BIONEER

# IR Brief

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## Obtains Top-Tier European CE-IVDR Class D Certification for Molecular Diagnostic Kits targeting Major Chronic Viruses (HIV-1, HBV, HCV)


HIV-1·HBV·HCV MDX Kit ▲

- **Accelerating Entry into Global Procurement Markets with Room-Temperature Transport Technology**
- **Fully Automated Workflow from Specimen Tube Opening to Processing — 93 Specimens Processed in Two Hours**

As part of the Pan-Governmental Medical Device R&D Project, Bioneer's quantitative diagnostic kits for hepatitis B virus (HBV) and hepatitis C virus (HCV), designed for its fully automated molecular diagnostic system, ExiStation™ FA 96, have obtained Class D certification, the highest risk classification under the European Union's In Vitro Diagnostic Medical Devices Regulation (CE-IVDR), following its HIV-1 diagnostic kit.

With the addition of HBV and HCV to its previously certified HIV-1 product, Bioneer has completed a quantitative diagnostic portfolio covering three major chronic viral infections: HIV-1, HBV, and HCV.

The achievement is also significant as the products were developed with Korean capital in a market traditionally led by foreign-invested companies. Bioneer plans to offer a differentiated supply model combining room-temperature-stable reagents with high-speed, fully automated diagnostic instruments, enabling rapid and accurate testing without cold-chain logistics.

## Targeting the KRW 9.2 Trillion Global Viral Load Testing Market

Global viral load testing is a high-value diagnostic market used to monitor treatment response, drug resistance, and disease progression. The global viral load testing market, including HIV and hepatitis, was estimated at KRW 9.2 trillion (USD 6.2 billion) in 2025, with HIV accounting for 42.8% of the market.[1] The HCV viral load testing market alone is projected to grow at a CAGR of 7.4%, from KRW 2.2 trillion (USD 1.48 billion) in 2026 to KRW 2.9 trillion (USD 1.98 billion) in 2030.[2]

Approximately 240 million people were living with chronic HBV infection and 47 million with HCV worldwide as of 2024.[3] In 2025, approximately 40.9 million people were living with HIV, with 32.1 million receiving antiretroviral therapy, supporting continued demand for regular viral load testing.[4]

**Room-Temperature Transport Enabled by Lyophilized Reagents** While the global viral load market has been dominated by multinational companies, cold-chain logistics remain a challenge. Bioneer's lyophilized PCR reagents can be transported at room temperature, reducing transportation and power costs and enabling efficient supply to regions with limited cold-chain infrastructure, including Africa, Southeast Asia, and Latin America.

The solution can also reduce the total cost of testing by minimizing refrigerated transportation and storage costs, power consumption, and product loss caused by cold-chain disruptions, making it well suited for large-scale public procurement in low- and middle-income countries.

## Fully Automated from Tube Opening to Processing — 93 Specimens in Two Hours

ExiStation™ FA 96 automates the entire workflow, from specimen tube opening and closing to nucleic acid extraction, real-time PCR analysis, and result generation. It can process up to 93 specimens within two hours, reducing operator exposure to high-risk specimens as well as cross-contamination and manual errors.

**Targeting European Hospitals and Global Public Procurement Markets** Bioneer plans to expand sales to European university hospitals and large clinical laboratories, while pursuing WHO Prequalification (WHO PQ) to enter public procurement markets in low- and middle-income countries through initiatives such as the Global Fund and PEPFAR.

By combining room-temperature-transportable reagents, fully automated tube handling, and high-throughput processing, Bioneer aims to establish a differentiated supply model and expand its presence across both advanced European markets and public procurement markets in Africa and other low- and middle-income regions.

1) Market Intelo, 「Global Viral Load Testing Market」, 2025.
2) Research and Markets, 「HCV Viral Load Testing Market – Global Forecast to 2030」
3) World Health Organization, 「Global Hepatitis Report 2026」, WHO, 2026.
4) UNAIDS, 「Global HIV & AIDS Statistics — Fact Sheet」, UNAIDS, 2026.


## -Eligible for Direct Contracts with Korea's Public Procurement Service Through 2029, with Opportunities to Participate in Pilot Purchasing Programs
## -A Positive Signal for Expansion into Domestic and Global Public Procurement Markets

Bioneer's high-throughput, fully automated molecular diagnostic system, ExiStation™ FA 96, has been officially designated as an Innovative Product in the Biohealth Sector by Korea's Public Procurement Service (PPS), recognizing its technological capabilities and public value.

