

## ***Advisory Notice – Updated 5-FU Sample Handling Instructions***

### **Centrifuge 5-FU whole blood with Sample Stabilizer up to 24 hours after collection.**

A benefit-risk analysis of the My5-FU Sample Stabilizer concluded that 5-FU whole blood samples with Sample Stabilizer may be processed into plasma up to 24 hours after blood collection. SBI studies have demonstrated that the rare change in 5-FU concentration upon 24-hour storage in whole blood is a result of a combination of preanalytical variables, and is not related to stabilizer performance. Additionally, the change does not affect 5-FU dose adjustment.

The use of the My5-FU Sample Stabilizer to store 5-FU blood samples reduces pre-analytical error, thus facilitating accurate assay results, and benefitting patients. 5-FU in whole blood treated with Sample Stabilizer and stored at room temperature may be processed into plasma up to 24 hours after draw. Samples handled in this way are suitable to determine dose adjustment based on 5-FU blood levels.

The following documents have been updated to reflect the change in 5-FU whole blood stability with My5-FU Sample Stabilizer.

- PI 5FU-RGT, rev 09 – My5FU Assay Package Insert
- PI 5-FU-STB, rev 10 – My5-FU Sample Stabilizer Kit Package Insert
- PI 5FU-STB-V, rev 03 – My 5-FU Sample Stabilizer Package Insert
- LIT MULT-003, rev 06 – MyCare Sample Collection and Handling Summary
- OPL 5FU-005, rev 06 – 5-FU Handling Wall Chart with Stabilizer Kit (English)
- OPL 5FU-006, rev 06 - 5-FU Handling Wall Chart with Stabilizer Kit (German)
- OPL 5FU-021, rev 03 – 5-FU Handling Wall Chart with Stabilizer Vial (English)
- OPL 5FU-022, rev 03 – 5-FU Handling Wall Chart with Stabilizer Vial (German)

There are no other changes to the 5-FU sample handling.

- Samples with My5-FU Sample Stabilizer are stable for 1 week at 2-8°C or room temperature. Instructions for handling of 5-FU samples without My5-FU Sample Stabilizer remains the same.

### **ACTIONS REQUIRED**

- 5-FU blood samples may be processed into plasma up to 24 hours after collection when stored at room temperature in the presence of the stabilizer.
- Obtain updated documentation listed above. Destroy obsolete versions of these documents.

### **QUESTIONS**

For questions or concerns pertaining to this Advisory Notice, please contact Saladax Technical Support by e-mail at [techsupport@saladax.com](mailto:techsupport@saladax.com) or by telephone at +1 610 419-6731, Option 1.