



**True Dose® kit is a CE-marked single use blood collection device that is intended for the self-collection of capillary blood for therapeutic drug monitoring of Epirubicin. The sample is shipped back to an ISO 13485:2022 accredited laboratory for analysis of Epirubicin concentration with a validated assay.**

### Technical Specification

Sample Type:	Whole blood
Blood Collection Volume:	50 µL
Collection Time:	Under 5 minutes
Tube Size & Material:	2 ml & Transparent Polypropylene (PP)
Kit Size & Weight:	170 x 97 x 21 mm & 65 g
Shipping:	Sample ships in UN3373 compliant packaging via standard post.
Sample Identification:	Integration with patient specific barcode for sample traceability
Device Storage:	Up to 25°C
Shelf life:	1 year at -18°C, 45 days at 2-8°C and 14 days at 25°C
Manufacturing and Assembly:	Sweden

### Patient-Centric Convenience



Cancer patients successfully collect blood samples at home at any time, without the need of visiting a lab.



### Reliable Results

Our technology eliminates the need for cooling during shipment, ensuring that samples arrive in optimal condition for analysis.

### Simplified workflow



Prescribe True Dose® kits effortlessly through your existing medical record system; we handle shipping, self-sampling, lab analysis, and direct result delivery for a seamless experience.



### Transportation Life

True Dose® kit maintains stability for up to 14 days during shipment at ambient temperatures (up to 25°C), simplifying logistics.

**Prescribing:**  
Doctor prescribes the True Dose® kit directly through the electronic medical record.

**Self-Sampling:**  
Patient conveniently collects the sample at home.

**Analysis:**  
Sample is analyzed by True Dose® accredited partner lab.



**Shipping:**  
True Dose® posts the kit to the patient.

**Shipping:**  
Patient posts the kit to the lab.

**Results:**  
Secure delivery of results directly back into the doctor's electronic medical record.



# Equivalency Data Analysis of Blood Matrix and Extraction Times

## Epirubicin Exposure Guidelines (Whole Blood)

Dose mg/m2	Expected AUC µg·h/L (µmol·h/L)	Low Exposure µg·h/L (µmol·h/L)	Therapeutic Range µg·h/L (µmol·h/L)	High Exposure µg·h/L (µmol·h/L)
60	~5600 (10.3)	< 4000 (7.4)	4000–6500 (7.4–12.0)	> 7000 (12.9)
75	~6000 (11.0)	< 4200 (7.7)	4200–6800 (7.7–12.5)	> 7500 (13.8)
90	~7500–9000 (13.8–16.6)	< 5000 (9.2)	5200–9000 (9.6–16.6)	> 9500 (17.5)
100	~9000–10000 (16.6–18.4)	< 6000 (11.0)	6000–10500 (11.0–19.3)	> 11000 (20.2)
120	~12000–13000 (22.1–23.9)	< 8000 (14.7)	8500–13500 (15.6–24.8)	> 14000 (25.8)

AUC (Area Under the Curve) values assume 1-hour IV infusion and LC-MS/MS quantification in whole blood. Liver function, age, and drug interactions impact exposure. Based on Robert et al. (1994), Sandström et al. (2006), FDA NDA 020-214.

### Objective:

To evaluate the effect of storage time on analytical results in incubated whole blood using the True Dose® method compared to Gold Standard method.

### Findings:

Higher signal: True Dose® samples analysed after 3 and 7 days showed the highest epirubicin response (110.5% and 112.7%, respectively) compared to the Gold Standard method (100%)

### Improved consistency:

Greater variability was observed at 0h and 18h, while prolonged extraction improved both the linearity and lowered the variability

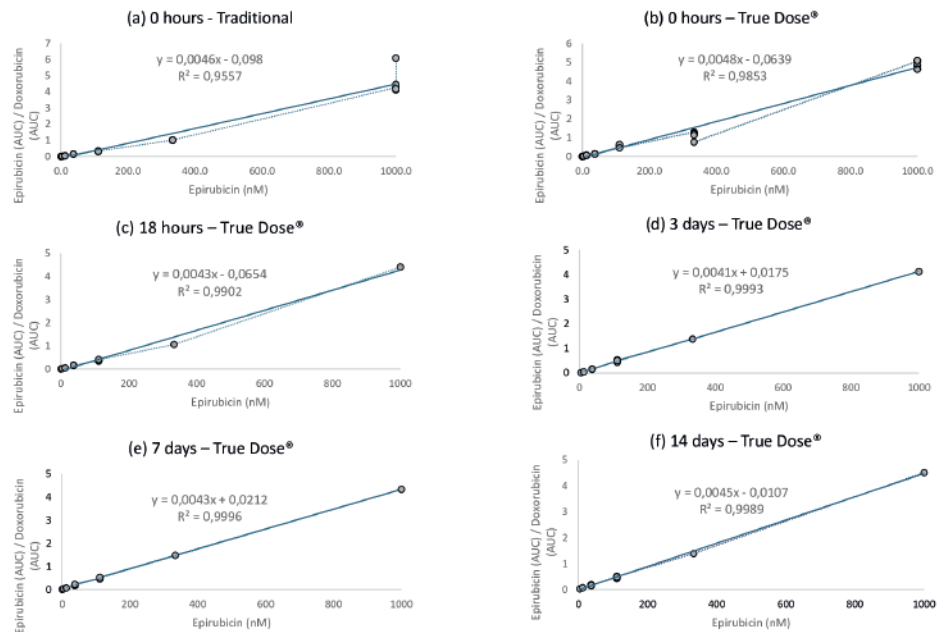


Figure 1. Linearity of Epirubicin Quantification Using Traditional vs. True Dose® Sampling Over Time. Linear regression plots showing the ratio of Epirubicin (AUC) to Doxorubicin (internal standard) across increasing Epirubicin concentrations (0–1000 nM).

Samples (n)	Linearity R2	Response (y)	Response rel S5 7d (%)	Response Rel S1 Gold Std (%)
35	0,9888	46,611	100	11,3
35	0,9908	45,655	98	9,4
15	0,9933	48,055	103,1	14
15	0,9999	51,51	110,5	19,7
15	0,9999	52,528	112,7	21,3
15	0,9999	42,183	90,5	2

Table 1. Effects on prolonged incubation rel direct processing, AUC of Epi vs Epi concentration (0-1000 nM)

### Conclusion:

Prolonged extraction improves epirubicin response and measurement consistency, with optimal results at 3–7 days.