ANALYTICAL PERFORMANCES OF A NEW VWF ACTIVITY ASSAY ON STA-R ANALYZER : STA-VWF:RCO (STAGO)

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INTRODUCTION

We evaluated analytical performances of new automated VWF activity assay, STA - VWF:RCo Stago, on STA-R analyzer. This kit is intended for quantitative determination of Ristocetin Cofacteur activity of von Willebrand factor (VWF:RCo) in plasma by turbidimetric method based on platelet aggregation in presence of ristocetin.

MATERIALS & METHODS

Method precision was evaluated following CLSI EP-05 guidelines. Five samples were tested : 2 dedicated STA - VWF:RCo Control 1&2 and 3 frozen plasma samples from patients with a low, normal and high VWF:RCo activity respectively around 20%, 70% and 100%. All samples were tested in duplicate with 3 lots of STA - VWF:RCo over 20 days, including 2 runs per day. The calibration curve was performed Run 1 Day 1, and was rerun only if the QC were not in assigned range.
Between-lot and within-lab precisions were calculated for each plasma samples pooling results of the 3 lots. Repeatability was calculated for each sample and for each lot.

RESULTS

➤ **Reagents**

| Reagents	STA - VWF:RCo Platelets & Ristocetin	On board stability: 8 hours
Calibrator	STA - VWF:RCo Calibrator	On board stability : 4 hours
Controls	STA – VWF:RCo Control 1&2	On board stability: 8 hours Control 1 [50 ; 80]% Control 2 (25 ; 40]%
	Titrated controls and calibrator per lot	

➤ **Method precision**

▪ Repeatability and within Lab precision for each lot

Assay Reagent Lot	Sample	N	Mean (%)	Repeatability		Within-Lab	
				SD	%CV	SD	%CV
Lot 1	Control 1	80	65	5.3	8.2	6.8	10.4
	Control 2	80	33	3.3	10.1	3.9	12.1
	Low level	80	22	1.1	4.9	1.3	6.0
	Normal level	80	82	11.5	14.0	13.4	16.4
	High Level	80	112	4.1	3.6	5.1	4.5
Lot 2	Control 1	80	62	4.9	7.9	5.6	9.1
	Control 2	80	29	3.4	11.5	3.6	12.3
	Low level	80	20	1.7	8.9	2.0	10.4
	Normal level	80	75	7.7	10.2	8.6	11.5
	High Level	80	98	7.3	7.4	8.1	8.3
Lot 3	Control 1	80	63	4.2	6.7	4.9	7.9
	Control 2	80	30	2.3	7.5	3.0	9.9
	Low level	80	18	1.3	7.1	1.8	10.2
	Normal level	80	73	6.4	8.8	7.2	9.9
	High Level	80	99	9.7	9.8	13.1	13.2

▪ Between-Lot precision for all lots combined

Assay Reagent Lot	Sample	N	Mean (%)	Repeatability		Between-Lot		Within-Lab	
				SD	%CV	SD	%CV	SD	%CV
All lots combined	Low level	240	20	1.4	7.0	2.0	10.1	2.6	13.3
	Normal level	240	76	8.8	11.5	4.7	6.2	10.8	14.2
	High Level	240	103	7.4	7.1	7.7	7.4	12.1	11.7

➤ **Quality Control**

Assay of controls during 40 runs
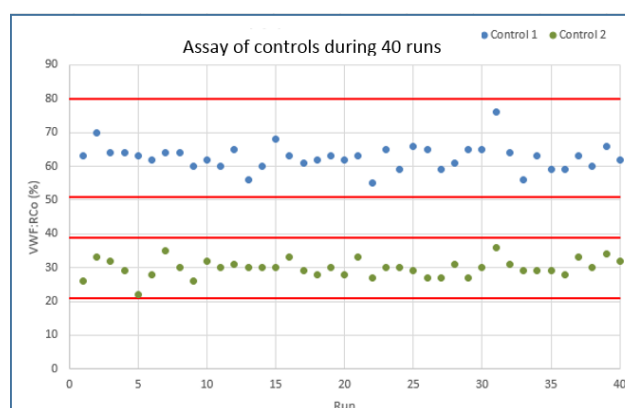
Calibration curve stability was tested over at least 20 non-consecutive days.

CONCLUSION

The new automated STA - VWF:RCo assay on STA-R analyzers displays satisfactory analytical performances. Repeatability remains below 15% and within-laboratory precision is below 17%, suggesting an acceptable lot-to-lot consistency, in accordance to the French « standards of acceptability in haemostasis » guidelines, GEHT 2014.