

Waters New Bioseparations Tools Accelerate and Improve Development of RNA-based Vaccines and Therapies Using LC-MS Analysis

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News Summary:

- Waters new LC-MS grade reagents, enzymes, and software simplify large molecule RNA analysis to accelerate and improve development of mRNA vaccines, personalized cancer therapies, and innovative drugs for genetic disorders.
- Novel digestion enzymes deliver complete RNA sequence coverageⁱ for more confident characterization, while new LC-MS-grade reagents increase sensitivity and improve detection accuracy of RNA components.ⁱⁱ
- New waters_connect™ MAP Sequence software accelerates RNA oligonucleotide mapping using semi-automated workflows that reduce data processing time over manual techniques, enabling routine monitoring of key product attributes.

MILFORD, Mass., Oct. 10, 2024 /PRNewswire/ -- Waters Corporation (NYSE: WAT) today introduced a comprehensive set of sample preparation enzymes, reagents, and waters_connect software that simplify sequence and modification confirmation of large molecule RNA therapeutics using liquid chromatography-mass spectrometry (LC-MS) analysis. When used together in a workflow, these bioseparations tools help accelerate and improve the development of innovative large molecule RNA-based pharmaceuticals, such as CRISPR sgRNA and mRNA therapeutics.

Waters new enzymes, reagents, and software help simplify the confirmation of sequence and modifications of RNA molecules

Large molecule RNA (ribonucleic acid) therapeutics represent some of the most exciting and potentially life-saving developments in pharmaceuticals today. They include new and more effective vaccines for diseases like COVID-19, personalized cancer treatments, as well as emerging CRISPR RNA therapies that address challenging genetic conditions, such as sickle cell anemia.

"As RNA-based therapies are prepared for widespread use, more direct composition measurements are needed to ensure stability, safety, and effectiveness for patients," said Erin Chambers, Vice President, Consumables and Lab Automation at Waters Corporation. "The combination of Waters enzymes, reagents, and software are specially designed to simplify the confirmation of sequence and modifications of complex molecules. These analytical tools can accelerate RNA therapeutic development and lower barriers for use by LC-MS non-experts."

"As innovators looking to help our customers advance nucleic acid-based therapies and reduce the burden of serious diseases, we are always seeking new technologies to improve characterization and accelerate development," said Arnaud Delobel, PhD, R&D and Innovation Director at Quality Assistance S.A. and beta tester of the Waters RNA analytical tools. "Waters new enzymes efficiently digest mRNA and sgRNA with short incubation times and data processing in MAP Sequence allows the user to obtain reproducible results quickly with confidence."

The Waters RNA analytical tools include:

- **Enzymes:** Two novel enzymes, RapiZyme™ MC1 and RapiZyme Cusativin, are used in a simplified three-step protocol that provides complete LC-MS sequence coverage over traditional digestion methods enabling more confident characterization of RNA molecules.iii
- **Reagents:** IonHance™ HFIP, an LC-MS-grade reagent, is formulated to improve ionization and delivers increased spectral clarity and detection accuracy of RNA components.
- **Software:** New MAP Sequence application on the waters_connect software platform simplifies RNA LC-MS oligo mapping workflows to accelerate analysis and data processing time over manual techniques using spreadsheets.

Used together within a workflow, the tools generate an LC-MS fingerprint to confirm product identity, purity, and efficacy. The tools improve sequence coverage, LC-MS spectral data quality, and data interpretation. Supported by the compliance-ready waters_connect software platform, these tools help transition LC and LC-MS-based digestion analysis from discovery and development to release and at-line process analytical testing.

Waters RapiZyme RNAses and IonHance HFIP are now available. The new MAP Sequence App on waters_connect software will be available on October 18, 2024.

Additional Resources

- Learn more about the [Waters RNA Analytical Tools](#)
- Listen to our webinar "[Cracking the Code: Analyzing mRNA and sgRNA with Advanced Enzymes, Mass Spectrometry, and Informatics](#)" on Oct. 16 at 11:00am ET
- Join Waters at the PharmSci 360 conference for an expert session on "[Oligo Mapping of Large RNA Therapeutics by Novel Enzyme Specificities](#)" with Dr. Bala Addepalli, Waters Director, R&D New Modalities Portfolio on Oct. 21, at 11:00am ET

- Follow and connect with Waters via [LinkedIn](#), [Twitter](#), and [Facebook](#)

About Waters Corporation (www.waters.com)

Waters Corporation (NYSE: WAT), a global leader in analytical instruments and software, has pioneered chromatography, mass spectrometry, and thermal analysis innovations serving the life, materials, food, and environmental sciences for more than 65 years. With approximately 7,500 employees worldwide, Waters operates directly in 35 countries, including 14 manufacturing facilities, and with products available in more than 100 countries.

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i 100% RNA sequence coverage achieved for HPRT sgRNA digested with RapiZyme MC1 and RapiZyme Cusativin compared to traditional digestion methods such as RNase T1. Waters Application Note 720008539EN: "Tunable Digestions of RNA Using RapiZyme RNases to Confirm Sequence and Map Modifications" .

ii IonHance HFIP reagents are certified to contain less than 100 ppb sodium and less than 100 ppb potassium content, resulting in reduced adduct formation and improved sensitivity of RNA detection compared to commercially available HFIP. Waters Application Note 720008540EN: "Evaluating IonHance Hexafluoroisopropanol (HFIP) for Enhanced LC-MS Oligonucleotide Analysis"

iii Waters RapiZyme RNase protocol simplifies sample preparation with three steps including reagent preparation, RNA digestion, and heat inactivation without the need to add chemical denaturants and enzyme inhibitors.

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