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Hôpitaux Universitaires Genève

Geneva, December 21, 2023

Report on rapid assessment of SARS-CoV-2 Antigen Rapid Diagnostic Test for Omicron JN.1 and other BA.2.86-derived variants

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As new variants of SARS-CoV-2 emerge, the performance of existing diagnostics, particularly antigen-detecting rapid diagnostic tests (Ag-RDTs), must be evaluated to ensure their effectiveness. Recently, World Health Organization (WHO) classified the Omicron JN.1 variant, derived from the parent lineage Omicron BA.2.86, as a "Variant Of Interest" (VOI). Besides the VOI JN.1, there are other lineages circulating, also derived from BA.2.86 (e.g. JN.2, JN.3, …)

Most Ag-RDT validation studies were conducted before the emergence of the Omicron JN.1 variant and its descendants, prompting the need for further assessment when new variant arises. This report presents an assessment of the performance of SARS-CoV-2 Ag-RDTs in detecting the JN.1 and other BA.2.86-derived variants by using left-over patient samples that were sequenced.

We assessed retrospectively the accuracy of a commercially available Ag-RDT, the Panbio™ Rapid Antigen Test for SARS-CoV-2 (Abbott) for its ability to detect Omicron JN.1 and other BA.2.86-derived variants currently cirulating. **Omicron JN.1 and other BA.2.86-derived variants can be detected by AG-RDT (Table 01). In our hands and with the sample collection used, the estimated limit of detection for this assay was between 22-24 cycle threshold (CT) values of the reference RT-PCR (Roche Cobas, target ORF1ab and E gene).**

Our assessment has some limitations, as retrospective testing with left-over samples cannot fully replace a clinical validation study. Optimally, assessment of diagnostic sensitivity would be performed at the point of care, however such validations are hardly possible anymore due to the epidemiological situation and low testing uptake for SARS-CoV-2 that limit the possibility of clinical diagnostic validation studies.

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Tabel 1. Characteristics and test resulst for the Ag-RDT Panbio tested with left-over patient samples

Patient samples	**CT value** RT-PCR (Roche Cobas)		**Pangolin lineage**	**GISAID_ID**	**Panbio** Rapid Antigen Test for SARS-CoV-2 (Abbott)	
	ORF1ab	**E**				
HUG-01	15,3	15,3	JN.1	EPI_ISL_18603646	+	+
HUG-02	15,7	16	JN.1	EPI_ISL_18603645	+	+
HUG-03	16,4	16,4	JN.5	EPI_ISL_18538088	+	+
HUG-04	16,5	16,3	JN.1	EPI_ISL_18603643	+	+
HUG-05	16,5	16,5	JN.5	EPI_ISL_18538100	+	+
HUG-06	17,8	18	JN.3	EPI_ISL_18538109	+	+
HUG-07	17,9	17,7	JN.5	EPI_ISL_18538095	+	+
HUG-08	18,7	18,5	JN.1	EPI_ISL_18603661	+	+
HUG-09	18,7	18,4	JN.1	EPI_ISL_18603663	+	+
HUG-10	19,1	18,9	JN.1	EPI_ISL_18603638	+	+
HUG-11	19,2	19,1	JN.5	EPI_ISL_18538096	+	+
HUG-12	19,8	19,3	JN.1	EPI_ISL_18603656	+	+
HUG-13	19,9	19,1	JN.3	EPI_ISL_18603689	+	+
HUG-14	21,5	21,2	JN.5	EPI_ISL_18538063	+	+
HUG-15	21,8	22,1	JN.1	EPI_ISL_18603686	+	+
HUG-16	21,8	21,8	JN.1	EPI_ISL_18603681	+	+
HUG-17	22,3	22,6	JN.2	EPI_ISL_18538126	+	+
HUG-18	22,4	22,8	JN.1	EPI_ISL_18603659	-	-
HUG-19	23,7	23,7	JN.5	EPI_ISL_18538097	+	-
HUG-20	23,9	24,4	JN.2	EPI_ISL_18538093	+	+
HUG-21	25,6	26,2	JN.1	EPI_ISL_18603674	-	-
HUG-22	26	25,6	JN.1	EPI_ISL_18538052	-	-
HUG-23	26,1	26,3	JN.1	EPI_ISL_18538134	-	-
HUG-24	27,3	26,5	JN.5	EPI_ISL_18538101	-	-
HUG-25	29,4	30,3	JN.1	EPI_ISL_18538083	-	-
HUG-26	30,4	30,5	JN.1	EPI_ISL_18538068	-	-
HUG-27	31	31,1	JN.1	EPI_ISL_18603682	-	-

Methods

We assessed the accuracy of the Ag-RDT: the Panbio™ Rapid Antigen Test for SARS-CoV-2 by Abbott. Here, we retrospectively tested well-characterized nasopharyngeal SARS-CoV-2 leftover patient samples (n=27) confirmed to belong to Omicron JN.1 and other BA.2.86 descendants, determined by full-genome sequencing. The Ag-RDT was conducted following the manufacturers' instructions, with the exception that each patient sample, collected in viral transport medium (VTM) was diluted using the provided buffer at a 1:1 ratio. The diluted samples were then applied in duplicate to the Ag-RDT. Negative control using the Ag-RDT buffer without virus were included. A positive result was defined as the presence of a visible test band alongside a visible control band („+"), a negative result was defined as absence of a visible test band alongside a visible control band („-").

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