# OBTAINING A NORMAL RANGE OF SALIVARY IGA LEVELS IN HUMANS

Technical White Paper

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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.

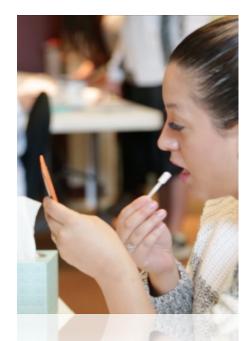
Typically, salivary IgA is determined by a laboratory test called ELISA in which samples are sent to a specialized laboratory for testing. A new instrument that is small, portable, and easy to use has been developed and used in small settings in Europe to assess the immune system status of elite athletes. In this study, 4Life aimed to obtain the normal range of salivary IgA with this instrument by analyzing samples from 4Life employees.

# **STUDY**

There were three studies conducted, which, combined, included 67 participants. Saliva sample collection 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.

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





### RESULTS AND DISCUSSION

Across the 67 participants in the three studies, the average salivary  $\lg A$  was 125.6  $\mu g/ml$ . Salivary  $\lg A$  levels ranged from 25  $\mu g/ml$  to 344  $\mu g/ml$ . Two data points were statistical outliers (344  $\mu g/ml$  and 330.1  $\mu g/ml$ ). The lowest level of 25  $\mu g/ml$  was from a participant who reported having a "compromised immune system." The 25th–75th percentile was 81.3  $\mu g/ml$ –168.1  $\mu g/ml$ . The 5th–95th percentile was 40.3  $\mu g/ml$ –273.8  $\mu g/ml$ .

## CONCLUSION

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