EVALUATION OF STANDARDISATION CAPABILITY OF CURRENT CARDIAC TROPONIN I (CTNI) ASSAYS BY A CORRELATION STUDY: RESULTS OF AN IFCC PILOT PROJECT

JR Tate,1 DM Bunk,2 RH Christenson,3 JH Barth,4 A Katrukha,5 JE Noble,6 MP Panteghini,7 H Schimmel,8 L Wang,2 for the IFCC Working Group on Standardization of Cardiac Troponin I (WG-TNI).

1Pathology Queensland, Royal Brisbane and Women’s Hospital, Herston, Qld 4029 Australia; 2Material Measurement Laboratory, National Institute of Standards and Technology, Gaithersburg, MD, USA; 3Department of Pathology, University of Maryland School of Medicine, Baltimore, MD, USA; 4Clinical Biochemistry, Leeds Teaching Hospitals NHS Trust Leeds General Infirmary, Leeds, UK; 5HyTest Ltd, Turku, Finland; 6Analytical Science Group, National Physical Laboratory, Teddington, UK; 7Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy; 8European Commission, Joint Research Centre, Institute for Reference Materials and Measurements, Geel, Belgium

jill.tate@health.qld.gov.au

Introduction
The International Federation of Clinical Chemistry and Laboratory Medicine Working Group on the Standardization of Cardiac Troponin I performed a pilot study in collaboration with industry to investigate the feasibility of preparing a commutable cTnI reference material (RM). The study aimed to test whether serum pools prepared from patient sera could be used as an RM to standardise cTnI measurement.

Methods
cTnI-positive serum samples from 90 patients with suspected acute myocardial infarction were used to prepare seven pools in the range, 200–10,000 ng/L. All samples were assessed for method comparison by 16 cTnI commercial assays according to predefined testing protocols.

Results
Each assay was assessed against median cTnI concentrations measured by 16 cTnI assays using Passing-Bablok regression analysis of 79 patient samples with values above each assay’s declared detection limit. We observed a 10-fold difference in cTnI concentrations for lowest to highest measurement results. At 190 ng/L cTnI concentration, average variation of pools reduced from 49% (range, 43–55%) to 16% (range, 14–19%), at medium concentrations (814, 1634 and 1845 ng/L) from 35% (range, 34–36%) to 13% (range, 11–15%), and at high concentrations (4155 and 7517 ng/L) from 25% (range, 24–27%) to 7% (range 7.0–7.4%). For patient samples at low cTnI concentration, average variation reduced from 40% (range, 11–65%) to 22% (range, 11–38%), at medium concentration from 37% (range, 16–63%) to 20% (range, 7–58%), and at high concentration from 29% (range, 13–63%) to 14% (range, 7–42%). Overall, assays demonstrated negligible bias after recalibration; however, a few samples showed substantial positive and/or negative differences for individual cTnI assays.

Conclusion
cTnI values for pooled samples were equivalent within acceptable limits after straightforward assay realignment. The study indicates that pools are a viable alternative for providing large volumes of commutable sample for use as a surrogate matrixed RM for cTnI standardisation.