

ORANGE BIOMED CLEARED TO SCALE PRODUCTION OF ITS POCKET-SIZED A1C DEVICE

Global GMP certification paves the way for mass production of lab-quality A1C testing in a portable format

SEATTLE, WA, UNITED STATES, September 3, 2025 /EINPresswire.com/ -- [Orange Biomed](#)—the inventor of the world's first pocket-sized, microfluidic-based A1C analysis device, dedicated to improving access and accuracy in chronic condition care—just cleared a major hurdle on its path to market. The company announced that it has

received Good Manufacturing Practice (GMP) certification for in vitro diagnostic medical devices from Korea's Ministry of Food and Drug Safety, giving it the official go-ahead to scale production of its pocket-sized portable diabetes testing device.

The logo for Orange Biomed, featuring the word "ORANGE" in red and "BIOMED" in red with a green leaf-like shape integrated into the letter "O".

“

This certification proves we can manufacture to global standards and deliver a product people can trust.”

Yeaseul Park, CEO and Co-Founder of Orange Biomed

The device, called the [OBM rapid A1c](#), packs lab-quality hemoglobin A1C testing into a small, easy-to-use unit that works not only in hospitals and clinics but also in pharmacies and even at home. It's powered by the world's first single-cell microfluidic analysis technology, which allows faster, more accurate testing compared to conventional A1C meters—potentially making daily diabetes management far more accessible.

“We think portable, patient-friendly devices like ours will change how people manage chronic conditions,” said Yeaseul Park, CEO of Orange Biomed. “This certification proves we can manufacture to global standards and deliver a product people can trust.”

Orange Biomed is already gaining global recognition. It was recently named to Fortune Korea's “Top 40 Emerging South Korean Healthcare Innovations” and has raised more than USD 7.5

million. The company has showcased its technology at international forums, including the American Diabetes Association's Innovation Hub and the Diabetes Technology Meeting (DTM). The company is now preparing a 510(k) FDA submission as it eyes the U.S. market.

About Orange Biomed

With U.S. headquarters in Seattle, WA, Orange Biomed was launched in 2021 by Duke University alumnus Dr.

Unghyeon Ko and Yeaseul Park to solve unmet diabetes-focused healthcare needs. The healthcare startup innovates cutting-edge technology for diabetes management, including OBM rapid A1c.



The global impact of OBM rapid A1c was recognized in 2024 when the Korean Hospital Association honored it with the prestigious KHF Innovation Award for its revolutionary application of microfluidic technology conducting single-cell analysis.

In 2025 and beyond, Orange Biomed is focused on bringing OBM rapid A1c to U.S. patient-oriented healthcare. The company is preparing a 510(k) submission to the FDA for potential over-the-counter (OTC) clearance of its product, followed by a point-of-care (POC) application submission, further expanding access to innovative diabetes care solutions and more.

Learn more: <https://www.orangebiomed.com>

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