

Intelligent Bio Solutions Initiates Clinical Study Supporting FDA Clearance and Planned U.S. Market Entry

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Interference Study designed to validate system specificity in the presence of potentially interfering substances commonly encountered in real-world settings

Company expects to complete the study by mid-July 2026, with plans to include results in its FDA 510(k) submission package, along with data from the concurrent Method Comparison Study

NEW YORK, June 16, 2026 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced the initiation of an Interference Study to support its FDA 510(k) submission for U.S. market clearance of its Intelligent Fingerprinting Drug Screening System for detection of the opiate codeine.

The Company has again partnered with CenExel Clinical Research, Inc. to complete the clinical study. The Interference Study will assess how potentially interfering substances may impact the Intelligent Fingerprinting Drug Screening System's accuracy and reliability. The study will enroll 75 healthy adult participants who will be evaluated under both undosed and dosed conditions while handling substances that could potentially interfere with test results. This rigorous protocol aims to show the system maintains codeine specificity, even when subjects have handled everyday substances before testing.

Interference testing is a critical FDA requirement that validates whether a diagnostic system can distinguish the target analyte from other substances encountered in daily life or workplace environments. The study evaluates whether handling common interferents affects the system's ability to accurately detect codeine, preventing false-positive or false-negative results that could have serious consequences for workplace drug screening programs.

The study's protocol includes multiple collection time points, with results confirmed via liquid chromatography-tandem mass spectrometry ("LC-MS/MS") analysis. This comprehensive approach ensures accurate system performance in varied real-world scenarios.

"Interference testing is critical to delivering a specific, reliable drug screening solution," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "By rigorously testing how everyday substances might affect our system, we address a fundamental workplace drug screening concern by delivering results employers and employees can trust. This study is an important step toward FDA clearance and reinforces the robustness of our drug testing technology."

The Interference Study will run concurrently with the Company's Method Comparison Study and follows the clinical Cut-off Study that commenced in January 2026. Together, these three complementary studies form a comprehensive clinical package designed to meet FDA 510(k) requirements and demonstrate the safety, accuracy, usability, and specificity of the Intelligent Fingerprinting Drug Screening System.

The study will follow FDA guidance and ICH GCP (International Council for Harmonisation Good Clinical Practice) Guidelines. The Company expects to finish the study by mid-July 2026. Results will be included in its FDA 510(k) submission package, along with data from the Cut-off Study and Method Comparison Study.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering intelligent, rapid, non-invasive testing solutions. The Company believes that its Intelligent Fingerprinting Drug Screening System will revolutionize portable testing through fingerprint sweat analysis, which has the potential for broader applications in additional fields. Designed as a hygienic and cost-effective system, the test screens for the recent use of drugs commonly found in the workplace, including opiates, cocaine, methamphetamine, and cannabis. With sample collection in seconds and results in under ten minutes, this technology would be a valuable tool for employers in safety-critical industries. The Company's current customer segments outside the U.S. include construction, manufacturing and engineering, transport and logistics firms, mining, drug treatment organizations, and coroners.

For more information, visit: <https://ibs.inc/>

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation

Reform Act of 1995, and involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, statements regarding Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefits from its partnerships and collaborations, secure regulatory clearance or approvals, and timelines to enter the U.S. Market, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, actual results may differ materially from those expressed or implied by such statements. Intelligent Bio Solutions Inc. has attempted to identify forward-looking statements by terminology, including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," and "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those described in Intelligent Bio Solutions' public filings with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of the date of this release. Intelligent Bio Solutions undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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