

Troponin I and CA 15-3 fingerprints on immunoassay platforms and the consequence for harmonization/ standardization



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Introduction

Harmonization and standardization of laboratory measurement techniques have a common goal: to obtain equivalence of measurement results to correctly interpret test results and give the correct medical advice independent of time and place of analysis. However, the majority of measurement techniques are still not harmonized or standardized. This is particularly challenging in the field of immunoassay since internationally recognized reference materials and/or measurement procedures are often missing as the measurand itself often is poorly defined.

Here, we assess the comparability of measurement results of different sources of the **breast cancer marker CA 15-3** (Figure 1) and the **cardiac marker Troponin I** (Figure 2) on common, commercially available immunoassay instrument platforms.

Results

CA 15-3:

- Sources 1 and 3 show similar measurement patterns on all instruments.
- Source 2 measures considerably lower on instruments 2, 4 and 5.
- No lot-to-lot variation for tested sources was observed.

Troponin I:

- Sources A and C have a similar measurement pattern on all tested instruments. However, source C shows lower differences between measurement results on tested instruments than source A.
- Sources B and D display unique measurement patterns, with particularly large differences between measurement results observed for source D.
- Differences in measurement results on the five tested instrument platforms were matrix-independent for the four evaluated Troponin I sources.

Conclusions

Each source of a given analyte can have a **unique fingerprint** when measurement results from various instrument platforms are compared. Therefore, **clearly defined measurands** are a prerequisite to make measurement results from immunoassays comparable across laboratories.