ExiStation™ FA 96 will retain its status as an Innovative Product for three years, from June 26, 2026, through June 25, 2029.

Under the designation, ExiStation™ FA 96 will be eligible for direct contracts without separate competitive bidding procedures with central government agencies, local governments, and public institutions during the three-year period. The system will also be eligible for pilot purchasing programs funded by the PPS, helping Bioneer secure initial sales channels in the public sector.

During the same period, public institutions purchasing ExiStation™ FA 96 will be covered by a "purchase immunity" provision, which protects purchasing officials from liability for any issues arising after purchase, unless they are found to have acted intentionally or with gross negligence. The designation is expected to lower barriers to adoption among public healthcare institutions, including regional disease response centers under the Korea Disease Control and Prevention Agency (KDCA), metropolitan and provincial Institutes of Health and Environment, and military hospitals.

### Fully Automated, Safety-First Design Optimized for Next-Generation Public Health Infrastructure

ExiStation™ FA 96 is a "True Full Automation" molecular diagnostic system that fully automates the entire testing workflow—from specimen tube opening and closing to real-time PCR and result analysis—without operator intervention.

ExiStation™ FA 96 is also designed with healthcare worker safety as a top priority. The system features automatic tube de/re-capping, a sealed negative-pressure design, and HEPA and ozone filters to help prevent aerosol exposure and cross-contamination risks when handling high-risk pathogens.

The system also offers competitive advantages in terms of efficiency. Its compact design reduces the required footprint to as little as one-quarter that of competing high-throughput systems, measuring 164 × 75 cm, significantly easing space constraints in laboratories. At the same time, its high-speed processing enables flexible, high-volume testing with results delivered in just two hours.

ExiStation™ FA 96 has obtained Class D certification, the highest risk classification under the stringent European In Vitro Diagnostic Medical Devices Regulation (CE-IVDR). In addition to quantitative PCR assays for HIV, HBV, and HCV, the system has also been certified for a five-pathogen respiratory panel capable of multiplex detection, positioning it to support preparedness for future pandemics.

### Synergy with KOICA GearUp Selection — Targeting Global Public Procurement Markets

Bioneer plans to expand its public procurement achievements into global markets.

On July 20, Bioneer was selected as a "GearUp Global Focus Company" by the Korea International Cooperation Agency (KOICA). KOICA GearUp Global provides tailored support to selected companies based on their needs, ranging from identifying Official Development Assistance (ODA) projects and participating in bids to preparing proposals and strengthening their capabilities to secure contracts.

A Bioneer diagnostics business division official said, "The designation of our product as an Innovative Product by the Public Procurement Service, following Korea's rigorous technology evaluation process, and our selection as a KOICA GearUp supported company for development assistance projects taking place around the same time demonstrate the public value and technological capabilities of our products."

The official added, "Building on these innovative references, we will not only establish a strong foothold in Korea's public procurement market but also actively participate in overseas public procurement and ODA projects to expand global market opportunities for K-Bio."


# AI Designs, ExiProgen Builds
# Protein Synthesis for the Desktop Biofoundry Era

How are the antibody therapeutics we commonly encounter produced? Animal cells (CHO cells) are placed in a large bioreactor and carefully cultured over several weeks, followed by a process of selectively isolating and purifying only the produced proteins. The same goes for insulin, a diabetes treatment. It is manufactured by inserting the insulin gene into E. coli, culturing them in large quantities, and extracting only the desired protein.

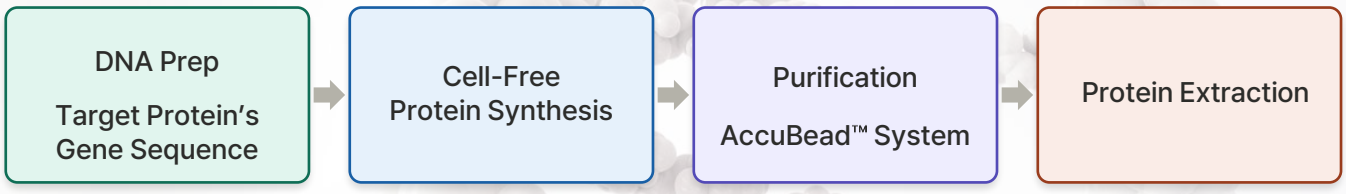
For a long time, the common sense in producing protein biopharmaceuticals was that it must be obtained by 'culturing living cells.' Culturing cells, disrupting them, and purifying only the target proteins required significant manual labor and took anywhere from a few days to several weeks.

