

# TESTING A NEW USER-FRIENDLY INSTRUMENT TO MEASURE IMMUNE SYSTEM STRENGTH THROUGH SALIVARY IGA LEVELS

Technical White Paper

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## OBJECTIVE

Determine the effectiveness of a new user-friendly instrument that can measure immune system strength from IgA in human saliva.

## BACKGROUND

Salivary IgA is a marker of immune system activity. IgA, which is an antibody, stands for immunoglobulin A. Your body produces IgA as your first line of defense against external invaders. It can be found in saliva, tears, sweat, and the gastrointestinal tract.

Typically, salivary IgA is determined by a laboratory test in which samples are sent to a specialized laboratory for testing. A new instrument that is small, portable, and easy to use has been developed by SOMA Biosciences and used in small settings in Europe to assess the immune system status of elite athletes. In this study, 4Life tested the reliability of this instrument for potential future use by 4Life Affiliates.

## STUDY

For this study, we recruited eight healthy adults and provided them with instructions on how to collect the saliva sample. This protocol included a questionnaire assessing the last time the participant ate, drank, or brushed their teeth.

We analyzed the samples to determine 1) variability of salivary IgA levels, 2) whether the results were repeatable, 3) the impact of an empty or full stomach on salivary IgA levels, and 4) the correlation of salivary IgA levels with this instrument and the laboratory test.



## RESULTS AND DISCUSSION

We measured the intra-day variability by collecting saliva samples three times every five minutes. Intra-day individual variability of IgA levels ranged from 3% to 33% depending on the individual.

We collected inter-day variability samples at the same time in the morning and afternoon across three consecutive days. Variability for the morning levels ranged from 4% to 94% and for afternoon levels ranged from 3% to 61%.

Reproducibility of the results was high. Variability of the results was higher but still considered small. Incorrect use of the oral fluid collector added high variability. Different incubation time of 15 minutes versus 10 minutes added variability of up to 6.4%. Immediate reading of fresh samples versus reading of samples refrigerated for 15 hours also provided different results of up to 41% differences in IgA levels.

IgA levels we measured with the new instrument and with the laboratory test had a high correlation.

## CONCLUSION

The instrument showed high reproducibility when the participants followed protocols. The largest sources of variability occurred at the participant level, including incorrect sample collection and intra- and inter-day variability. Some individuals presented greater differences in their salivary IgA levels throughout the day and across days than others. Nevertheless, the instrument produced results that were similar to a well-established method.

Figure 1. Variability of the cube reader. Multiple readings of the same device produced an average relative standard deviation of 0.6%.

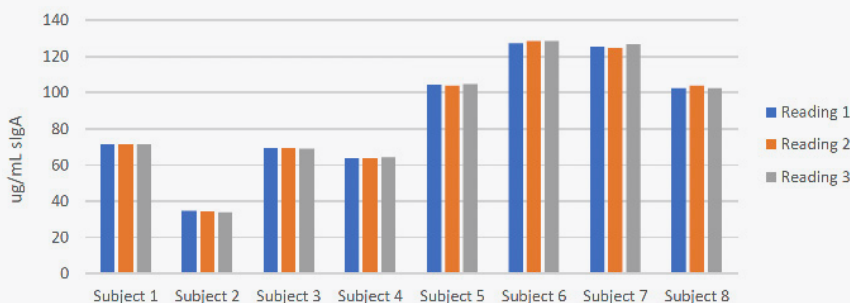


Figure 2. Variability of the device. A single reading of the three devices that contained the same sample produced an average relative standard deviation of 11%.

