Technical White Paper: Testing a New User-Friendly Instrument to Measure Immune System Strength Through Salivary IgA Levels

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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, also known as antibodies, 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 immune status of elite athletes. In this study, 4Life tested the reliability of this instrument for potential future use by 4Life distributors.

Experimental Methods

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. Participants were also given instructions to keep the oral fluid collector on top of the tongue without moving or sucking on it until the collector indicator turned blue. The oral fluid collector was immediately placed into an individual buffer bottle.

Each buffer bottle was inverted for two minutes. Two drops from each sample was added to the lateral flow device (LFD) and incubated for ten minutes. Reading of IgA level was performed by using an IPRO Cube Reader.

Samples were analyzed to determine 1) variability of salivary IgA level, 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 by Salimetrics®.

Results

The intra-day individual variability was measured by collecting saliva samples three times every five minutes. Intra-Day individual variability of IgA levels ranged from 3% to 33% relative standard deviation (RSD) depending on the individual.

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

Reproducibility of the cube reader's results was high with RSD of only 0.6%. Variability of the LFD's results was higher but still considered small with RSD of 11%. Incorrect use of the oral fluid collector by

sucking on it added high variability with RSD up to 156%. Different LFD incubation time of 15 minutes versus 10 minutes added variability up to 6.4%. Immediate reading of fresh samples versus reading of samples refrigerated for 15 hours also provided different results up to 41% differences in IgA levels.

IgA levels measured with the new instrument and with Salimetrics® test had a high correlation of R^2=0.883 (total of 32 samples).

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

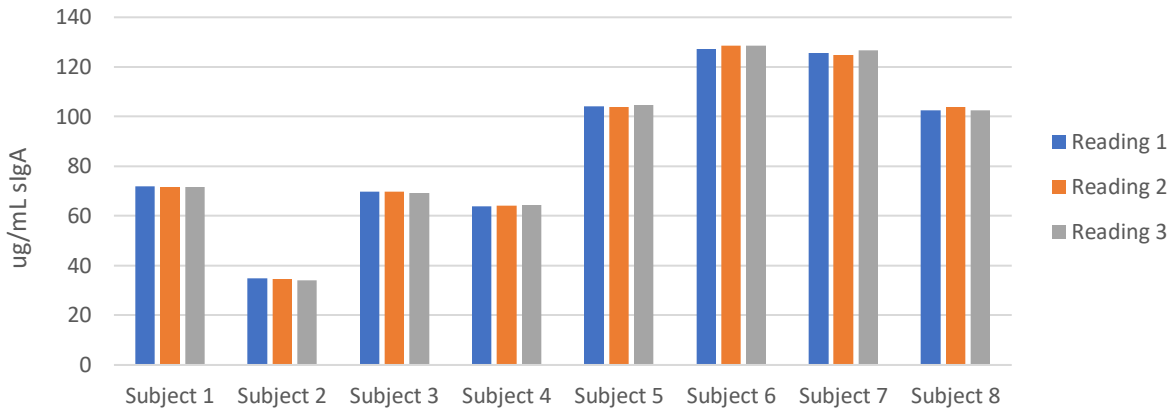


Figure 2. Variability of the lateral flow device (LFD). Single reading of the three LFD that contained same sample produced an average relative standard deviation of 11%.

