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Top science down under
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Waters Corporation Lunchtime Industry Workshop

Tuesday, 18 September, 13:00 - 13:55, room B3

TRANSITIONING RESEARCH BASED TDM ASSAYS INTO A HIGH-THROUGH-PUT CLINICAL SERVICE

BC McWhinney
Analytical Chemistry Unit, Chemical Pathology, Pathology Queensland, Herston Hospitals Complex, Brisbane, Qld

Historically, mass spectrometry had been of limited use in clinical laboratories; however, the combination of electron spray ionisation (ESI) methods with tandem mass spectrometry has opened up this technology to the clinical laboratory arena. Tandem mass spectrometry found its way into clinical laboratories in the early 1990s, with the analysis of acylcarnitines and amino acids from neonatal blood spots. During the past decade, liquid chromatography tandem mass spectrometry (LC-MS/MS) has played an increasingly important role in clinical analysis.

Over this time LC-MS/MS has had to overcome a number of challenges and there are still others to overcome. It is now routinely used in laboratories with applications for therapeutic drug monitoring (TDM), endocrinology, toxicology and pharmacology. The majority of LC-MS/MS methods used in the clinical lab can be placed under the IVD test category, since they were "home brewed." The labs implementing this technology are expected to develop the test and undertake a thorough validation before putting these tests into routine use. The transition of research-based assays into routine clinical service can be a very torturous path with associated challenges to overcome. This presentation will show several examples of this process and the importance of developing and validating assays that make the transition as smooth as possible.

APPROACH FOR ANALYSING INFLIXIMAB IN SERUM BY LC-MS/MS IN TDM

Dominic Foley
Senior Scientist, Clinical Scientific Operations, Waters Corporation, Wilmslow, UK

This talk will take you through the workflow of a kit-based approach to quantifying the monoclonal antibody infliximab in TDM using LC-MS/MS technology.

MAbs represent a growing class of therapeutics due to their target specificity, lower toxicity and higher potency. However, use of MAbs can be expensive and their long-term use can result in a loss of response, reducing efficacy. Through the use of a standardized workflow using a kit-based approach, we will show that infliximab serum concentrations can be reproducibly measured, providing a more suitable alternative to enzymatic linked detection.