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Clinical relevance of analyte levels for commercial Tumor Marker Multi Constituent Controls

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Abstract:

Background: Performance testing of laboratory methods requires access to control samples similar to patient samples, with analyte concentrations at medically relevant levels and stability over long periods. Several Multi Constituent Tumor Marker Control kits are available for this purpose. **Objective:** The objective of this study was to compare the performance of six commercially available Multi Constituent Tumor Marker Control kits with particular focus on clinically relevant analyte concentrations. **Material and Methods:** AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, FreePSA, PSA and the novel marker HE4 were determined for six Multi Constituent Tumor Marker Control kits: Bio-Rad Liquichek™ (REF 548X), Bio-Rad Lyphocheck® (REF 368X), CliniQA Liquid QC™ (REF 91302), MAS® T-marker (REF TUM-S1), Fujirebio Diagnostics TM Control (REF 108-20) and Randox Quality Control Sera (REF IA2633). Abbott Architect values according to instructions for use (IFU) were compared. Controls lacking assigned values for FreePSA and PSA were analysed according to IFU in Architect FreePSA and Total PSA assays (REF: AFP 7K67, CA15-3® 2K44, CA19-9™XR 2K91, CA125II 2K45, CEA 7K68, Ferritin 6C11, FreePSA 6C07, Total PSA 6C06). A comparison was made of control matrix and stability claims for open use according to information provided in IFU. **Results:** All six control kits contained at least one level of each marker at concentrations corresponding to healthy individuals (according to Architect IFU) and one elevated level. Exceptions were Liquichek and Lyphocheck lacking CA19-9 within normal range and Randox lacking CA19-9 and CEA within normal range. The novel ovarian cancer biomarker HE4 was only included in the Fujirebio control. Clinically relevant %FreePSA levels were only noticed in the Fujirebio and CliniQA controls, with approximately 30% and 10% FreePSA, respectively. The other controls had >90% FreePSA. All six controls had open use stability for ≥ 7 days at 2-8°C. The analyte limiting prolonged stability at 2-8°C was FreePSA. For extended open use stability, storage at $\leq -20^\circ\text{C}$ was recommended for Lyphocheck (≤ 30 days), Fujirebio (≤ 60 days) and Randox (≤ 28 days). Freezing and thawing was not recommended for Liquichek, MAS and CliniQA, however they had open use stability for ≤ 30 days at 2-8°C. According to IFU Lyphocheck, Fujirebio and Randox are lyophilized human serum based controls. The other three controls are provided in liquid form; Liquichek is non serum based, MAS is based on human serum and CliniQA on human plasma. Liquichek and Lyphocheck contain constituents of animal origin. **Conclusion:** Clinically relevant analyte levels and an appropriate sample matrix are the most important parameters for any quality control material. The only multi constituent tumor marker controls with clinically relevant %FreePSA levels were the Fujirebio and CliniQA controls. The other controls contained >90% FreePSA and would therefore be less suitable for quality control of Total PSA assays. Fujirebio Diagnostics TM control is currently the only control that offers the novel marker HE4. The open use stability was acceptable for laboratory praxis for all six tumor marker controls. **Reference:** Lilja H, Ulmert D, Vickers A. Prostate-specific antigen and prostate cancer: prediction, detection and monitoring. *Nature Reviews Cancer*

8, 268-278 (2008).

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