

ASSAY PERFORMANCE

Menstrual Blood Loss Quantitated as Alkaline Hematin

Method	Colorimetric
Matrix	Menstrual Blood on Feminine Hygiene
	Products
Storage Temperature	Ambient
LLOQ	2.5 mL
ULOQ	50 mL
Precision & Accuracy	
LLOQ QC	15.9% CV; 7.3% Bias
Low QC	3.1% CV; -1.6% Bias
Mid QC	11.8% CV; -5.1% Bias
High QC	4.9% CV; -3.3% Bias
Above Range QC (2x Dilution)	9.6% CV; -1.9% Bias
Stability	
Short-Term (Bench-Top)	33 hours for extract
Long-Term	56 days on product at RT
	56 days as venous blood at 4C
	43 days as venous blood at RT
Comments	Method validated for Tampons, Pads
	and Pantiliners. Method also validated in
	the presence of human urine and
	vaginal secretions
Method Number	V2344B1. [Data for Kotex]