Excellent Performance of INDICAID™ Antigen Rapid Diagnostic Test on COVID-19 Clinical Samples with Moderate-high Viral-Loads during the Omicron Epidemiological Wave in Cameroon

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BACKGROUND

The World Health Organisation recommends the use of COVID-19 antigen rapid diagnostic tests (AgRDT) with at least **80% sensitivity and 97% specificity**. In the era of Omicron variants harbouring several mutations in the viral genes, we sought to ascertain the performance of **INDICAID™ COVID-19 AgRDT** with reference to PCR.

OBJECTIVES

1)Evaluate the sensitivity and the specificity of INDICAID™ AgRDT
2)Evaluate the positive (PPV) and the negative predictive values (NPV) of INDICAID™ AgRDT
3)Evaluate the turn-around-time of INDICAID™ AgRDT
4) Evaluate the genetic diversity and its effect on INDICAID™ AgRDT performance.

METHODS

- An observational laboratory-based study was conducted from March to August 2022 among consenting individuals tested for SARS-COV2 infection at the Virology laboratory of the Chantal BIYA International Reference Centre, Yaoundé-Cameroon. Nasopharyngeal samples were processed both on **INDICAID™ COVID-19 AgRDT** and on DaAn Gene real-time PCR as per national guidelines. Sensitivity, specificity, positive and negative predictive values of **INDICAID™ COVID-19 RDT** were evaluated according to viral load.

RESULTS & DISCUSSIONS

A total of 565 nasopharyngeal samples were tested from individuals aged ≥21 years (53.98% males), all residing in Yaoundé and its surroundings,

Overall positivity rate was **5.66%(32) with RT-PCR** versus **1.24%(7) with INDICAID™ COVID-19 AgRDT**.

Table1:
Comparison of PCR vs. RDT considering a PCR positvity threshold of 37 (national positivity threshold)

		PCR Positivity at CT<37		
		Positive	Negative	
INDICAID	POSITIVE	07	00	07
	NEGATIVE	25	533	558
		32	533	Total: 565

At PCR CT<37, (mean CT = 33.1±3.86), sensitivity of INDICAID™ AgRDT was 21.9% (95%CI: [12.5 – 21.9]); specificity was 100% (95%CI: [99.4 – 100]); kappa = 0.346 (95%CI: [0.189 – 0.346]), **suggesting a poor concordance between PCR and rapid test**. PPV was 100% (95%CI: [57.3 – 100]) and NPV was 95.5% (95%CI: [95 – 95.5]).

Tabl2:
Comparison of PCR vs. RDT considering a PCR positvity threshold of 25 (moderate to high viral loads)

		PCR positivity at CT<25		
		Positive	Negative	
INDICAID	POSITIVE	05	02	07
	NEGATIVE	00	558	558
		05	560	Total: 565

At PCR CT<25, (mean CT = 21.2 ± 2.34), sensitivity was 100% (95%CI : [51.3 – 100.0]); specificity was 99.6% (95% CI: [99.2 – 99.6]); kappa = 0.832 ([95%CI : 0.422- 0.832]), suggesting an **excellent concordance between PCR and rapid test**.

PPV was 71.4% (95% CI : [36.7 – 71.4]) and NPV was 97.7% (95% CI: [97.1 – 97.7]).

Importantly, COVID-19 sequences generated were **100% OMICRON**, sub-variant BA.1.

Conclusions

For patients infected with **moderate-high viral loads**, INDICAID™ AgRDT has **high intrinsic (sensitivity and specificity) and extrinsic (predictive values) performances for the diagnosis of COVID-19**. With its simplicity and short turn-around-time (15±2min), INDICAID™ COVID-19 AgRDT is a reliable tool to prevent the spread of COVI-19 at community-level, even on circulating Omicron variants.

Recommendations

- **Wide use of INDICAID™ COVID-19 AgRDT for rapid diagnosis of asymptomatic cases with moderate to high viral loads.**

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