However, as AI technology deeply enters life science research, changes are occurring in this long-held common sense. While scientists previously spent long periods conducting experiments and waiting for results, the paradigm is shifting to AI predicting proteins based on data first, followed by rapid experimental validation of those predictions.

At the center of this shift is ExiProgen™. This equipment, which produces proteins when genetic information is input, can be called a 'Protein Printer'—a compact, automated production unit that can be used directly inside the laboratory.

## Input Genes (DNA) and Output Proteins... Cell-Free Protein Synthesis Technology

ExiProgen™ takes a completely different path from conventional methods through Cell-Free Protein Synthesis technology. Instead of culturing whole cells, 'protein synthesis tools (cell extracts)' previously extracted from other cells are prepared in kit form. By loading the kit and the DNA of the protein to be synthesized into the device, proteins are synthesized directly without living cells.




▲ ExiProgen System Workflow

Bioneer's patented AccuBead™ purification system, based on magnetic nanoparticles, works alongside this process to automatically filter out impurities and precisely extract only the high-purity target protein. From DNA input to final protein, the device completes a fully automated, one-stop workflow with minimal human involvement.

## Dramatically Faster

The old method took days to weeks to obtain a single protein. This protein printer can produce up to 16 proteins simultaneously in just six hours.

That means when AI recommends multiple protein candidates, they can be turned into physical results and screened within a day, maximizing R&D efficiency for new drugs and materials.

## Even Proteins Toxic to Cells Can Be Made

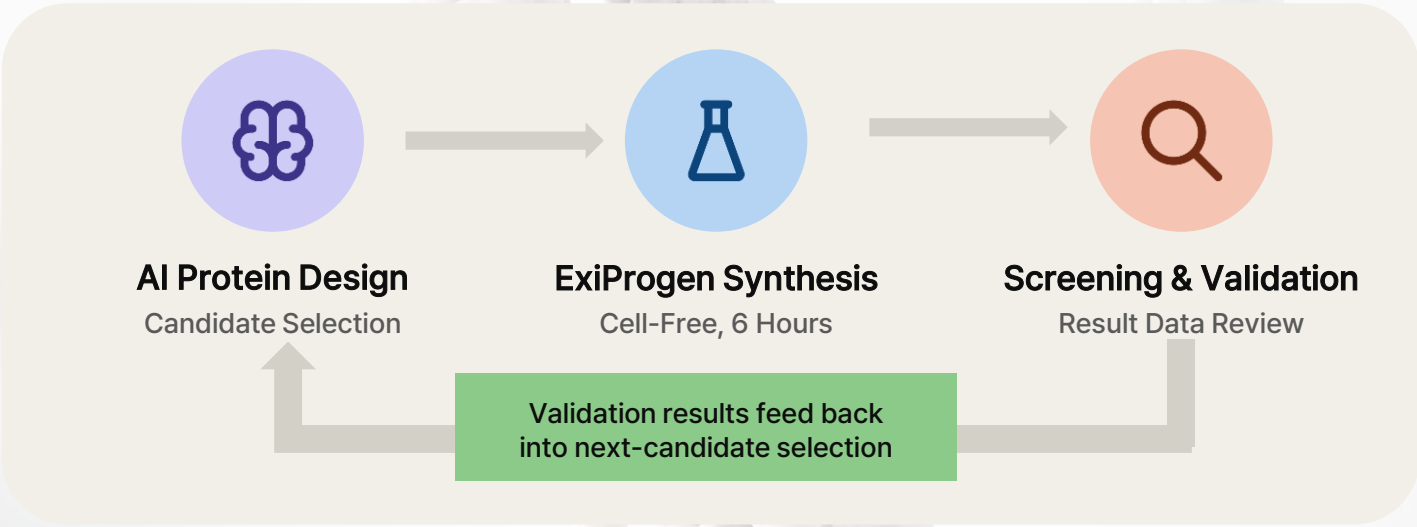
The old method, using living cells, had one major weakness: if the target protein was toxic to the cell, the cell itself would die, making the protein impossible to obtain — and complex-structure proteins were often produced poorly.

