

Intelligent Bio Solutions Achieves Above 98% Accuracy in Method Comparison Study, Supporting Planned 2026 FDA 510(k) Submission

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Multi-site clinical study delivers strong performance data for Intelligent Fingerprinting Drug Screening System

NEW YORK, Sept. 01, 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 results of its latest Method Comparison Study for its Intelligent Fingerprinting Drug Screening System (the "System") to detect the opiate codeine. Conducted across three independent U.S. clinical sites, the study represents the most comprehensive evaluation of the System in the Company's FDA 510(k) clinical study program. The study results show substantially improved performance compared to the Company's prior Method Comparison Study, announced in November of 2024.

The purpose of the study was to evaluate the System's consistency and reliability across diverse clinical environments. The study followed established clinical research guidelines and evaluated the sensitivity, specificity, and accuracy of the Intelligent Fingerprinting Drug Screening System in pre-employment and workplace screening environments.

Method Comparison Study Results

	Site 1	Site 2	Site 3	Total
Parameter				
True Negative	48	45	51	144
False Negative	1	2	1	4
True Positive	27	27	16	70
False Positive	0	0	0	0
Sensitivity	96.4%	93.1%	94.1%	94.6%

Specificity	100%	100%	100%	100%
Accuracy	98.7%	97.3%	98.5%	98.2%

The System demonstrated accuracy above 98%, sensitivity above 94%, and specificity of 100% for the opiate codeine. These figures represent a notable increase from the Company's previous study, which reported approximately 94% accuracy and 82% sensitivity. The System's 100% specificity, unchanged from the prior study, continues to confirm its ability to correctly identify samples that do not contain the target drug, a critical requirement for workplace drug testing applications where false positives can carry significant consequences. Results were measured against a validated liquid chromatography-tandem mass spectrometry ("LC-MS/MS") reference method.

"These results have been a long time in the making," said Harry Simeonidis, President and CEO of Intelligent Bio Solutions. "Our System was already delivering 100% specificity, but we knew we needed to close the gap on sensitivity. Moving from approximately 82% sensitivity to above 94%, and in doing so lifting our overall accuracy to above 98%, is the outcome we were working toward. With this study complete, we now have everything we need for our 510(k) submission, which remains on track for submittal in calendar 2026."

The results form a critical component of the Company's 510(k) submission package. With all data collection now complete, the Company has accelerated its filing timeline and expects to submit its 510(k) application in September 2026, supporting its planned entry into the U.S. market following FDA clearance.

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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