Kenota Health System Receives FDA Clearance and CLIA Waiver Marketing Approval for IgE Testing

First ever CLIA-waiver approved IgE test will deliver in-office results to allergy specialists

The Kenota 1 System

WATERLOO, ONTARIO, CANADA, June 3, 2024 /EINPresswire.com/ -- Kenota Health announced today that its Kenota 1 Total IgE test system has received 510(k) clearance and CLIA waiver marketing approval from the U.S. Food and Drug Administration for the semi-quantitative detection of total IgE. This marks a major accomplishment for the diagnostic company.

This is a major step towards enabling US Allergists and Immunologists to test patients more effectively in their offices. The Kenota 1 Total IgE test will be used by specialists to determine total IgE levels in patients in less than 30 minutes using only a small volume of fingerstick blood. Following a simple setup, the test proceeds without operator intervention. After processing, the results can conveniently be transferred to the attending physician, allowing allergists/immunologists to take immediate steps in the patient care journey. The test is intended to be an aid in the clinical diagnosis of IgE-mediated allergic disorders.

> “This achievement marks the beginning of a new era for IgE testing by delivering rapid, actionable results for allergists and immunologists.”
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> *Moufeed Kaddoura, Founder and CEO*

This waiver was granted based on Kenota’s data, demonstrating its ease-of-use and insignificant risk of reporting an erroneous result. “Kenota has performed rigorous testing with our novel technology and demonstrated that when you truly listen to your customers, great things happen. I am so proud of the team and thankful to our physician

advisors for guiding us to this monumental achievement" added Kenota CTO Chris Harder.

With the Kenota 1 instrument now cleared, Kenota Health continues to develop panels for specific IgE allergen tests, to be submitted to FDA. Using only 4.5 microliters of blood per test gives the Kenota 1 the capability of running between 15-60 IgE tests per run in 30 minutes.

"We are ecstatic to achieve this landmark, which is the culmination of 5 years of development and innovation, catalyzed by some of the most brilliant minds coming together to solve the world's most pressing health issues" commented Moufeed Kaddoura, Founder and CEO of Kenota Health. "This achievement marks not only the beginning of a new era for IgE testing, but also paves the way for Kenota's technology to provide rapid and actionable results for many other biomarkers".

Moufeed also stated that "Kenota Health is keen on forging collaborations with other industry participants to establish its technology as the go-to solution for in-office testing."

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 system to test for patient's allergic sensitizations in the clinic within 30 minutes. Kenota's team is composed of allergists, scientists, engineers, and business operators with experience bringing dozens of tests to the market.

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