ExiProgen™ avoids this problem entirely by not using living cells. Proteins that are toxic or structurally complex can be reliably produced inside this single device.

## No Large Lab Required

Through this protein printer, Bioneer is enabling individual labs to handle everything from gene design to protein production in-house, without large, costly facilities. This is what's called a 'desktop biofoundry' — cutting-edge research made possible with a small, automated device that fits on a lab bench instead of a large factory.

## AI Meets Biology: Cutting Time to Reality




▲ ExiProgen Cuts Experiment Time, Maximizes Efficiency

No matter how good a protein AI designs, if it takes a long time to actually build and verify it, that prediction remains just a possibility. ExiProgen™ cuts that verification process from days or weeks down to six hours, obtaining the desired protein without cell culture and turning AI predictions into experiments quickly.

With gene design through protein production now possible on a single desktop device — no large lab or costly equipment required — more researchers can access new drug and material R&D.

The shorter the time from prediction to experiment, the sooner the new therapeutics and materials we encounter will arrive.

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# Bioneer Signs Exclusive CosmeRNA Deal with Polish Distributor

▲ Bioneer promotes CosmeRNA at WTC 2026 Paris

## -Deal, initial order secured in WTC 2026 Paris follow-up meeting
## -Building a European B2B network for global sales

Bioneer recently agreed on an exclusive distribution deal for its hair-care brand CosmeRNA with a prospective Polish distributor, securing an initial order.

The deal came together during follow-up meetings after The World Trichology Conference 2026 Paris (WTC 2026 Paris), held July 12 in Paris. Bioneer discussed market-entry strategy, clinic/salon distribution, and local launch plans with B2B distributor candidates from France, Spain and Poland, reaching a signed agreement with the Polish candidate.

WTC is an academic trichology conference hosted by the International Association of Trichologists (IAT). CosmeRNA first presented at WTC 2025 in the US last year and returned this year for its second consecutive appearance.

At the conference, Brazilian dermatologist and scalp-care specialist Dr. Ademir Leite Jr. presented CosmeRNA's SAMiRNA technology, explaining its mechanism, application cases, and how it differs from PRP and exosome approaches, drawing strong interest and questions from hair loss and scalp health specialists.

Bioneer said it will follow up with roughly 100 global expert and potential-partner contacts gathered at the conference.

The company plans to work with its distributors in each country to leverage their clinic, salon, and scalp/skin-care professional networks, reinforcing CosmeRNA's positioning as a professional-use product and rolling out sales and marketing strategies tailored to each market.


▲ CosmeRNA, RNA-based premium scalp care

# AceBiome, Lotte Home Shopping Advance BNRThin into Japan


AceBiome took part in LIFESTYLE Week TOKYO 2026, held June 24–26 at Tokyo Big Sight, through a partnership with Lotte Home Shopping, promoting BNRThin's product competitiveness and brand value to Japanese distributors and health-food buyers.

During the exhibition, Lotte Home Shopping, as AceBiome's partner, ran a BNRThin promotional booth and discussed product supply, sales-channel building, and marketing cooperation with local distributors and buyers, helping AceBiome assess consumer demand and distribution conditions in the Japanese health-functional-food market.

BNRThin is Korea's first body-fat-reduction probiotic brand, built on AceBiome's core functional ingredient, Lactobacillus gasseri BNR17. BNR17 is a probiotic isolated from Korean breast milk.

Through a product portfolio addressing both body-fat management and gut health, BNRThin has expanded its footing in the domestic market, growing into a leading diet-probiotic brand with cumulative sales of 20 million units and KRW 1 trillion in revenue.

On the final day of the exhibition, August 26, AceBiome signed an MOU with Lotte Home Shopping to build BNRThin's global brand and expand overseas sales channels. The two companies plan to jointly pursue distribution-channel development, sales strategy, and marketing across Japan and other major Asian markets in stages.

Building on this agreement, AceBiome plans to move its Japan market entry forward while expanding BNRThin's business opportunities into Vietnam and other Asian markets, drawing on its proven domestic brand performance and R&D capabilities in functional probiotics to grow its presence with overseas consumers.


