

Hitachi Chemical Diagnostics, Inc. Receives FDA 510(k) Clearance for OPTIGEN® AP 3600™, an advanced solution for multiplex allergy testing

(MOUNTAIN VIEW, CA) March 20, 2019 – Hitachi Chemical Diagnostics, Inc. (hereinafter “HCD”), a global leader in multiplex allergy in vitro diagnostics (IVD), announced today that it received 510(k) clearance from the U.S Food and Drug Administration (FDA) for its new high capacity allergy testing instrument, OPTIGEN® AP 3600™ (AP3600).

“The AP3600 provides the connectivity, throughput and automation to bring multiplex allergy diagnostics to the commercial reference laboratory,” says Noriaki Kawata, President and Chief Executive Officer at HCD. “The instrument brings the feature set and functionality required by today’s reference laboratories and maintains a cost-effective and operationally efficient form factor, making it suitable for regional clinics and labs.”

High capacity automation – The AP3600 delivers increased throughput and true walk-away time. The new high capacity instrument can process up to 100 panels, or as many as 3,600 individual allergen results, in a single day.

High quality, reliable results – The AP3600 features the same proven technology used in the OPTIGEN® Allergen-Specific IgE IVD products. The assay platform provides medical professionals with a front-line screening approach for panel allergy diagnosis.

Simplicity of design and ease of operation – The AP3600 provides clinical laboratories with a streamlined process flow from sample collection tube to result. The fully automated system features an on-board, user-friendly operating system; bi-directional Laboratory Information System (LIS) interface; and internal barcode scanners for accurate sample and result identification. An internal controller, traceable to an international standard, automatically verifies instrument performance prior to each sample analysis, greatly reducing preanalytical process times. Kit to instrument on-board reagents further reduce hands-on time for laboratorians.

About Hitachi Chemical Diagnostics, Inc.

Hitachi Chemical Diagnostics, Inc., a subsidiary of Hitachi Chemical Co. America, Ltd., San Jose, California is headquartered in the heart of Silicon Valley in Mountain View, California, and is a global leader of multiplex in vitro allergy diagnostics. The company works with industry leaders, laboratories, and distributors in more than 40 countries. The company holds many in vitro allergy testing technology patents and continues to pioneer advancements in the field. Visit www.hcdiagnostics.com to learn more.

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