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Development and validation of a new mariPOC influenza A virus test with enhanced sensitivity

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Background: mariPOC® (ArcDia International Ltd, Finland) is an automated diagnostic system for rapid testing of acute infectious diseases. mariPOC® respi is a multianalyte test that identifies 11 pathogens causing respiratory tract infections. The influenza A virus (IAV) method of the respi test has shown 77–92% sensitivity and 98–100% specificity compared to PCR or DFA (Ivaska et al 2013; Tuuminen et al. 2013; Sanbonmatsu-Gámez et al. 2015). The current mariPOC® IAV method has been shown to well detect different subtypes, including avian influenzas, and to report slightly more true positives compared to lateral flow (LF) tests. We aimed to develop and validate an even more sensitive IAV test, targeting a highly conserved epitope, to bridge the gap against PCR and DFA (direct fluorescent antibody).

Material/methods: Analytical sensitivity of the new IAV test was studied against the current IAV test with dilution series of purified seasonal IAV subtypes (H1N1, H1N1 swine and H3N2). IAV subtype recognition of the new IAV test was also studied against potentially pandemic IAV subtypes (H2N2, H5N1, H7N3, H7N9 and H9N2).

The performance of the new IAV test was studied against a LF test (CerTest Biotec, ZV862001P) with 198 frozen nasopharyngeal aspirates that were leftovers from routine diagnostics (ISLAB, Finland). The samples were collected during the influenza season of 2015–2016. The samples were pretreated and analysed according to manufacturers' instructions. The LF results were analysed blind by two persons and documented by photography. Samples with discrepant results were resolved using PCR and/or DFA.

Results: The new mariPOC® IAV test showed order of magnitude better analytical sensitivity (1.5 ng/ml for H1N1) than the current IAV test with seasonal IAV subtypes. The new IAV test also recognised well all the other tested IAV subtypes.

In a retrospective study with clinical samples, the new IAV test detected 13 IAV true positive samples and no false positives (table). The LF test had sensitivity of 77% (10/13) compared to the new mariPOC® IAV test. Specificities for the new mariPOC® IAV test and the LF test were 100% (185/185) and 96% (178/185), respectively.

		LF test		
		Positive	Negative	Total
mariPOC®	Positive	10	3	13
	Negative	7	178	185
	Total	17	181	198

Conclusions: The new mariPOC® IAV test was shown to be analytically ten times more sensitive than the current IAV test. The test showed broad IAV subtype recognition suggesting that it is likely able to detect any new arising pandemic variants. The new test was clinically significantly more sensitive than the LF test, although the number of IAV positive samples was small. Our results indicate that the new mariPOC® IAV test enables the detection of seasonal as well as pandemic IAV subtypes with improved sensitivity. The magnitude of the improvement suggests that in clinical use the new test considerably bridges the gap to PCR.