

HTG's New HTG Transcriptome Panel Launched with Commercial Availability in the U.S. and Europe

August 5, 2021

HTG Transcriptome Panel designed to measure approximately 20,000 mRNA targets using the HTG EdgeSeq technology Intended to serve as one of the technological cornerstones for the recently announced HTG Therapeutics Business Unit

A third white paper highlighting the HTG Transcriptome Panel's design, performance, and broad applicability now available

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After nearly 18 months of feasibility testing, design and development, HTG has completed formal design verification, and has produced a third white paper (White Paper Three) which provides an overview of the design and performance of the HTG Transcriptome Panel.

"Today's release of the HTG Transcriptome Panel represents the culmination of months of hard work on this exciting next-generation panel by our Tucson-based development teams. The commercially available panel includes several important chemistry improvements, such as advanced probe design, reduced background and improved sensitivity, while retaining all the benefits of the HTG EdgeSeq technology that our customers have come to expect and appreciate. Given its broad gene coverage, this highly versatile product is intended to be used for profiling disease, identifying new drug targets, developing molecular classification tools, and biomarker discovery. The HTG Transcriptome Panel is expected to be one of the technological cornerstones for our recently announced therapeutics business unit, where it will be used to profile and inform target identification and drug discovery," said Dr. Marian Navratil, Senior Vice President of Research & Development.

White Paper Three further demonstrates the design and performance of the HTG Transcriptome Panel, including:

- Low sample input In the studies performed, the recommended sample input for formalin-fixed paraffin-embedded (FFPE) samples was determined across five different cancer types (melanoma, lung, breast, prostate and colorectal) to be much less than a typical core needle biopsy, and most often less than a single FFPE section.
- Robustness of the final workflow and panel A precision study using five cancer types (melanoma, lung, breast, prostate and colorectal) run across multiple production lots, operators, days, and instruments achieved overall high precision in FFPE samples, illustrating that the HTG Transcriptome Panel is robust and repeatable.
- Accuracy of differential expression The accuracy of differential expression was evaluated in a direct comparison to RNA-Seq across multiple cancer indications. These results were consistent with the previous findings from feasibility which demonstrated accuracy using a spiked-in reference material in a complex FFPE matrix, a tissue mixture study, and a direct comparison to RNA-Seq. Together these studies illustrated equivalent accuracy of differential expression analysis compared to RNA-Seq.
- Robust alternative to RNA-Seq These studies demonstrate that the HTG EdgeSeq technology is a robust alternative to RNA-Seq for gene expression profiling, in addition to maintaining advantages such as lower sample input, extraction-free chemistry and the ability to test low-quality and limited quantity FFPE tissue specimens.

In addition to the launch of its HTG Transcriptome Panel, HTG has commercially released for immediate availability HTG EdgeSeq Reveal version 4.0.0, adding additional features and software functionalities to support, among other things, data analysis for the HTG Transcriptome Panel.

Byron Lawson, Senior Vice President and Chief Commercial Officer added, "We have seen significant interest in and anticipation for our HTG Transcriptome Panel since we introduced the panel to our EAP collaborators in late 2020. We will continue to work with our EAP collaborators to highlight real-world applications using the panel to answer complex research questions in oncology, immunology, and other fields. We are very pleased with the response this product has already received from EAP and non-EAP customers alike and look forward to beginning work on several planned programs with additional customers who have been waiting for our final product release to begin studies. We look forward to the additional opportunities that we believe the HTG Transcriptome Panel will create for HTG as our sales teams begin to broadly sell the product with the commercial release for sale in the U.S. and Europe."

About HTG:

HTG is focused on NGS-based molecular profiling. The company's proprietary HTG EdgeSeq technology automates complex, highly multiplexed molecular profiling from solid and liquid samples, even when limited in amount. HTG's customers use its technology to identify biomarkers important for precision medicine, to understand the clinical relevance of these discoveries, and ultimately to identify treatment options. Its mission is to empower precision medicine. To learn more, visit www.htgmolecular.com.

Safe Harbor Statement:

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding: our HTG Transcriptome Panel, including its expected uses, capabilities and performance; potential future opportunities and programs using the HTG Transcriptome Panel; the utility and use of our HTG EdgeSeq technology; and our ability to grow our customer base and penetrate new markets. Words such as "believe," "will," "planned," "intend" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based upon management's current expectations, are subject to known and unknown risks, and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation, risks associated with the impact of the COVID-19 pandemic on us and our customers; the risk that our HTG Transcriptome Panel and/or HTG EdgeSeq technology may not have the utility and be used by our customers as we expect; risks associated with our ability to develop and commercialize our products, including the HTG Transcriptome Panel: the risk that our products and services may not be adopted by biopharmaceutical companies or other customers as anticipated, or at all; our ability to manufacture our products to meet demand; the level and availability of third party payor reimbursement for our products; our ability to protect our intellectual property rights and proprietary technologies; our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; competition in our industry; additional capital and credit availability; our ability to attract and retain qualified personnel; and product liability claims. These and other factors are described in greater detail in our filings with the Securities and Exchange Commission, including without limitation our Quarterly Report on Form 10-Q for the period ended March 31, 2021. All forward-looking statements contained in this press release speak only as of the date on which they were made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Source: HTG Molecular Diagnostics, Inc.