

# Saliva is a valid specimen for detection of respiratory viruses



This study evaluates the clinical performance of DIANA Biotechnologies RT-PCR Diagnostic Kits (**DB-1250** and **DB-1251**) for multiplex detection of respiratory viruses from two different specimen types - **nasopharyngeal swabs** and **saliva**. Additionally, it compares two different types of sample pretreatment - **standard RNA isolation** and **DBdirect™ isolation-free technology**. The study was conducted on **459 paired samples** of nasopharyngeal swabs and saliva, collected between December 2022 and March 2023, in collaboration with three clinical laboratories, making it the **most comprehensive study of its kind to date**.

## Tested Pathogens

- Influenza A (IAV)
- Influenza B (IBV)
- SARS-CoV-2
- RSV

## Diagnostic Kits Tested

- **DB-1250** RT-PCR Respiratory panel 1: SARS-CoV-2/Flu/RSV
- **DB-1251** DBdirect™ Respiratory panel 1: SARS-CoV-2/Flu/RSV

## Key Findings:

### Saliva is comparable to nasopharyngeal swabs for detecting respiratory viruses

- **Sensitivity:** Saliva showed more than 90% PPA (positive percent agreement) compared to paired swab samples for detection of SARS-CoV-2, IAV, IBV and RSV viruses.
- **DB-1250 Kit Efficacy:** The kit is able to detect all tested pathogens from isolated saliva samples.
- **Sample Quality Impact:** Swab samples depend on the collection technique, with inconsistencies potentially leading to false negatives. Saliva samples, however, provide uniform results due to consistent sample collection (spitting).

### DBdirect™ isolation-free technology can be used for detection of respiratory viruses from nasopharyngeal swabs

#### Isolated Swabs vs. Isolated Saliva

**Reference:** isolated RNA from nasopharyngeal swab (DB-1250)

**Tested:** isolated RNA from saliva (DB-1250)

DB-1250 / DB-1250	TP	FN	TN	FP	PPA	NPA
SARS-CoV-2	100	9	322	2	91.7 %	99.4 %
Influenza A	65	6	357	5	91.5 %	98.6 %
Influenza B	28	3	401	1	90.3 %	99.8 %
RSV	43	3	383	4	93.5 %	99.0 %

All samples (isolated RNA from nasopharyngeal swab or saliva) were measured with DB-1250.

#### Isolated Swabs vs. DBdirect™ Swabs

**Reference:** isolated RNA from nasopharyngeal swab (DB-1250)

**Tested:** DBdirect™ nasopharyngeal swab (DB-1251)

DB-1251 / DB-1250	TP	FN	TN	FP	PPA	NPA
SARS-CoV-2	101	8	334	0	92.7 %	100 %
Influenza A	71	1	371	0	98.6 %	100 %
Influenza B	29	3	411	0	90.6 %	100 %
RSV	37	7	399	0	84.1 %	100 %

Isolated RNA samples from nasopharyngeal swabs were measured with DB-1250. Samples of nasopharyngeal swab were measured with DB-1251 without prior RNA isolation.

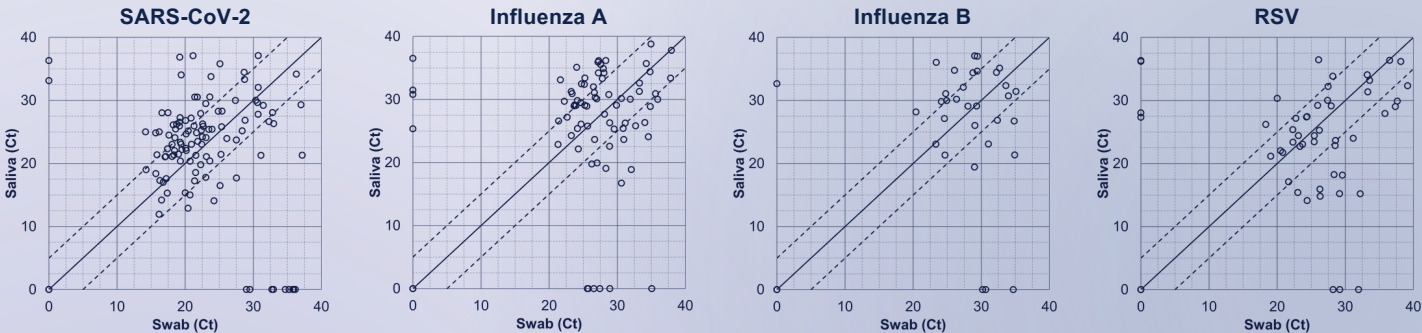
Samples with Ct values up to 40 were considered positive. As **true positive (TP)** were considered all samples which scored positive in reference as well as in tested conditions. As **false positives (FP)** were considered samples which scored positive in tested conditions only. Samples positive only in reference were considered as **false negative (FN)**, while samples negative in both reference and tested conditions were considered as **true negative (TN)**. **Positive percent agreement (PPA)** was calculated as number of TP divided by the sum of TP and FN, while **negative percent agreement (NPA)** was calculated as TN divided by the sum of TN and FP.

