

# Kenota Health Announces FDA Submission for Allergy Testing System

WATERLOO, ON, CANADA, July 20, 2023 /EINPresswire.com/ -- Kenota Health is pleased to announce that the FDA has accepted a Dual Track (Dual 510(k) and CLIA Waiver by Application) submission for their new device, the Kenota 1 System and Kenota 1 Total IgE assay. The system, with its first assay (total IgE), has been designed to bring quantitative IgE testing to the allergy clinic without the need for a full CLIA laboratory license.



The Kenota system has been in development for over four years, with the first FDA meeting in August 2019. Kenota Health completed its internal verification studies in 2022 and finished its CLIA Waiver studies in April 2023.

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*Moufeed Kaddoura, Founder and CEO*

The CLIA Method Comparison study was conducted at three U.S. allergy clinics earlier this year, recruiting over 360 patients, with both fingerstick and venous blood samples, that demonstrated close correlation with an industry-standard laboratory assay.

Kenota CEO and Founder, Moufeed Kaddoura, commented that “we're extremely encouraged by the milestones we've achieved that move us closer to our goal of improving the standard of care for allergy patients.”

Kenota's CTO, Chris Harder, also commented “both the quality of the results of our CLIA studies and the ease-of-use feedback received were excellent validation of the product we've designed.”

With the FDA review of the current submission underway, Kenota Health has begun development work on panels of specific IgE allergen tests to be submitted to FDA under the

510(k) process.

Disclaimer: The Kenota products and assays described above have not been reviewed by U.S. FDA and are not available for sale in the United States. Performance characteristics for the Kenota 1 System have not yet been determined and will be subject to FDA review under the 510(k) Pre-market Submission process.

## About Kenota Health

Kenota Health is a medical technology company based in Waterloo, Canada, with a plan to elevate healthcare with the world's best data and testing. Their first product is a rapid point-of-care system to test for allergic sensitization in the clinic within 30 minutes. Kenota's team is composed of scientists, engineers and operators passionate about transforming the way allergists diagnose and treat allergies.

Moufeed Kaddoura

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