

5-FU Results with Confidence

From Degradation-Free Sample Collection to Best-in-Class Analysis

The My5-FU Reagent Kit with parameters for all commonly used clinical chemistry analysers

Clinical studies have clearly demonstrated that getting 5-FU exposure right has significant clinical benefits:

- Improved clinical outcomes
- Reduced toxicity
- Lower treatment costs
- Improved patient quality of life



The My5-FU Sample Stabilizer*

Our stabilizer is the only commercially available stabilizer which ensures sample integrity by stabilizing 5-fluorouracil in blood samples collected for analysis with LC-MS or IA. Stabilizer is important to eliminate pre-analytical errors. Also available as a single-use injectable sample stabilizer.

*US and European patents



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Value of 5-Fluorouracil Testing

Personalized Chemotherapy Dose Optimization with a Simple Blood Test

The majority of patients on 5-FU infusion regimens are underdosed.¹⁻⁵

- It is well-recognized that dosing by body surface area is inadequate^{6,8}
- A recent German Registry Study of 454 patients and 37 unique centers confirms underdosing issue in 60% of patients⁹
- A wide range of doses is needed for optimal exposure

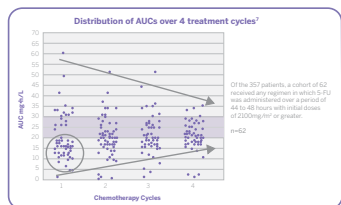
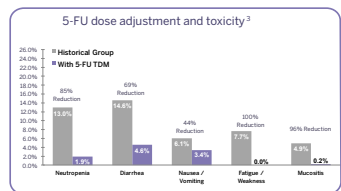
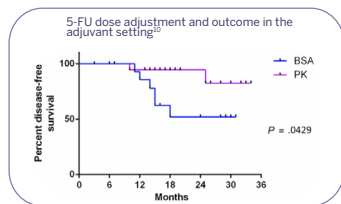
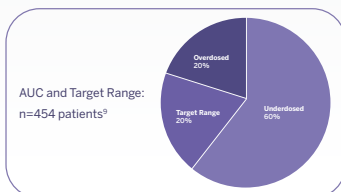
Dose adjustment is effective at reducing variability in exposure; patients can be adjusted into target range.^{3,6}

- Published dosing algorithms can be used to personalize 5-FU dosing²

Adjusting patients into target range reduces toxicities and improves outcomes.^{1,3,5,10}

Implementing testing into practice has been demonstrated.^{3,4}

The EMA has included 5-FU TDM in its recent recommendation.¹¹ As such, the monitoring of 5-FU must now be considered best medical practice.



1. Capitan O, et al. Individual Fluorouracil Dose Adjustment in FOLFOX Based on Pharmacokinetic Follow-Up Compared With Conventional Body-Area-Surface Dosing: A Phase II, Proof-of-Concept Study. *Clin Colorectal Cancer*. 2012;11(4):263-267.

2. Kaldale RR, et al. Modeling the 5-fluorouracil area under the curve versus dose relationship to develop a pharmacokinetic dosing algorithm for colorectal cancer patients receiving FOLFOX6. 2012;17(3):296-302.

3. Wilhelm M, et al. Prospective, multi-center study of 5-fluorouracil (5-FU) therapeutic drug management (TDM) in metastatic colorectal cancer (mCRC) patients treated in routine clinical practice. *Clin Colorectal Cancer*. 2016;15(4):381-388.

4. Barthelemy PS, et al. Pharmacokinetic (PK)-guided optimization of 5-fluorouracil (5FU) exposure in colorectal cancer (CRC) patients: U.S.-based clinical practice experience. *J Clin Oncol*. 2014;32(5s):abstr 3574.

5. Gamelin F, et al. Individual fluorouracil dose adjustment based on pharmacokinetic follow-up compared with conventional dosing: results of a multicenter randomized trial of patients with metastatic colorectal cancer. *J Clin Oncol*. 2008;26(13):2099-2105.

6. Baker SD, et al. Role of body surface area in dosing of investigational anticancer agents in adults. 1991-2001. *J Natl Cancer Inst*. 2002;94(24):1883-1888.

7. Saam J, et al. Body surface area-based dosing of 5-fluorouracil results in extensive interindividual variability in 5-fluorouracil exposure in colorectal cancer patients on FOLFOX regimens. *Clin Colorectal Cancer*. 2011;10(3):203-206.

8. Felici A, et al. Dosing strategies for anticancer drugs: the good, the bad and body-surface area. *Eur J Cancer*. 2002;38(13):1677-1684.

9. Hofheinz R-D. Kolorektale Tumore. Oral presentation at: Onko Update; February, 2018; Berlin, Germany.

10. Kline CL, et al. Personalized dosing via pharmacokinetic monitoring of 5-fluorouracil might reduce toxicity in early- or late-stage colorectal cancer patients treated with infusional 5-fluorouracil-based chemotherapy regimens. *Clin Colorectal Cancer*. 2014;13(2):119-126.

11. EMA recommendations on DPD testing prior to treatment with fluorouracil, capecitabine, tegafur and flucytosine. April 2020 <https://www.ema.europa.eu/en/medicines/human/affairs/fluorouracil-fluorouracil-related-substances-capecitabine-tegafur-flucytosine-containing-medications>.