

Asep Medical Validates its Sepset^{ER} Diagnostic Test in Patients in Leading Scientific Journal, *Nature Communications*.

May 27, 2025 — Asep Medical Holdings Inc. ("Asep Medical" or the "Company") (CSE: ASEP) (OTCQB: SEPSF) (FSE: JJ8) is pleased to announce that its subsidiary Sepset Biosciences Inc. ("Sepset") has demonstrated the efficacy of its Sepset^{ER} test in a peer-reviewed publication in one of the world's leading journals, *Nature Communications*. The test results validated the Sepset^{ER} test in over 3,000 patients from existing independent cohorts, demonstrating 87% accuracy in early intensive care unit (ICU) patients. The *Nature Communications* publication can be viewed <u>here</u>. It overcomes the issue that current diagnostics have a poor ability to identify patients at risk of developing sepsis.

The actual test format, which uses polymerase chain reaction (PCR) that is available in nearly all hospitals, was evaluated in 248 patients and showed 94% sensitivity in predicting that a patient would be diagnosed with sepsis within the following 24 hours, as defined by the Sepsis-3 international standard of high Sequential Organ Failure Assessment (SOFA) scores (greater than a score of 2). Sepsis is defined as organ dysfunction/failure triggered by the body's improper response to an infection.

Sepsis is a major global health concern, with 49 million cases occurring each year and resulting in 11 million deaths, which accounts for 19.2% of all fatalities worldwide. Almost all COVID-19 fatalities were due to sepsis.

"The information from the Sepset test empowers physicians to make decisions about the urgent initiation of sepsis protocols, which involve intensive efforts to combat the disease, including protocol initiation and antimicrobial administration. Research has clearly demonstrated that every hour of delayed diagnosis and treatment of septic patients increases their mortality risk by 7.6%," stated Dr. Rob Stenstrom, Emergency Physician at St. Paul's Hospital and Medical Director of Asep Medical. "The Sepset^{ER} diagnostic assay could have a major impact on mortality risk in patients with sepsis."

The research team initially examined blood samples from 586 hospital patients with suspected sepsis. Using machine learning (a type of AI), Sepset researchers identified six key genes that show changes when the body's immune system is starting to dangerously dysregulate. Identifying this six-gene signature – called "Sepset" — in the patient's blood was key to predicting whether their condition would worsen in the first 24 hours. The test was then validated retrospectively in 3,178 patients. "This demonstrates the immense value of AI in analyzing extremely complex data and both identifying the important genes for predicting sepsis and constructing an algorithm to



accurately predict if a patient is at risk from this deadly disease, sepsis," said Dr. R.E.W. (Bob) Hancock, CEO of Sepset and Asep Medical and University of British Columbia Killam professor.

The test was further developed on a Point-of-Care ("PoC") platform in collaboration with the National Research Council of Canada. Point-of-care (PoC) devices are used to obtain rapid diagnostic results at the bedside or in a clinic and can be used prospectively in hospitals, doctors' offices, or remote clinics. A stand-alone centrifugal microfluidics PoC platform that integrates the entire automated workflow for detecting the Sepset classifier using a drop of the patient's blood was tested on the patient's blood samples¹. This PREcision meDicine for CriTical care (PREDICT) system had a high sensitivity of 92% (correctly diagnosing 92% of patients) and specificity of 89% (correctly eliminating 88% of patients as not requiring expensive and advanced sepsis care) in identifying the risk of imminent clinical deterioration in patients with suspected sepsis.

Based on this exciting data, the Canadian Institutes for Health Research recently announced a non-dilutive grant to the team who performed these studies (led by Unity Health Toronto physician and study lead author, Claudia dos Santos and including Sepset employees) for \$543,150 to conduct an investigator-initiated, prospective, singlecentre, observational study to assess the performance of the PREDICT-PB in the "real world" near-patient environment.

Dr. Bob Hancock, inventor of the technology and co-investigator on the publication, commented, "PoC devices offer a more immediate diagnosis of impending sepsis at the patient's bedside. Our exciting trial results have provided a strong validation of the Sepset^{ER} diagnostic technology. This bodes well for our regulatory clinical studies in North America and beyond." Additionally, Asep Medical's affiliated authors on the publication include Dr. Evan Haney, Chief Scientific Officer and Dr. Peter Zhang, Senior Data Scientist.

About Asep Medical Holdings Inc. & Sepset Biosciences Inc.

Asep Medical Holdings Inc. (asepmedical.com) is dedicated to addressing the global issue of antibiotic failure by developing novel solutions for significant unmet medical needs in human medicine. The Company's lead product was developed through its subsidiary, Sepset Biosciences Inc., which utilizes proprietary diagnostic tools to enable the early and timely identification of sepsis. In addition, it controls two other subsidiaries, ABT Innovations Inc. (broad-spectrum therapeutic agents to address multi-drug resistant biofilm infections), and SafeCoat Medical Inc. (an antimicrobial peptide, anti-fouling medical device coating technology).

Sepset Biosciences Inc. (<u>sepset.ca</u>) is developing a diagnostic technology that involves a patient gene expression signature that helps assess the development of severe sepsis, one of the significant diseases leading to antibiotic



failure, since antibiotics are the primary treatment for sepsis. Sepsis was responsible for nearly 20% of all deaths on the planet in 2017 and essentially all deaths due to COVID-19 and other pandemics. The Sepset^{ER} test is a bloodbased gene expression assay that is straightforward to implement, and results are obtained about an hour after taking a blood sample in the emergency room or intensive care unit. This proprietary diagnostic technology differs from current diagnostic tests, enabling the risk assessment for progression to severe sepsis within 60 minutes of initiating the test. Bacterial culture, the gold standard, provides a diagnosis after ~15 hours but can be as long as three days. Asep Inc. believes its test will enable physicians to make critical, early decisions regarding appropriate therapies, thereby reducing overall morbidity and mortality due to sepsis.

FOR MORE INFORMATION, OR TO ARRANGE AN INTERVIEW WITH DR. HANCOCK OR DR. STENSTROM, PLEASE CONTACT —

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END NOTES

 Malic, L., P.G.Y. Zhang, P. Plant, L. Clime, C. Nassif, D. da Fonte, E.E. Haney, B.-U. Moon, V. Sit, D. Brassard, M. Mounier, E. Churcher, J.T. Tsoporis, R. Falsafi, M. Bains, A. Baker, U. Trahtemberg, L. Lukic, J.C. Marshall, M. Geissler, R.E.W. Hancock, T. Veres, C.C. dos Santos. 2025. A machine learning and centrifugal microfluidics platform for bedside prediction of sepsis. Nature Communications