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### Title

Tumor Marker Multi Constituent Controls for use in Quality Assurance of assay performance: The importance of clinically relevant analyte levels and appropriate matrix composition

### Authors

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### Abstract

**Introduction:** Quality Assurance of Tumor Marker assays require access to control materials that closely resemble patient samples. Several Multi Constituent Tumor Marker Control kits are marketed for this purpose. The objective of this study was to compare six commercially available products in terms of analyte levels and control matrix.

**Materials and Methods:** The analyte levels for AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, Free PSA and Total PSA were determined for six Multi Constituent Tumor Marker Control kits: Fujirebio Diagnostics Tumor Marker Control (Gothenburg, Sweden), Liquichek™ (Bio-Rad Laboratories, Irvine, CA), Lyphocheck® (Bio-Rad), Liquid QC™ (CliniQA Corporation, San Marcos, CA), MAS® T-Marker (Microgenics Corporation, Fremont, CA) and Quality Control Sera (Randox Laboratories, Oceanside, CA). To evaluate matrix composition, the different control materials and normal serum samples were analyzed with a Serum Protein Electrophoresis (SPE) kit.

**Results:** All kits contained one control where the levels for each analyte corresponded to the normal range and at least one control with analyte levels in the pathological range. Clinically relevant percentages of Free PSA to Total PSA were only observed in the controls from Fujirebio and CliniQA, with 30% and 10% Free PSA respectively. The remaining control materials tested contained  $\geq 90\%$  Free PSA. The Fujirebio Diagnostics, Inc. and Lyphocheck controls showed similar pattern on SPE compared to normal serum samples, including bands in the albumin, alpha-, beta- and gammaglobulin regions. Alpha- and beta globulin bands were merged for the CliniQA control. The Liquichek, MAS and Randox controls showed a distinct albumin band only.

**Conclusions:** Clinically relevant analyte levels and appropriate sample matrix are the most important parameters for any quality control. The Fujirebio Diagnostics, Inc. and CliniQA controls showed a clinically relevant ratio of Free PSA to Total PSA, and were the identified as suitable for quality assurance of Total PSA assays. The controls with a matrix most similar to patient samples were Fujirebio Diagnostics and Lyphocheck.