METROLOGICAL TRACEABILITY OF A NEW WATERS MASSTRAK™ VITAMIN D ASSAY

INTRODUCTION
Robust metrological traceability has been incorporated in to the design, development and manufacture of the Waters MassTrak™ Vitamin D kit*. The kit metrological traceability has been designed and developed to meet the requirements of ISO 17025:2003: In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control material. Traceability is further assured through participation in the Vitamin D Standardisation Certification Program (VDSCP). The robust metrological traceability of the MassTrak™ Vitamin D kit* as well as a comprehensive review of the kit performance characteristics will be presented.

INTENDED USE
The Waters MassTrak™ Vitamin D kit* is for the quantitative determination of 25-hydroxyvitamin D3, 25-hydroxyvitamin D2 in human plasma and serum using an automated liquid handling system and Waters ACQUITY UPLC® I-Class/Xevo® TQD IVD System. Results are to be used as an aid in the assessment of vitamin D sufficiency.

METROLOGICAL TRACEABILITY
• Metrological traceability of the MassTrak™ Vitamin D kit* to NIST SRM2972 has been established.
• Primary calibrators were prepared using certified reference materials containing 25-hydroxyvitamin D2 (25OHD2) and 25-hydroxyvitamin D3 (25OHD3).
• Interferences were determined using reference measurement procedures developed by Dr. Linda Thienpoint et al. which were validated using a JCTLM-listed isoctane dilution liquid chromatography mass spectrometry methodology (C8RMP4 and C8RMP3) demonstrating traceability to NIST SRM2972.
• All MassTrak™ Vitamin D kit calibrators and quality control lots are value assigned using the assigned primary calibrators.
• The concentration values assigned to the MassTrak™ Vitamin D kit calibrators and quality control lots are verified in a value confirmation process. The value confirmation of the calibrators involves the measurement of independently assigned quality control material.

VDSCP
• Waters enrolled in the CDC Vitamin D Standardisation Certification Program (VDSCP) for 25OHD in serum, which assesses bias and precision of assays relative to reference measurement procedures.
• The VDSCP consists of 10 blinded patient samples which assess bias and precision of assays relative to ISO 17511:2003: Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control material.
• Following CLSI EP05-A3, single site precision was determined using four serum panels (Panel A-0) and two MassTrak™ Vitamin D quality controls.

PRECISION
• Following CLSI EP05-A3. Single site precision was determined using four serum panels (Panel A-0) and two MassTrak™ Vitamin D quality controls.
• Precision performance for 25OHD2, 25OHD3 and Total 25OHD, total precision CVs ≤ 9.0% and repeatability within run CVs ≤ 8.1% for 4 patient pools and Quality Controls across the 20 days (n = 40).
• Precision was verified in a multi-site precision evaluation conducted at three sites providing a total imprecision of ≤ 6.8 %CV for 25OHD2 and 25OHD3 and total 25OHD.

SENSITIVITY
• Following CLSI EP17-A2, 25OHD3 limit of detection and limit of quantification were 2.7nmol/L and 7.3nmol/L respectively.

CARRYOVER
• The carryover of the assay was determined to be 0.87nmol/L for 25OHD2, 0.37nmol/L for 25OHD3 and 1.24nmol/L for Total 25OHD, which is significantly lower than the Limit of Quantification of the assay for the analytes.

LINEARITY
• Following CLSI EP6-A. The analytes 25OHD2 and 25OHD3 were demonstrated to be linear from 10nmol/L to 375nmol/L, within a range of ± 10% in this interval. Total 25OHD method was demonstrated to be linear from 20nmol/L to 750nmol/L, within ± 10% in that interval.

CONCLUSION
The MassTrak™ Vitamin D kit* calibrator materials are traceable to NIST SRM2972 via a documented unbroken chain of calibrations.

REFERENCES
4. A2, EP17

*MassTrak™ Vitamin D Kit is not available for sale in the United States

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