Measuring range of the MIRAM® GAGome Kit in general-population urine

Retrospective classification of published cohort concentrations against the measuring intervals of FRUOU-CS and its predecessor kit

SUMMARY The MIRAM® GAGome Kit for quantification of urine CS disaccharides (FRUOU-CS) has validated analytical measuring intervals (AMIs) of 1–25 µg/mL for 0S CS, 1–10 µg/mL for 4S CS and 0.7–4 µg/mL for 6S CS. A published population-cohort study [1] used its predecessor kit (IVDUV1), which had wider upper limits, but did not quantify 6S CS below a concentration of 1 µg/mL. Classifying the study's concentrations against the AMIs of both kits shows that no more than 0.8% of values for any analyte would have exceeded the FRUOU-CS upper limits, and that more 6S CS values fall within the FRUOU-CS AMI than within the previous kit's (84.8% vs 64.4%). For 0S CS and 4S CS the lower limit is 1 µg/mL in both kits, below which 57.1% and 28.2% of values fall respectively.

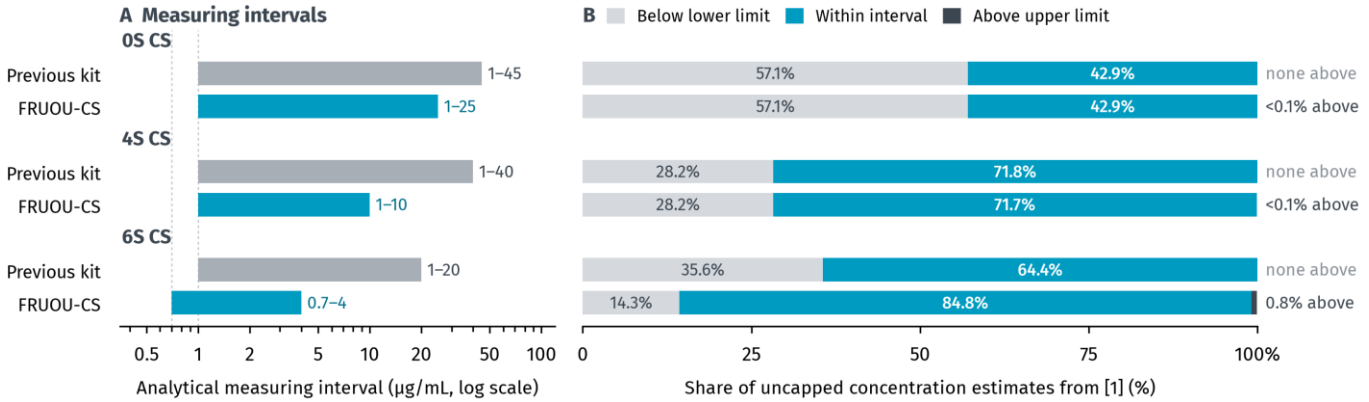


Figure 1. (A) AMIs of the predecessor kit and FRUOU-CS (log scale). (B) Concentration estimates from [1] classified as below, within or above each AMI. All values were measured with the predecessor kit; the classification against FRUOU-CS is retrospective, not a new measurement.

BACKGROUND AND APPROACH

A recently published population-cohort study [1] measured urinary 0S CS, 4S CS and 6S CS by UHPLC-MS/MS in 24-hour urine samples from 5,436 adults. It used the predecessor of FRUOU-CS (product no. IVDUV1), which is based on the same analytical method but had higher upper limits for all three analytes and a higher low-end limit for 6S CS of 1.0 µg/mL rather than 0.7 (Figure 1A). This note examines whether the FRUOU-CS AMIs would have introduced meaningful measuring-range limitations in that study. In the published analysis, results outside the AMI were set to the nearest limit. Here, the original concentration values, before that substitution, were classified against the AMIs of both kits (Figure 1B).

RESULTS

Upper limits. The FRUOU-CS upper limits are lower than those of the predecessor kit: 25 vs 45 µg/mL for 0S CS, 10 vs 40 µg/mL for 4S CS and 4 vs 20 µg/mL for 6S CS. Even so, only about 0.8% of 6S CS values and fewer than 0.1% of 0S CS and 4S CS values would have exceeded them. No values exceeded the upper limits of the predecessor kit.

Lower end for 6S CS. The FRUOU-CS lower limit is 0.7 µg/mL, against 1.0 µg/mL for the predecessor kit. Concentrations of 0.7–1.0 µg/mL were detectable but not validated for quantification with the previous kit and fall within the validated range of FRUOU-CS [2]. The share of 6S CS values within the AMI rose from 64.4% to 84.8%; 14.3% remained below the FRUOU-CS lower limit.

Lower end for 0S CS and 4S CS. Both kits have a lower limit of 1.0 µg/mL, so the shares below it are the same: 57.1% for 0S CS and 28.2% for 4S CS. Within the AMI were 42.9% of 0S CS values and 71.8% (previous kit) vs 71.7% (FRUOU-CS) of 4S CS values. This is an existing feature of the measuring range at these concentrations, not a new limitation of FRUOU-CS.

INTERPRETATION AND LIMITATIONS

The suitability of an AMI is not determined by its width alone, but also by how well it aligns with the concentrations in the intended samples. In this application, the FRUOU-CS upper limits would have added very few out-of-range values, while its 0.7 µg/mL limit for 6S CS improved validated coverage at the low end. Researchers working with comparable samples should expect many 0S CS and some 4S CS values below the AMI and plan their statistical handling in advance.

The comparison is retrospective and uses estimates obtained with the predecessor kit rather than new measurements with FRUOU-CS. It therefore shows how the AMIs align with these data, not analytical agreement between the kits or whether the study's conclusions would have been the same. The samples come from one European cohort and one sample type. The case-cohort design includes participants later diagnosed with cancer, so the shares are unweighted and are not population prevalence estimates; they should not be generalised to other sample types without supporting data.

REFERENCES

[1] Gatto F, Davies MPA, Dabestani S, Field JK, O'Donnell EK. Multi-cancer risk prediction in asymptomatic adults using urinary glycosaminoglycan profiling. *Cancer Epidemiol Biomarkers Prev.* 2026. doi:10.1158/1055-9965.EPI-26-1059

[2] MIRAM GAGome Kit (FRUOU-CS) Application Note. Elypta AB.