Value of Coag-Sense®
Direct Clot Detection PT/INR Technology

Characteristic	Coag-Sense® PT2	CoaguChek XS
Tests Performed	PT/INR – CLIA waived and Self-Test	PT/INR – CLIA waived and Self-Test
Core Technology	**Direct micro-mechanical detection of clot**	**Electrochemical**. Thrombin generation converts a substrate
Tech In Simple Terms	A clot is "seen" and reported immediately without any secondary conversions. Testing time is actual PT time	First chemical reaction, then electric signal which is "converted" into INR using algorithm. PT time is calculated
Accuracy	99% of ALL INR differences to a reference thromboplastin were found within the combined ISO acceptance limits of ± 0.5 INR or ± 30 %[1]	97% of INR ≤4.5 differences to a reference thromboplastin were found within the combined ISO acceptance limits of ± 0.5 INR or ± 30%[1]
Precision (Repeatability)	**<2.5% CV**	<4.5% CV
Color Touch Screen	**Yes – Instructions in plain language, no error codes**	No – Mystery error codes
Memory	**2,000 patient results, 1,000 operator IDs, 500 QC results**	300 patient results
Connectivity	**Yes – Wi-Fi, Ethernet, Bluetooth, USB**	No – Must upgrade to Plus model and docking station
True Controls	**Yes – Control strips identical to patient strip with real plasma added**	No – "QC" channel is only moisture-detection, procedural, NOT functional QC. Must upgrade to Plus model for liquid controls
Barcode Scanning	**Yes using optional barcode scanner**	No – Must upgrade to Plus model
Hematocrit Range	**15%-60%**	25%-55%
Cleaning	**10% bleach acceptable**	No bleach. Requires alcohol with 10-minute contact time
WHO calibration	**Production lots directly calibrated against WHO tilt-tube std.**	Production lots adjusted to master lot (lot-to-lot variability)
Test Strip Price	**Significantly less expensive (50 strips per kit)**	Significantly more expensive (48 strips per kit)
Safety Record	**Zero Adverse Events reported to FDA, zero recalls in 9 years**	Thousands of Adverse Events reported to FDA, numerous recalls and Urgent Medical Device Correction Updates (UMDCs)
Meets FDA proposed PT/INR requirements[2]	**YES - Offers true PT time, true quality controls, not sensitive to hemoglobin and hematocrit levels**	NO – Calculated PT time, control is moisture-detection only–not a quantitative test of reagent or system performance, sensitive to hemoglobin and hematocrit levels

1. Respective company white papers
2. http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM482361.pdf