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News Release

Microbix & API Ensuring Flu Tests Can Detect H5N1 Strain

Pilot Proficiency Testing Program to Validate Accuracy of Molecular Assays

MISSISSAUGA, ON & TRAVERSE CITY, MI – January 13, 2025 – Microbix Biosystems Inc. (**TSX: MBX, OTCQX: MBXBF, Microbix®**), a life sciences innovator, manufacturer, and exporter, and American Proficiency Institute (**API**), a groundbreaking supplier of proficiency testing (“**PT**”) to over 20,000 clinical laboratories, announce the start of a pilot PT program to ensure that molecular diagnostic (“**MDx**”) assays can detect the emerging H5N1 strain of the Influenza A virus (“**H5N1 Flu**”).

Strains of the Flu are named according to variations in the proteins that help them to infect host cells – the Hemagglutinin (“**H**”) protein and the Neuraminidase (“**N**”) protein. There is a heightened risk of a pandemic when one or both of the H or N proteins have not been circulating in human populations. H5N1 is such a relatively novel strain of the Flu virus, which has demonstrated the ability to infect birds, cattle, and humans. H5N1 Flu is now circulating on multiple continents and may become a new pandemic, with it having demonstrated a staggering rate of severe pneumonia and death across those infected thus far.

It is therefore critical to prove whether established MDx tests can accurately and reliably detect H5N1 Flu. Such MDx Flu tests include both regulator-approved assays and laboratory-developed tests, respectively classed as “**IVD**” and “**LDT**”. Clinical labs must objectively prove that every such assay they are using can reliably detect H5N1 Flu – requiring novel quality assessment products (“**QAPs™**”) and new PT programs.

Microbix and API have been collaborating to fulfill this critical and urgent need. Using its virology and synthetic biology expertise, Microbix has created a novel QAP that provides the whole genome of H5N1 Flu, but which does not require use of nor contain any infectious materials. In turn, API is initiating a proficiency testing program whereby clinical labs can independently confirm their MDx assays and the established workflows in use will reliably detect H5N1 Flu. This pilot PT program is now live, and API will invite a limited number of labs to participate before such a program is offered to all API clients.

Sue Harmer, President of API, commented, “API believes it is critical that we determine which widely-used MDx assays can or can’t reliably detect H5N1 Flu. Such knowledge is critical for mounting an effective health system response to this emerging pandemic threat. The API team is proud to be collaborating with Microbix and our clinical lab customers to initiate a PT program that fulfills this urgent need.”

Cameron Groome, CEO & President of Microbix, also commented, “We’re pleased to create the QAPs that enable this vital API PT program to determine which MDx tests will or won’t detect H5N1 Flu. Whether it is classical techniques or cutting-edge synthetic biology, Microbix is fully-staffed and equipped to safely create and manufacture such critically-needed test control products for use around the world.”

Clinical labs can request to enroll in this API pilot PT program by reaching out to TechSupport@api-pt.com and enquiries about Microbix QAPs can be directed to customer.service@microbix.com.

About API

API is a groundbreaking provider of proficiency testing programs for more than 20,000 clinical laboratories around the world. Its programs support all areas of laboratory medicine and is dedicated to improving the accuracy and efficiency of clinical laboratory testing. API's PT programs are approved by the Centers for Medicare & Medicaid Services (CMS), accepted by the College of American Pathologists (CAP), and are internationally accredited under the ISO/IEC 17043:2010 standard through the American Association for Laboratory Accreditation (A2LA). API offers over 300 programs for proficiency testing, as well as free continuing education and competency testing.

About Microbix Biosystems Inc.

Microbix Biosystems Inc. creates proprietary biological products for human health, with over 100 skilled employees and sales now targeting C\$ 2.0 million or more per month. It makes and exports a wide range of critical ingredients and devices for the global diagnostics industry, notably antigens for immunoassays and its laboratory quality assessment products (QAPs™) that support clinical lab proficiency testing, enable assay development and validation, or help ensure the quality of clinical diagnostic workflows. Its antigens drive the antibody tests of approximately 100 diagnostics makers, while QAPs are sold to clinical lab accreditation organizations, diagnostics companies, and clinical labs. Microbix QAPs are now available in over 30 countries, supported by a network of international distributors. Microbix is ISO 9001 & 13485 accredited, U.S. FDA registered, Australian TGA registered, Health Canada establishment licensed, and provides IVDR compliant CE marked products across the EU.

Forward-Looking Information

This news release includes "forward-looking information," as such term is defined in applicable securities laws. Forward-looking information includes, without limitation, discussion of H5N1 and tests for it, the QAPs, the PT program, API, or their relevance, Microbix's products or services, business and business results, goals or outlook, risks associated with financial results and stability, development projects such as those referenced in its presentations, regulatory compliance and approvals, sales to foreign jurisdictions, engineering and construction, production (including control over costs, quality, quantity or timeliness of delivery), currency exchange rates, maintaining adequate working capital or raising new capital on acceptable terms or at all, and other similar statements about anticipated future events, conditions or results that are not historical facts. These statements reflect management's current estimates, beliefs, intentions, and expectations; they are not guarantees of future performance. Microbix cautions that all forward-looking information is inherently uncertain, and actual performance may be affected by many material factors, some of which are beyond its control. Accordingly, actual future events, conditions and results may differ materially from the estimates, beliefs, intentions, and expectations expressed or implied in the forward-looking information. All statements are made as of the date of this news release and represent Microbix's judgement as of the date of this new release, and it is under no obligation to update or alter any forward-looking information.

Please visit <https://microbix.com> or www.sedar.com for recent Microbix news and filings.

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