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

Johannes Bauer[1], Piotr Chylenski[1], Leonila F. Hope[1], Jane A. Awuh[1]

[1] SERO AS, Department for Research and Development, Stasjonsveien 44, 1396 Billingstad, Norway

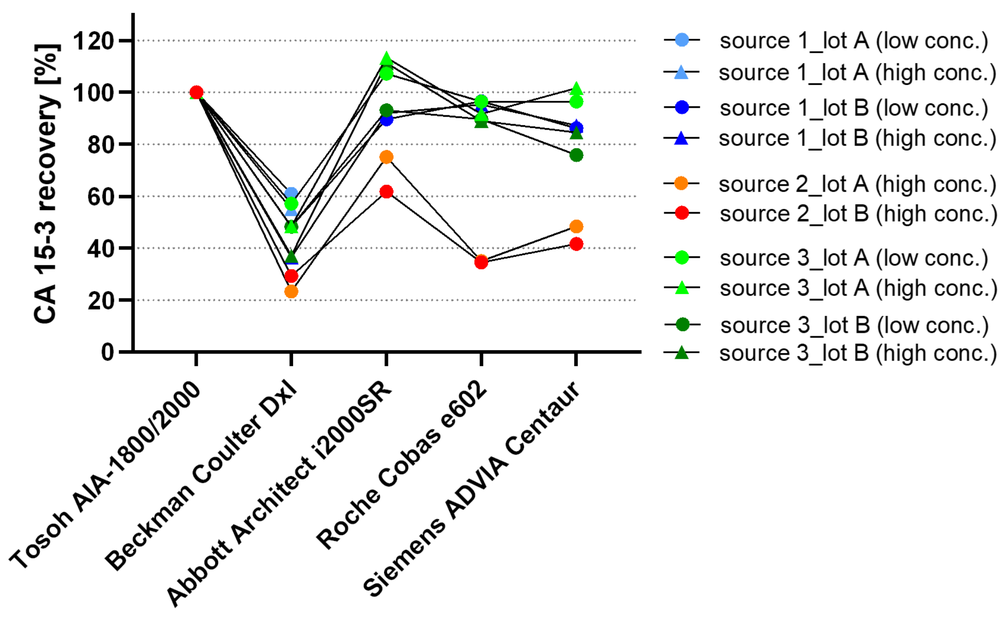
contact: FoU@sero.no

Introduction

Harmonization and standardization of laboratory measurement techniques aim for equivalent measurement results to correctly interpret test results and give the correct medical advice independent of time and place of analysis. However, harmonization of immunoassay measurement techniques is largely lacking since internationally recognized reference materials and measurement procedures are missing, also because the measurand itself is often poorly defined.

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

CA 15-3



Results

- Differences in measurement ratios were independent of CA 15-3 concentration
- CA 15-3 sources 1 and 3 showed similar measurement patterns on all tested platfoms
- CA 15-3 source generally measured lowest, particularly on Roche Cobas e602 and Siemens ADVIA Centaur with little CA 15-3 lot-to-lot variation

Figure 1
Measurement ratios of three different CA 15-3 sources in same matrix on five common commercial immunoassay instrument platforms. Two lots of each CA 15-3 source were tested at two concentrations (low conc. ≈ 30 kU/L, high conc. ≈ 60 kU/L). Results were normalized against instrument 1 and given in % recovery towards instrument 1. All data points are averages from duplicate measurements.

Troponin I

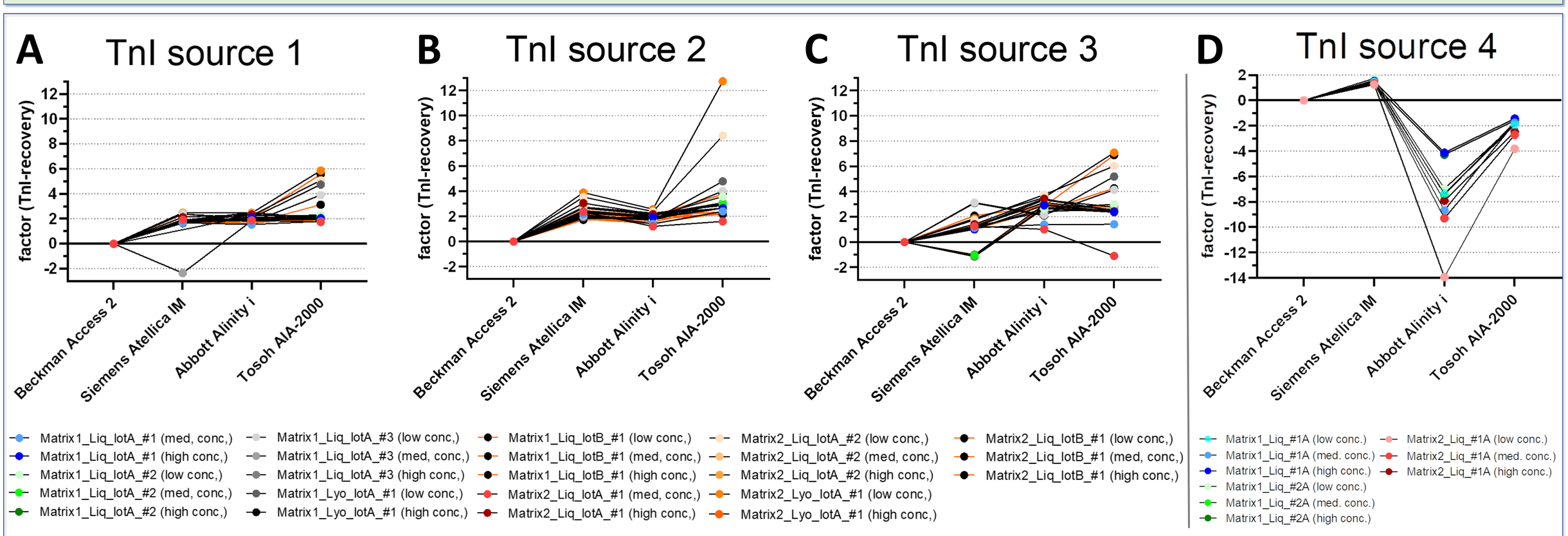


Figure 2
Measurement ratios of four different Troponin I sources in two matrices on four commercial immunoassay instrument platforms. 23 different lots were produced for TnI-sources 1-3, 9 lots were produced for source 4. All data points are averages from duplicate measurements. Results were normalized against instrument 1 and presented as factors towards instrument 1 (positive factor = x times higher, negative factor = x times lower). Liq: liquid batches, Lyo: lyophilized batches; Used TnI-lots for a given source are indicated as lotA or lotB. #1,2,3: running number for batches prepared in same matrix, same form, with same TnI-lot, and same concentration range (low conc.: 5-50 ng/L, med. conc: 70-520 ng/L, high conc.: 900-13600 ng/L).

Results

- Differences in measurement ratios were independent of both TnI concentration and matrix
- TnI sources varied in their measurement ratios between instruments
- TnI sources showed different degrees of measurement variation on a given platform with little TnI lot-to-lot variation

Conclusions

Each analyte source can have **a unique fingerprint** when measurement results from various instrument platforms are compared. This unique fingerprint **comprises both measurement ratios across platforms and the degree of variation on a given platform**. Thus, **clearly defined measurands** are required to make measurement results comparable across laboratories.