# Technical Information:

All collected samples were stored at -80°C prior to processing. Sample handling was carried out according to the Instruction for Use for diagnostic kit DB-1250, and DB-1251, respectively (available online). For RNA isolation, column-based isolation kits were used (QIAGEN, QIAamp DSP Virus Spin Kit, REF#61704). The input sample volume for the isolation was 200 µL, and RNA was eluted into 50 µL (4× sample concentration). For DB-1250 kit a volume of 5 µL was added into RT-PCR reaction, while for the DB-1251 DBdirect™ isolation-free kit a volume of 2 µL was used into RT-PCR reaction. Overall, 10-times less sample is added to RT-PCR reaction using DBdirect™ kit (DB-1251) compared to the regular RT-PCR kit (DB-1250).

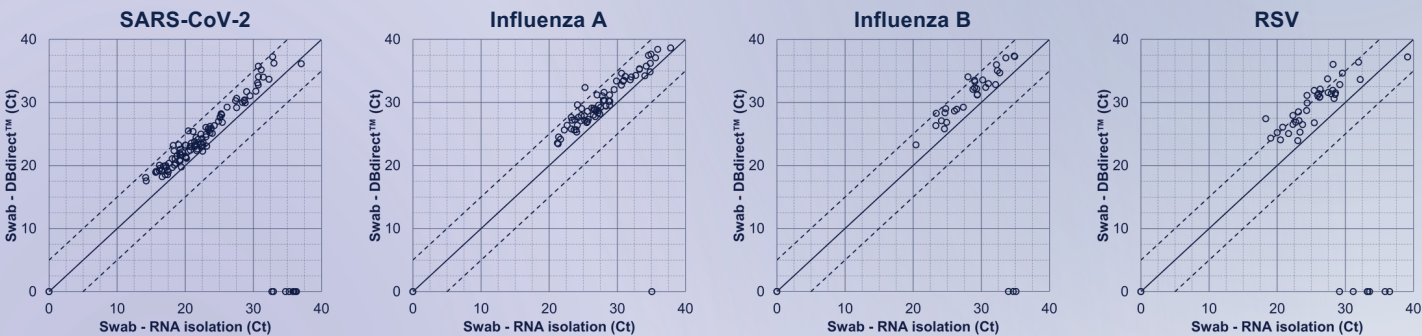
## Results:

Comparison of paired **SALIVA** and **SWAB** samples analyzed by **standard isolation procedure**



**Fig 1: Comparison of measured Ct for RNA isolated from saliva with reference measurement (RNA isolated from nasopharyngeal swab).** The detection of each virus is plotted in one graph. The Ct from the measurements of tested samples (RNA isolated from saliva; y-axis) is plotted against the Ct of reference samples (RNA isolated from nasopharyngeal swab; x-axis). Values lying on the y-axis indicate that the sample was detected only in the tested samples (RNA isolated from saliva), while values on the x-axis indicate that the sample was detected only in the reference samples (RNA isolated from nasopharyngeal swab).

Comparison of **SWAB** samples analyzed by **DBdirect™ isolation-free** and by **standard isolation** procedures



**Fig 2: Comparison of measured Ct for nasopharyngeal swab (without prior RNA isolation) with reference measurement (RNA isolated from nasopharyngeal swab).** The detection of each virus is plotted in one graph. The Ct from the measurements of tested samples (nasopharyngeal swab; y-axis) is plotted against the Ct of reference samples (RNA isolated from nasopharyngeal swab; x-axis). Values lying on the y-axis indicate that the sample was detected only in the tested samples (nasopharyngeal swab), while values on the x-axis indicate that the sample was detected only in the reference samples (RNA isolated from nasopharyngeal swab).

## Ordering Information:

Name	Cat. No.	Package Size
RT-PCR Respiratory Panel 1: SARS-CoV-2/Flu/RSV	DB-1250	100 rxns
DBdirect™ Respiratory Panel 1: SARS-CoV-2/Flu/RSV	DB-1251	100 rxns
Saliva Collection Set 1.4IM	DB-1225	500 sets

## About DIANA Biotechnologies

We are a Czech biotech company engaged in **research and development in molecular applications for academic and diagnostic labs (IVDR), development of monoclonal antibodies, and drug discovery services.** We build on a **team of top scientists** with unique expertise in molecular biology, biochemistry, organic and medicinal chemistry, pharmacology, and laboratory automation.



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