



**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 Tamoxifen. The sample is shipped back to an ISO 13485:2022 accredited laboratory for analysis of Tamoxifen 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 before sampling:	14 days at 25°C
Shelf life after sampling:	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.



# Clinical Background & References: Tamoxifen Therapeutic Drug Monitoring (TDM)

**Purpose:** This document is an educational overview to support understanding of tamoxifen pharmacology and laboratory reporting. It does **not** provide patient-specific treatment recommendations and should **not** be used to replace clinical judgment, local guidelines, or shared decision-making. Any dosing changes remain the responsibility of the treating physician or healthcare team.

## Why Monitor Tamoxifen?

- Tamoxifen is a prodrug. The clinical effect depends on the metabolism of active compounds, especially (Z)-endoxifen (Figure 1).<sup>(1)(2)</sup>
- Exposure varies due to CYP2D6 activity, co-medications, liver function, hormonal status, and adherence.
- TDM helps identify patients with subtherapeutic exposure and supports safe optimization of therapy.<sup>(3)</sup>
- Steady state is typically reached after  $\geq 6$  weeks on a stable daily dose.

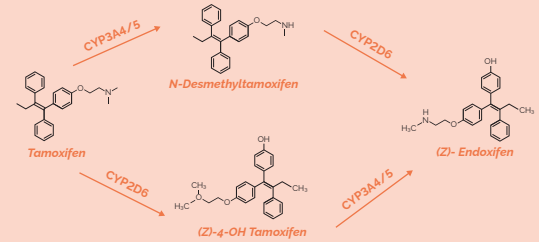


Figure 1. Metabolism of Tamoxifen – mechanism

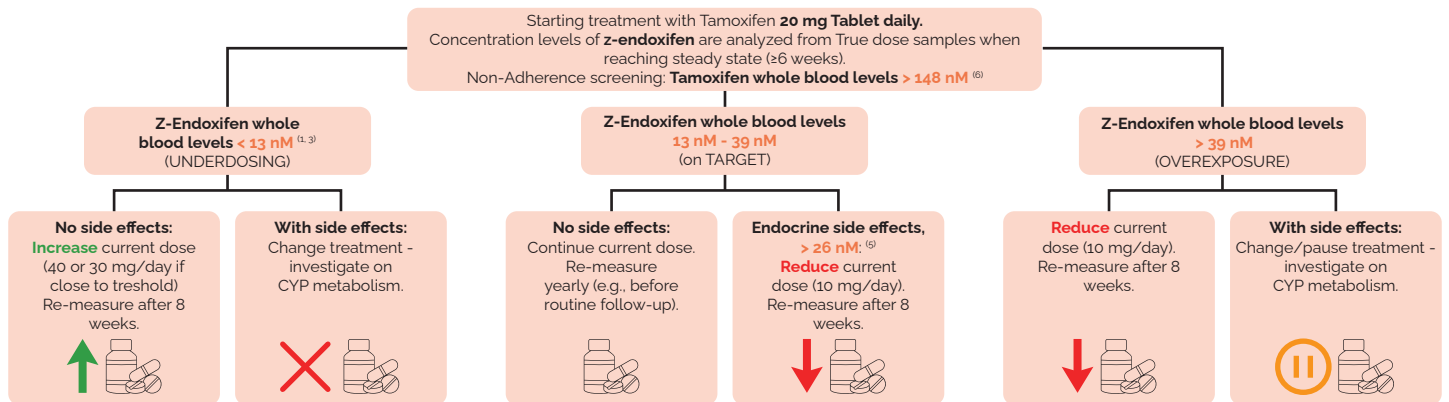
## Actionable Targets (Whole Blood, steady state) \*

Presenting whole-blood targets aligns with reports clinicians receive.

- **(Z)-Endoxifen therapeutic target:  $\geq 13$  nM** (whole blood)
- **Pragmatic upper range (asymptomatic):  $\sim 39$  nM** (whole blood) ( $\approx 3\times$  efficacy threshold; individualize to tolerability)
- **Tamoxifen non-adherence screen:  $\geq 148$  nM** (whole blood)

Re-test windows:  $\sim 8$  weeks after a dose change or interacting drug change; otherwise, annually at routine follow-up, or sooner if adherence/interaction/physiology concerns arise.

**Guidance for dose-adjustment of Tamoxifen**, considering whole blood levels of its metabolite Z-Endoxifen and whole blood levels of Tamoxifen in case a non-adherence screening is necessary.



## Interpreting whole-blood (Z)-Endoxifen results – educational bands

(These examples are descriptive of the literature and not directives.)

- Below target:  $< \sim 13$  nM  
*Literature associates plasma  $< 16$  nM<sup>(4)(5)</sup> with higher recurrence risk;  $< 13$  nM in whole blood corresponds to  $\sim 16$  nM plasma. Published studies have examined dose escalation (often to 30–40 mg/day) when levels are below the target.*
- Within pragmatic efficacy band:  $\sim 13$ – $39$  nM  
*Derived from the 16 nM target and an upper range  $\sim 3\times$  that threshold used in several studies when asymptomatic.*
- Above pragmatic upper range:  $\geq 39$  nM  
*In studies of patients with endocrine side-effects and higher levels, dose reduction strategies have been explored while maintaining levels near the threshold.<sup>(5)</sup>*

Non-adherence screen (Tamoxifen): Whole-blood  $\sim 148$  nM ( $\approx 55$  ng/mL plasma) is frequently used as a conservative threshold in adherence studies.<sup>(6)</sup>

## Practical Checks Before Interpreting

- Confirm adherence and sampling time (time since last dose)
- Review CYP2D6-inhibiting drugs (e.g., paroxetine, fluoxetine, quinidine, terbinafine) and other interactions
- Note significant weight or hepatic function changes

## REFERENCES:

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## \* Footnote on Plasma vs Whole Blood

Most published thresholds are in plasma (e.g., (Z)-endoxifen  $\geq 16$  nM). For consistency with whole-blood reporting, this background presents whole-blood equivalents. Map whole-blood to plasma by dividing by blood/plasma (B/P) ratios: END B/P = 0.81, TAM B/P = 0.91<sup>(4)</sup>. This preserves comparability with the literature while keeping day-to-day interpretation in the same matrix as reported results.