



Performance Evaluation of the Coagu-Sense® PT/INR Monitoring System using Hart Biologicals Certified Plasma Line Set

Materials and Methods – Hart Plasma Line Set Performance on Coagu-Sense PT/INR POC System

The Hart Biologicals Ltd. (Hartlepool UK) PT/ INR Line Plasma Set kit have recently become available which include plasma samples certified against the International Reference Preparations (IRP) RBT 16 and RTF 16. The plasma set includes 5 samples ranging from 1 INR to greater than 5 INR. Hart Biologicals states that the plasma line set can be used to determine system (Coagulometer and Thromboplastin combination) specific International Sensitivity Index (ISI) values or derived local INR values. The Hart Biologicals PT/ INR Line Plasma Set is based on the European Concerted Action on Anticoagulation (ECAA) PT/INR Line Plasma Set.

CoaguSense, Inc. contracted with a third-party laboratory (RPI, Inc.) to run the Hart plasmas on the Coagu-Sense POC PT/INR analyzer as well as their MLA laboratory analyzer. The Hart PT/INR Line Set Part# HB-4452-FG, lot# 1591-11 was used in this analysis. The plasma samples were recalcified by adding 50.9 µL plasma to 20µL 50mM CaCl₂ prior to running on the Coagu-Sense analyzer.

The Coagu-Sense PT/INR monitoring system is a CLIA waived portable analyzer that uses a micromechanical means to directly detect a clot from whole blood. The Coagu-Sense test strip contains only recombinant thromboplastin. The test strip does not contain polybrene or other blockers that could potentially interfere with the clotting reaction or require complex corrective algorithms. The system is a simple timer, timing from when the blood or plasma is applied to when the clot is picked up by a rimless spoked wheel. It is a true prothrombin time system and does not employ any algorithms to calculate the true clot time which is converted to INR. Coagu-Sense test strip lot# 180203 was used in this analysis on two Coagu-Sense meters SN 18213 and SN 7068.

Hart Biologicals Batch 1591-11 certified INR values from package insert

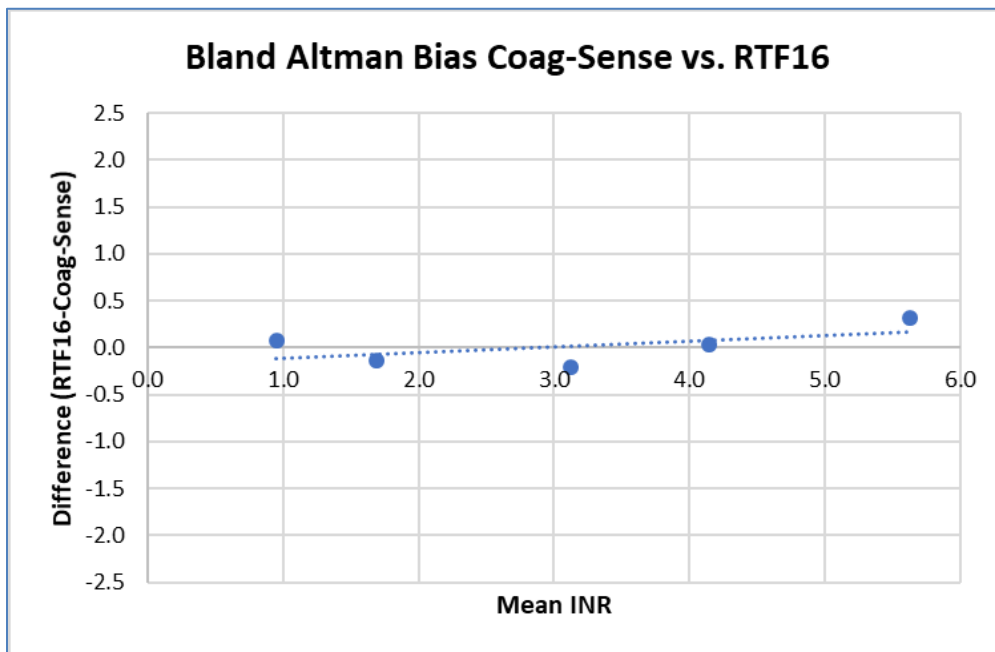
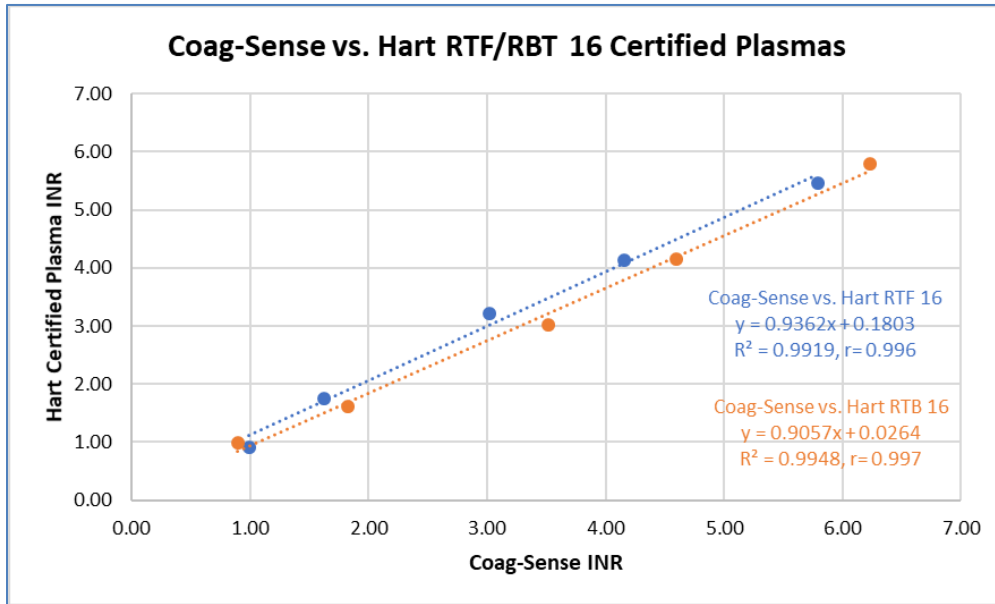
Sample #	Hart Plasma #	INR RBT 16	INR RTF 16
1	3635-2	0.97	0.99
2	3636-2	1.75	1.62
3	3637-2	3.14	3.02
4	3638-2	4.48	4.16
5	3639-2	6.88	5.79