# AceBiome Showcases R&D, Product Portfolio at Microbiology Congress

AceBiome took part in the 2026 Annual Meeting and International Symposium of the Microbiological Society of Korea, held June 24–26 at HICO in Gyeongju, presenting its research capabilities and product portfolio as a microbiome specialist.

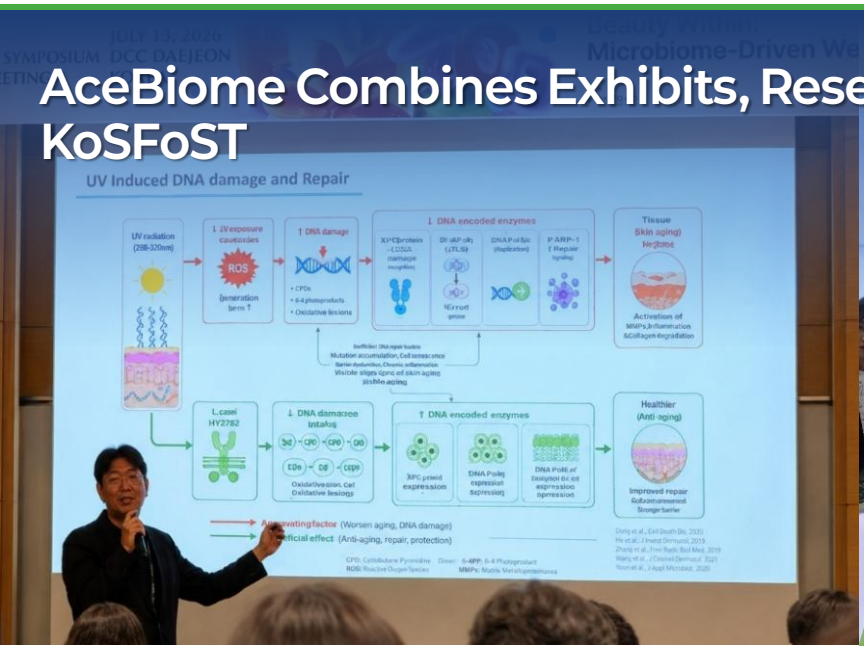
At the event, AceBiome ran a dedicated exhibition booth showcasing its BNR17-based body-fat probiotic brand BNRThin and its ParActin®-based joint-health product AnaParactin, presenting a functional-product lineup spanning body-fat, gut, and joint/bone health.

The booth served to share AceBiome's research direction and ingredient competitiveness with graduate students, researchers, and faculty attending the conference, introducing BNRThin and AnaParactin backed by clinical data.

AceBiome also joined the Career Lounge, running a recruiting booth for graduate students in science and engineering interested in microbiome, probiotics, and functional-material research.

Through this participation, AceBiome strengthened its scientific differentiation and brand recognition while expanding recruiting touchpoints for research talent.

# AceBiome Combines Exhibits, Research and Recruiting at KoSFoST





AceBiome took part in the 2026 KoSFoST International Symposium and Annual Meeting, held August 1–3 at the Daejeon Convention Center (DCC), expanding its industry recognition and academic network in food science, functional materials, and microbiome research.

AceBiome ran a dedicated booth showcasing its key health-functional-food brands, centered on BNR17-based BNRThin and ParActin®-based AnaParactin, addressing body-fat and joint-health needs and highlighting its ingredient-development capabilities to industry attendees.

AceBiome also joined the KoSFoST Job Fair 2026, presenting and consulting with students in food science, health-functional foods, food microbiology, and food biotechnology

to promote recruiting and share its R&D and career vision.

On the academic side, AceBiome sponsored the "Beauty Within: Microbiome-Driven Wellness" session, where principal researcher Chang-min Lee presented research on the skin-health effects of its proprietary strain Lacticaseibacillus paracasei subsp. paracasei ABF21013 (ACE-01), pointing to a research direction extending gut-focused microbiome technology into skin health and inner beauty.

Through this event, AceBiome combined product exhibits, academic presentations, and recruiting outreach. Going forward, the company plans to strengthen research evidence for ACE-01's skin-health benefits and expand market touchpoints for BNRThin and AnaParactin, while building its research hiring pipeline and industry-academia partnerships from the connections made at the job fair.