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Comparative evaluation of the My5-FU™ immunoassay and LC-MS/MS in monitoring the 5-fluorouracil plasma levels in cancer patients

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BACKGROUND
Chemotherapies of solid tumors commonly include 5-fluorouracil (5-FU). With standard doses of 5-FU, substantial inter-patient variability has been observed in exposure levels and treatment response. Recently, improved outcomes in colorectal cancer patients due to pharmacokinetically guided 5-FU dosing were reported. We aimed at establishing a rapid and sensitive method for monitoring 5-FU plasma levels in cancer patients in our routine clinical practice.

METHODS
Performance of the Saladax My5-FU™ immunoassay was evaluated on the Roche Cobas® Integra 800 analyzer. Subsequently, 5-FU concentrations of 247 clinical plasma samples obtained with this assay were compared to the results obtained by liquid chromatography-tandem mass spectrometry (LC-MS/MS) and other commonly used clinical analyzers (Olympus AU400, Roche Cobas c6000, and Thermo Fisher CDx90).

RESULTS
The My-FU assay was successfully validated on the Cobas Integra 800 analyzer in terms of linearity, precision, accuracy, recovery, interference, sample carryover, and dilution integrity. Method comparison between the Cobas Integra 800 and LC-MS/MS revealed a proportional bias of 7% towards higher values measured with the My5-FU assay. However, when the Cobas Integra 800 was compared to three other clinical analyzers in addition to LC-MS/MS including 50 samples representing the typical clinical range of 5-FU plasma concentrations, only a small proportional bias (≤1.6%) and a constant bias below the limit of detection was observed.

CONCLUSIONS
The My5-FU assay demonstrated robust and highly comparable performance on different analyzers. Therefore, the assay is suitable for monitoring 5-FU plasma levels in routine clinical practice and may contribute to improved efficacy and safety of commonly used 5-FU-based chemotherapies.

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