Coagu-Sense average PT seconds and calculated INRs using RTF & RBT ISI and MNPT values

#	CS SN 18213 PT Sec.	CS SN 7068 PT Sec.	CS AVG PT Sec.	CS INR RBT 16	CS INR RTF 16
1	15.1	15.8	15.5	0.90	0.91
2	27.6	27.8	27.7	1.82	1.76
3	46.4	48.7	47.6	3.51	3.22
4	59.7	59	59.4	4.60	4.13
5	76.4	76	76.2	6.23	5.47



The resultant INR values were analyzed using regression analysis; the correlation coefficient (r), slope and intercept were determined for the data set, and graphs of the regression and Bland Altman bias analysis results were generated.



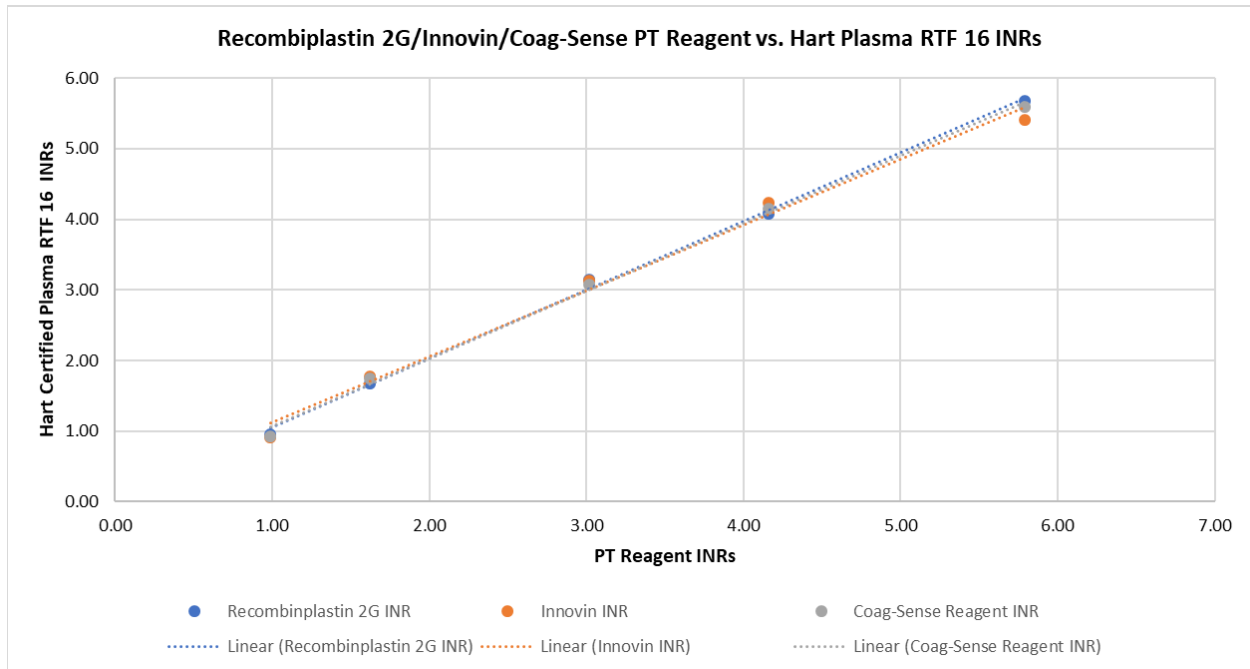
Materials and Methods– Hart Plasma Performance on MLA Lab Analyzer with Different Thromboplastins

The Hart Biologicals Ltd. were also processed on MLA lab analysis using three different thromboplastin reagents; Innovin (Dade, Inc.) lot# 549717 EXP 9/21/20, RecombiPlasTin 2G (Instrumentation Laboratory, Inc.) lot# N0587757 EXP 5/20 and Coag-Sense liquid test strip PT Reagent (CoaguSense, Inc.) lot# 171105. The Coag-Sense liquid test strip PT Reagent is the same reagent used in production of the Coag-Sense commercial test strips. Because the manufacturers of Innovin and Recombiplastin do not



publish their respective ISI and MNPT values, PT seconds on the MLA were converted to INR values using the ISI and MNPT derived from the Hart Plasma set.

Sample #	Hart Plasma RTF 16 INR	Recombinplastin 2G INR	Innovin INR	Coag-Sense Reagent INR
1	0.99	0.96	0.91	0.93
2	1.62	1.67	1.77	1.74
3	3.02	3.15	3.14	3.07
4	4.16	4.08	4.24	4.14
5	5.79	5.68	5.40	5.59



Conclusion

The Coag-Sense liquid PT reagent (same reagent in Coag-Sense test strips), Recombinplastin 2G reagent, and Innovin reagent all demonstrate strong correlation with the Hart Biologicals certified IRP RTF 16 published values and with each other. Application of the Hart IRP plasma line set to standard Coag-Sense PT/INR test strips produced a correlation of $r = 0.995$ and a mean bias of 0.1 INR.