

Technical White Paper: Obtaining a Normal Range of Salivary IgA levels in Humans

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Objective

Obtain a normal range of salivary IgA by using a new, user-friendly instrument in humans

Background

Salivary IgA is a simple way to measure immune system strength. IgA stands for immunoglobulin A. Immunoglobulins are a compound (antibody protein) within the immune system that protects the body from external invaders. IgA is found in saliva, tears, sweat, and in the gastrointestinal tract and is a first line of defense.

Typically, salivary IgA is determined by a laboratory test called ELISA 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 and used in small settings in Europe to assess the immune system status of elite athletes. In this study, 4Life aimed to obtain the normal range of salivary IgA with this instrument by analyzing samples from 4Life employees.

Experimental Methods

For this study, we recruited 40 adults without mouth infections. Saliva sample collection followed the same protocol as a previously conducted validation study. This protocol included a questionnaire that asked for the last time the participant ate, drank, or brushed their teeth. Participants were not required to refrain from drinking or eating prior to testing. Protocol also included instructions to keep the oral fluid collector on top of the tongue without moving or sucking on it until the collector indicator turned blue.

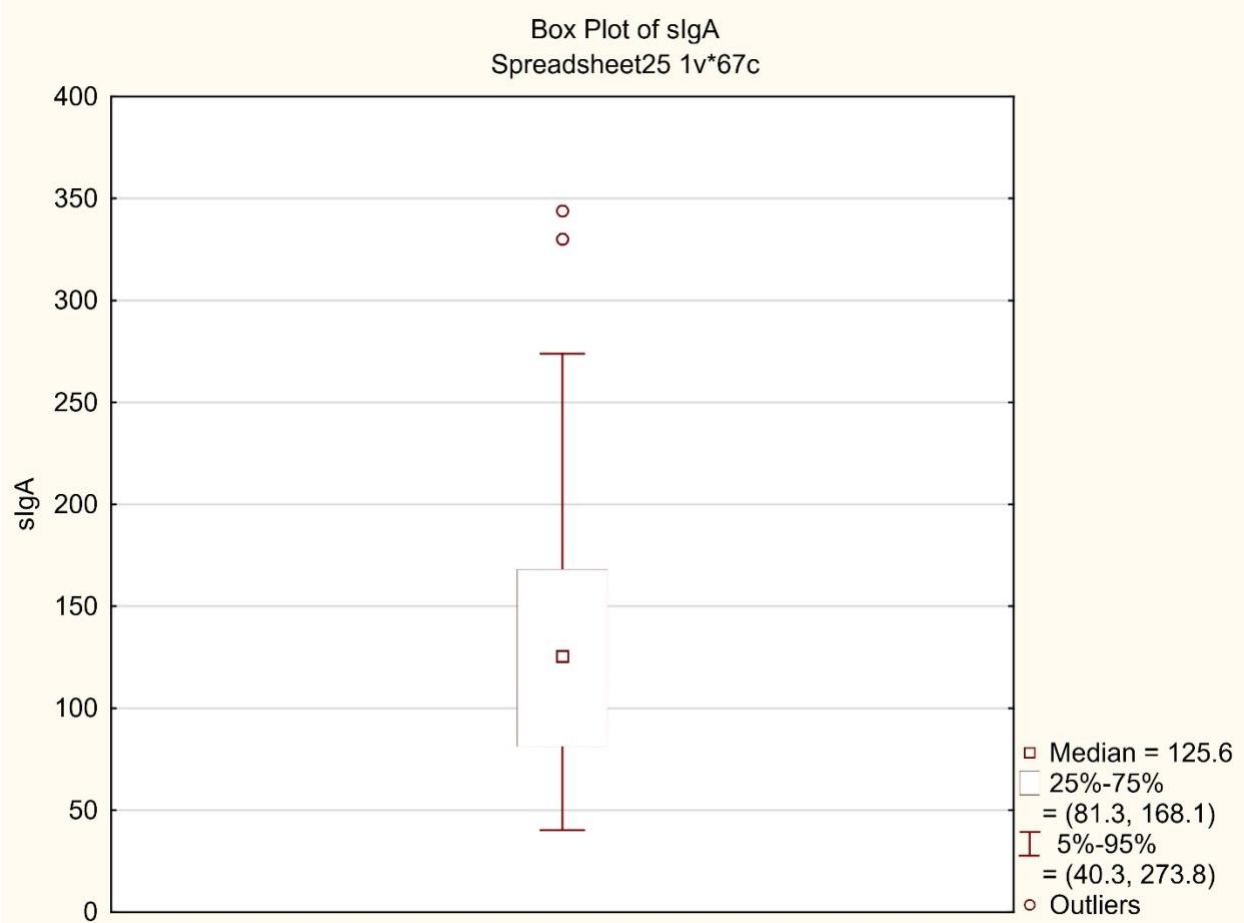
An oral fluid collector was used to collect saliva samples from the participants. After collecting the sample, the oral fluid collector was immediately placed into an individual bottle containing a buffer solution. Laboratory personnel performed sample handling and analysis. Each buffer bottle was inverted for two minutes. Two drops from each sample was added to the lateral flow device (LFD) and incubated for ten minutes. Measurement of salivary IgA level was performed using the IPRO Cube Reader (SOMA Biosciences).

Salivary IgA results obtained with this instrument from other studies were also included. Results from two other studies performed a few months prior were added to increase the sample size. The two other studies consisted of testing 8 or 19 healthy adults with the same protocol as the current study.

Results

A total of 67 participants were included. The average salivary IgA was 125.6 µg/ml. Salivary IgA levels ranged from 25 µg/ml to 344 µg/ml. Two data points were statistical outliers (344 µg/ml and 330.1 µg/ml). The lowest level of 25 µg/ml was from a participant who reported having a “compromised immune system.” The 25th–75th percentile was 81.3 µg/ml – 168.1 µg/ml. The 5th–95th percentile was 40.3 µg/ml – 273.8 µg/ml.

Figure 1. Range of salivary IgA level from 67 participants.



Conclusion

This pilot study that included 67 adult participants found a salivary IgA level to range from 25 $\mu\text{g}/\text{ml}$ to 344 $\mu\text{g}/\text{ml}$. Accredited laboratories have reported the normal range to be from 93–974 $\mu\text{g}/\text{ml}$ (Salimetrics®, with 21 adults), 118–641 $\mu\text{g}/\text{ml}$ (Genova Diagnostics, sample size not reported), and 25–168 $\mu\text{g}/\text{ml}$ (Quest Diagnostics™, sample size not reported). Results from current study match previously published data that utilized standard instrumentation.