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Report on rapid assessment of two SARS-CoV-2 Antigen Rapid Diagnostic Tests for Omicron EG.5-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. Most Ag-RDT validation studies were conducted before the emergence of the Omicron EG.5 variant and its descendants, prompting the need for further assessment when new variant arise. This report presents an assessment of the performance of two SARS-CoV-2 Ag-RDTs in detecting the Omicron EG.5 variant by using left-over patient samples.

We assessed retrospectively the accuracy of two commercially available Ag-RDTs: the Panbio™ Rapid Antigen Test for SARS-CoV-2 (Abbott) and 2019-nCoV Antigen Test (Wondfo) for its ability to detect Omicron EG.5-derived sub-lineages. **Both Ag-RDTs demonstrated comparable sensitivity in the detection of the virus (Table 01). Their performance was consistent with previously examined SARS-CoV-2 variants, performed by us with the same methodology. The estimated limit of detection for these assays for the investigated lineages was approximately around 25 cycle threshold (CT) values of the reference RT-PCR (Roche Cobas, target ORF1ab).**

Accurate and timely diagnostics play an essential role in mitigating SARS-CoV-2 transmission. In our hands, the two assessed Ag-RDTs have shown comparable sensitivity to earlier variants in a retrospective study of Omicron EG.5-derived sublineages. 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.

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Tabel 1. Characteristics and detailed sensitivity for the two Ag-RDTs tested with clinical patient samples

Patient samples	**CT value**	**Pangolin lineage**	**Panbio** Rapid Antigen Test for SARS-CoV-2 (Abbott)		**Wondfo** 2019-nCoV Antigen Test (Wondfo)	
HUG-1	14,5	EG.5.1.3	+	+	+	+
HUG-2	15,3	EG.5.1.1	+	+	+	+
HUG-3	15,8	EG.5.1.1	+	+	+	+
HUG-4	16,3	EG.5.1.1	+	+	+	+
HUG-5	16,6	EG.5.1.1	+	+	+	+
HUG-6	16,8	EG.5.1	+	+	+	+
HUG-7	16,9	EG.5.1.1	+	+	+	+
HUG-8	17,2	EG.5.1.1	+	+	+	+
HUG-9	18,8	EG.5.1	+	+	+	+
HUG-10	18,9	EG.5.1	+	+	+	+
HUG-11	19,2	EG.5.1.3	+	+	+	+
HUG-12	19,3	EG.5.1	+	+	+	+
HUG-13	19,4	EG.5.1	+	+	+	+
HUG-14	19,8	EG.5.1	+	+	+	+
HUG-15	20,3	EG.5.1	+	+	+	+
HUG-16	20,4	EG.5.1	+	+	+	+
HUG-17	22	EG.5.1	+	+	+	+
HUG-18	22,5	EG.5.1	+	+	+	+
HUG-19	23,2	EG.5.1	+	+	+	+
HUG-20	23,6	EG.5.1	+	+	+	+
HUG-21	24,5	EG.5.1.1	+	+	+	+
HUG-22	24,6	EG.5.1.1	+	+	+	+
HUG-23	24,7	EG.5.1.1	+	+	+	+
HUG-24	25,8	EG.5.1	-	-	-	-
HUG-25	26.6	EG.5.1.4	-	-	+	-
HUG-26	28,3	EG.5.1	-	-	-	-

Methods and collaboration

We assessed the accuracy of two Ag-RDTs: the Panbio™ Rapid Antigen Test for SARS-CoV-2 by Abbott and the Wondfo 2019-nCoV Antigen Test (Wondfo). Here, we retrospectively tested well-characterized nasopharyngeal SARS-CoV-2 leftover patient samples (n=26) confirmed to belong to the Omicron EG.5 sub-lineages by full-genome sequencing. Both Ag-RDTs were 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-RDTs. Negative controls 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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