatively elaborate chromatographic techniques. Recently, Thermo Fisher Scientific launched an immunoassay for use on clinical chemistry analyzers. The test is based on the turbidimetric quantification of the inhibition of microparticle-lamotrigine conjugate immunoagglutination by lamotrigine in the sample.

## Aim of the Study

To compare the analytical performance of the Thermo Fisher Scientific QMS<sup>®</sup> Lamotrigine Immunoassay on the Abbott ARCHITECT<sup>®</sup> c8000 clinical chemistry analyzer with an established high-performance liquid chromatography-ultra violet (HPLC-UV) procedure and develop an instrument-specific protocol that meets the CE marking requirements.

## Materials and Methods

The QMS<sup>®</sup> Lamotrigine Immunoassay was evaluated on the Abbott ARCHITECT<sup>®</sup> c8000 instrument according to the CLSI/NCCLS protocols for precision, linearity and method comparison. Precision was assessed with quality control material supplied by Thermo Fisher Scientific. Method comparison included serum samples that were previously determined using a commercially available HPLC-UV test kit [3]. Subsequent statistical analysis was performed according to Deming and Pearson.

## Results [4]

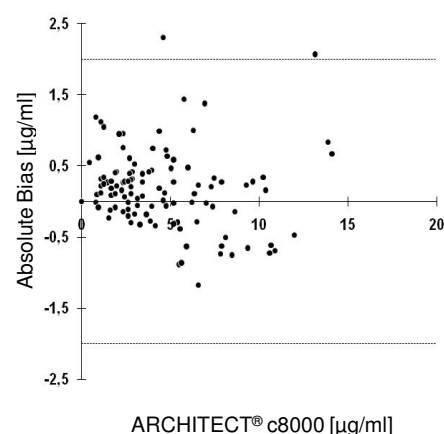
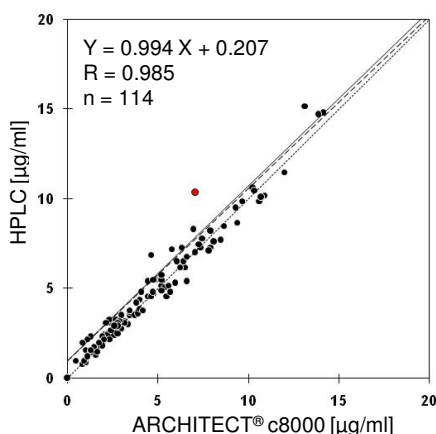
### Precision:

Controls:	L1	L2	L3
Expected value: [µg/ml]	1.80	13.5	22.5
Mean value: [µg/ml]	1.84	13.6	22.7
Within-Run SD: [µg/ml]	0.09	0.41	0.89
Within-Run CV: [%]	4.91	3.04	3.90
Total SD: [µg/ml]	0.11	0.68	1.10
Total CV: [%]	5.95	5.02	4.83

**Linearity:**  $Y = 0.98 X - 0.014$ ;  $R = 0.9995$

**Limit of Detection:** [µg/ml] 0.04

### Method Comparison:



## Conclusion

The data demonstrate that the Thermo Fisher Scientific QMS<sup>®</sup> Lamotrigine Immunoassay is a sensitive and precise method for measuring lamotrigine in serum on the Abbott ARCHITECT<sup>®</sup> c8000 clinical chemistry analyzer with excellent correlation to HPLC-UV, thus providing a time-efficient alternative to chromatography.

## References

- [1] Reimers, A. Trends and changes in the clinical use of lamotrigine. *Pharmacoepidemiol. Drug. Saf.* 2009, 18(2):132-9
- [2] Musenga, A. et al. Antipsychotic and antiepileptic drugs in bipolar disorder: the importance of therapeutic drug monitoring. *Curr. Med. Chem.* 2009, 16: 1463-1481
- [3] Chromsystems application bulletin Antiepileptic Drugs
- [4] Thermo Fisher Scientific method sheet QMS<sup>®</sup> Lamotrigine