Purigen Biosystems

PRESS RELEASE

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Purigen Biosystems Adds CE Mark for Ionic® Purification System Launch in UK and European Union

Company rapidly expanding commercial operations to enable more researchers to extract higher yields of DNA and RNA from FFPE samples in one hour with minimal hands-on time

PLEASANTON, Calif. – May 4, 2021 – Purigen Biosystems, Inc., a leading provider of next-generation technologies for extracting and purifying nucleic acids from biological samples, today announced the CE (Conformité Européene) marking of its Ionic® Purification System. Purigen has certified that its products comply with the European Union's performance, safety, and relevant product and service standards requirements. With the marking, Purigen is now able to support clinical and oncology researchers across the European Union and other CE Mark geographies, including the UK. Purigen is also expanding its commercial operations to help meet the growing worldwide demand for its best-in-class nucleic acid purification technology.

Launched in the US market in 2019, the small benchtop Ionic Purification System enables the automated extraction of nucleic acids with dramatically increased yield and quality from a wide range of sample types, including cultured or sorted cells and formalin-fixed, paraffin-embedded (FFPE) tissues. Biological samples are gently lysed and then loaded into the Ionic® Fluidics Chip. The system then applies an electrical field to the chip and the nucleic acids are isolated in their natural, native form using the company's core isotachophoresis (ITP) technology. Since the nucleic acids are not bound or stripped from fixed surfaces, nucleic acid loss and fragmentation are minimized while purification-induced bias is eliminated. The simplified workflow requires minimal hands-on time and produces higher yields of high-quality RNA and DNA that are truly representative of the starting sample.

"Over the past year, we have seen increasing interest in our innovative Ionic Purification System from around the world, especially in the UK and European Union," said Barney Saunders, PhD, CEO of Purigen Biosystems. "I'm proud that our team was able to quickly shift priorities to secure the appropriate regulatory approvals, which has enabled us to expand our commercial operations. Today, we are now able to empower more clinical researchers in Europe with the ability to maximize the utility of their precious samples."

Ionic Purification System Components

The complete Ionic Purification system includes the following components:

- **The Ionic® Purification Instrument** – A small benchtop system driven by a simple touchscreen interface that can process one Ionic® fluidic chip with eight samples in approximately one hour.
- **Ionic® FFPE to Pure DNA Kit** – Consists of six chips and a reagent set with all necessary enzymes and buffers to perform DNA extraction directly from as many as 48 FFPE tissue samples.
- **Ionic® FFPE to Pure RNA Kit** – Consists of six chips and a reagent set with all necessary enzymes and buffers to perform RNA extraction directly from as many as 48 FFPE tissue samples.
- **Ionic® FFPE Complete Purification Kit** – Consists of 12 chips and a reagent set with all necessary enzymes and buffers to perform simultaneous DNA and RNA extraction from 48 samples.
- **Ionic® Cells to Pure DNA Kit** – Consists of six chips and a reagent set with all necessary enzymes and buffers to perform cell lysis and DNA extraction from cultured or sorted cells in up to 48 samples.

PURIGEN® BIOSYSTEMS

About Purigen Biosystems

Purigen Biosystems is redefining nucleic acid sample preparation with an innovative platform based on the highly efficient isotachophoresis technology invented by Juan Santiago, PhD, and his team at Stanford University. Purigen's automated benchtop instrumentation and accompanying microfluidic chip purify nucleic acid samples from a wide variety of sources, including minute or otherwise challenging cancer samples. The purified nucleic acids are then immediately compatible with a wide range of downstream detection methods, including next-generation sequencing, PCR, and other genomic tests. For more information, visit www.purigenbio.com.

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