Newly developed dilute Russell's viper venom reagents for lupus anticoagulant detection

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INTRODUCTION

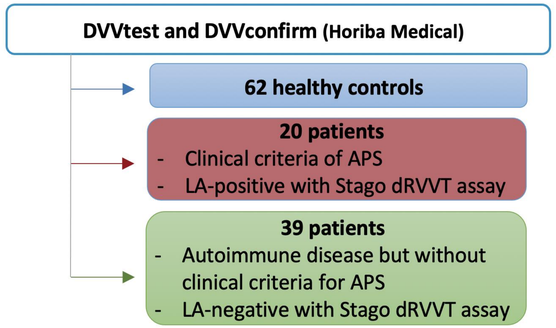
Dilute Russell's viper venom time (dRVVT) is one of the recommended assays for lupus anticoagulant (LA) detection. However, reagents variability affects diagnostic efficacy in LA testing and it is not clear whether all dRVVT reagents may be considered equivalent[1].

AIM

The objective of this study was to evaluate the analytical performances of a new formulation DVVtest/DVVconfirm (BioMedica Diagnostics) performed with the Yumizen G800 analyzer (HORIBA Medical) and to compare it with a currently available dRVVT assay performed on a STAR Max analyzer (Stago).

METHOD

Within-run and between-run imprecision were evaluated using low- and high quality control plasma samples (LAtrol Normal and Abnormal, Horiba Medical) .



APS; antiphospholipid syndrome

LA was considered positive if the screening test (DVVtest) and the LA ratio (DVVtest/DVVconfirm) were positive (threshold provided by the manufacturers)

RESULTS

Within-run and between-run coefficients of variation were consistent with manufacturer's data (**Table 1**).

			n	Mean (seconds)	SD (seconds)	CV (%)	CV (%) manufacturer
DVV test	Within-run	LAtrol Abn	13	107.9	1.6	**1.5**	3.3
		LAtrol N		49.1	0.5	**0.9**	2.0
	Between-run	LAtrol Abn	25	97.8	3.9	**4.0**	5.6
		LAtrol N		40.7	1.5	**3.7**	6.8
DVV confirm	Within-run	LAtrol Abn	13	48.7	0.8	**1.7**	3.6
		LAtrol N		39.9	0.8	**1.9**	1.8
	Between-run	LAtrol Abn	25	48.8	2.2	**4.5**	4.7
		LAtrol N		37.4	0.4	**1.0**	2.3

Table 1. Imprecision of the DVVtest and DVVconfirm assays.
Abn, abnormal; CV, coefficient of variation N, normal; SD, standard deviation

For DVVtest/DVVconfirm assay performed on the Yumizen G800 analyzer, sensitivity, specificity and negative predictive value were of 90%, 97% and 97.8%, respectively (**Table 2**).

	Sick	Healthy
Horiba LA+	18	2
Horiba LA-	2	60

Table 2. Sickness was determined on the basis of LA Stago test positivity and the presence of clinical criteria for APS.

Among the 39 patients who were LA-negative with Stago dRVV reagents, 6 were found positive with DVVtest/DVVconfirm including 2 patients with systemic lupus erythematosus and 2 patients with positive anticardiolipin and anti-beta 2 glycoprotein I antibodies, raising the question of the sensitivity/specificity of these assays.

CONCLUSIONS

The analytical performances of DVVtest and DVVconfirm reagents make it suitable for LA detection in clinical laboratories.

ACKNOWLEDGEMENTS

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REFERENCES

[1] Depreter B, Devreese KMJ. Dilute Russell's viper venom time reagents in lupus anticoagulant testing: a well-considered choice. Clinical Chemistry and Laboratory Medicine (CCLM) 2017;55:91–101.

CONTACT INFORMATION

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