Abbott Announces FDA Clearance For Its Alinity™ Ci-Series Next-Generation Diagnostic Systems

- Innovative, harmonized solutions for chemical chemistry and immunoassay testing will help laboratories and hospital systems achieve measurably better healthcare performance

ABBOTT PARK, Ill., Oct. 31, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) has secured U.S. Food and Drug Administration (FDA) 510(k) clearance for its Alinity™ ci-series instruments for clinical chemistry and immunoassay diagnostics. These innovative testing solutions were designed to help the lab more effectively address modern industry challenges, including aging populations, growing management of chronic diseases and increased access to care, which are driving increases in testing volume.

"Healthcare systems across the United States are under pressure to deliver better care for patients," saidBrian Blaser, executive vice president, Diagnostics Products, Abbott. "Labs and healthcare systems are looking for complete solutions that help them operate more efficiently while contributing to better clinical decision making and helping improve patient outcomes. FDA clearance is a key first step in bringing this important innovation to our U.S. customers as we work to gain approval for the full Alinity portfolio of instruments and assays."

The Alinity ci-series is part of a unified family of personalized solutions that are engineered for flexibility and efficiency. The design is based on insights from thousands of customers, resulting in a number of benefits including:

- **Smaller footprint:** Patented stacked design instead of linear makes it half the size of existing systems, allowing for cost-effective volume growth in less space.
- **Improved workflow and greater throughput:** Delivers more than 650 tests per hour per square meter[i], a significant increase compared to other available systems, with the capability to scale up for even greater throughput and the ability to run urgent tests without waiting for prior samples to complete testing.
- **Reduced wait time:** Continuous access to solutions and supplies, giving labs the ability to add tests and reagents without pausing or stopping instruments or testing cycles for prolonged periods of time.
- **Simplified design for error proofing:** Solution bottles designed to work like a lock and key provide error proofing benefits, ensuring the right solutions can only be inserted into the right location and prevent costly mistakes in the lab
- **Enhanced usability:** Intuitive menu design and easy-to-use interface, common to the Alinity family of instruments across the lab, helps manage strained staffing resources.

The "Alinity c" clinical chemistry system, and the "Alinity i" immunoassay system, can operate individually or as an integrated Alinity ci-series unit, allowing for greater productivity in half the footprint of current diagnostics systems. In addition to the instrument clearance, several clinical chemistry and immunoassay tests are now cleared in the U.S. for the system, with a comprehensive menu of tests expected to be available within a year of launch. The Alinity ci-series obtained CE Mark earlier this year and is available in Europe, Middle East, Asia and Latin America[ii].

"Alinity ci was designed using a different approach. We went beyond traditional market research and spent countless hours with our customers, listening to their challenges and observing how they work," said John Frels, Vice President, Immunoassay and Clinical Chemistry Research and Development. "With customer insights as our roadmap, the Alinity ci is engineered to simplify diagnostic testing while ensuring speed, accuracy and performance."

About Alinity
The Alinity portfolio includes clinical chemistry, immunoassay, blood and plasma screening, point of care, hematology and molecular diagnostics, along with Abbott's AlinIQ—a first-of-its-kind, holistic suite of professional services that combines expertise with process analysis and informatics. Alinity is helping labs and hospital systems solve some of their most pressing challenges to deliver better patient care with fewer resources. More information is available at abbott.com/alinity.

About Abbott
At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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[i] Dependent upon clinical chemistry and immunoassay test mix.

[ii] Instrument and test availability can vary by geography.

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