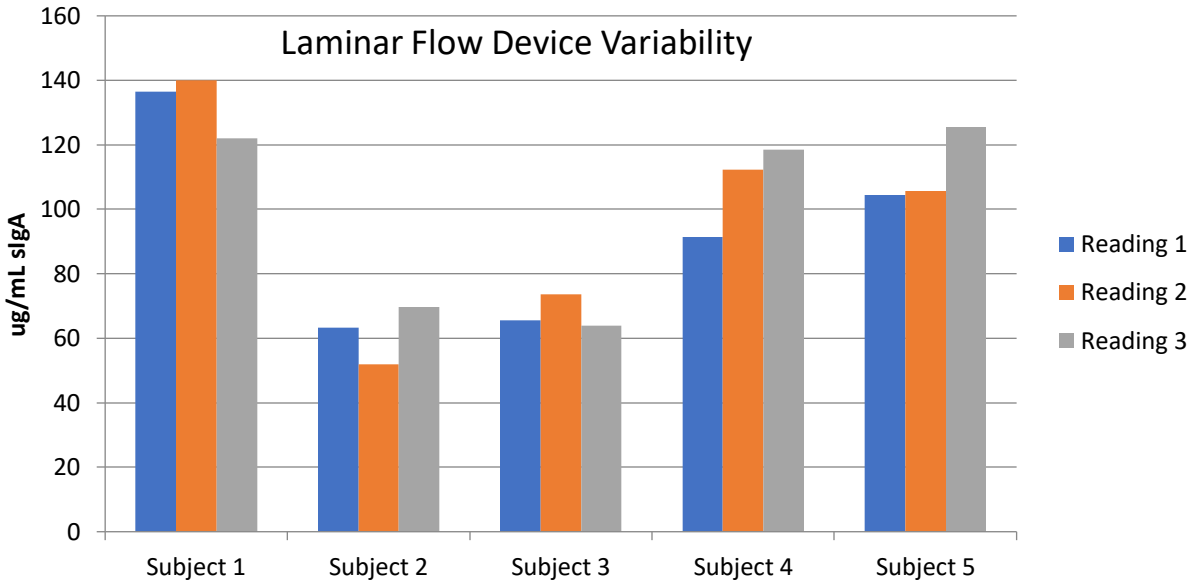
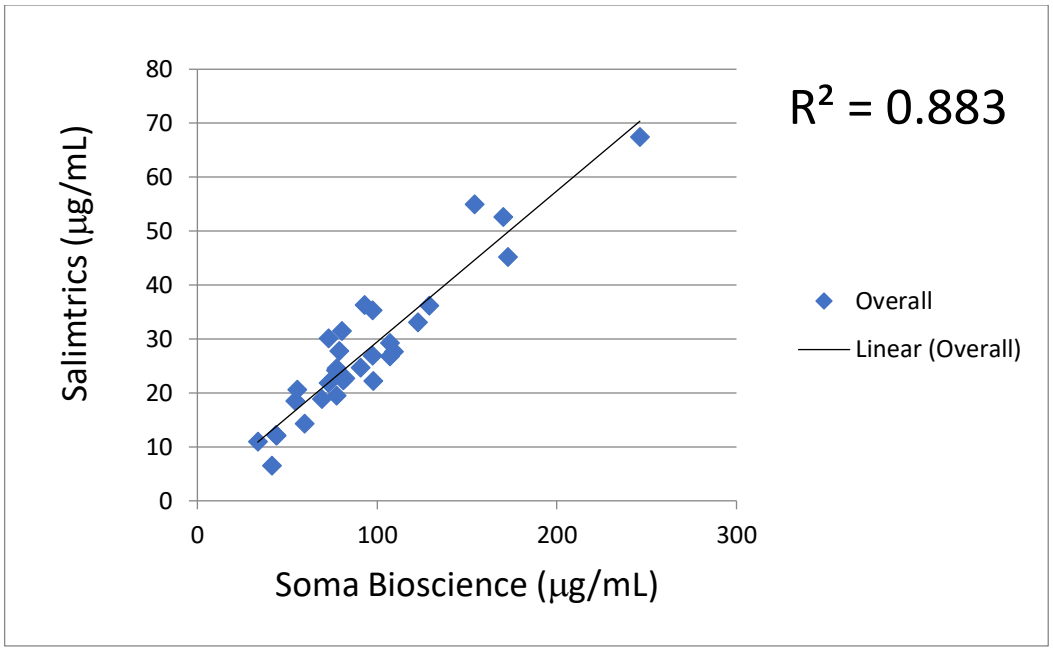


Figure 3. Correlation of salivary IgA levels with new instrument and Salimetrics® test.



Conclusion

Instrument showed high reproducibility when protocols were followed correctly. 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.