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Study Demonstrates Contrived Materials Can Reliably Validate Liquid Biopsy Tests

BLOODPAC Project Shows That Commercially Available Biosample Replacements Successfully Put Assay Performance to the Test

CHICAGO, Feb. 22, 2023 – The Blood Profiling Atlas in Cancer Consortium (BLOODPAC) published "Contrived Materials and a Data Set for the Evaluation of Liquid Biopsy Tests: A Blood Profiling Atlas in Cancer Community Study" in the February issue of *The Journal of Molecular Diagnostics*. The paper summarizes work led by BLOODPAC's JFDI (Just Freaking Do It) Working Group, to assess the consistency and usefulness of contrived materials, commercially available replacements for patient samples, across nine different validated assays.

"Patient biosamples are inherently limited, and contrived materials that mimic cell-free circulating tumor DNA are essential to putting liquid biopsy assays through their paces and ensuring that tests perform as intended," said Kelli Bramlett, Senior Director of R&D, Thermo Fisher Scientific and co-chair of the JFDI committee. "In our study, the tests performed successfully with the contrived materials and identified the allele frequencies we expected."

To explore the use of contrived materials in validating liquid biopsy assays, BLOODPAC worked with member companies to lead a comparative multicenter study of commercially available ctDNA formulations. The nine independent laboratories used their own proprietary testing procedures to evaluate the concordance, sensitivity, and specificity of these contrived materials with known variant-allele frequencies (VAFs). The contrived materials used in the study were the Multiplex I cfDNA Reference Standard Set by Horizon Discovery and Seraseq ctDNA Complete Mutation Mix by SeraCare Life Sciences Inc.

Study authors reported that assays were most concordant and sensitive when VAFs were greater than 0.1% and less concordant and sensitive when VAFs were lower than 0.1%, a finding consistent with prior studies evaluating the use of materials derived from patients. Findings demonstrate that contrived materials can help overcome the limited availability of clinical samples and help both assay developers and regulators understand the accuracy, reproducibility, and repeatability of tests.

"This project reflects the spirit of BLOODPAC's collaborative work. By demonstrating that contrived materials can reliably validate tests across settings and types, we've helped establish an important element of continuity in 'pressure testing' assays and ensuring they work as expected in clinical settings," said Lauren Leiman, Executive Director of BLOODPAC. "Because the materials we tested are 'off the shelf,' we're also ensuring that we're not creating a barrier to entry for innovators in the field."

The study methods align with guidelines established by the Association for Molecular Pathology (AMP) and build on prior work, including BLOODPAC's generic protocols for analytical validation and minimum technical data elements for liquid biopsy data submitted to public databases, as well as the CTDNA Quality Control Materials Project, led by the Biomarkers Consortium funded by the Foundation for the National Institutes of Health.

"As someone who manages biobanking activities and helps define protocols, BLOODPAC's JFDI program is exactly what we need to advance best practices in how we collect and store biospecimens, to ensure maximum utility for researchers, maximum impact for biospecimen donations, and ultimately, maximum clinical benefit for patients," said Stella Somiari, PhD, Senior Director at Windber Research Institute and member of BLOODPAC's Analytical Validation working group.

The results of this study open the door for BLOODPAC to contribute to initiatives that will, among other opportunities, deepen the understanding of how contrived materials perform in relation to clinical samples. Ongoing initiatives include BLOODPAC's own molecular residual disease (MRD) project, as well as its participation in the Cancer Moonshot 2.0 project PROMETHEUS (Project for Military Exposures and Toxin History Evaluation in US service members).

"To meet the needs of patients and to be useful in guiding important care decisions, regulators, clinicians and payers need to be able to trust the information delivered by liquid biopsy assays," said Bramlett. "Building rigorous and accessible methods for validating tests is an essential step in building an industry-wide standard, and helps accelerate the process of bringing innovative technologies to clinical settings that can improve patient outcomes."

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About the Blood Profiling Atlas in Cancer (BLOODPAC):

The Blood Profiling Atlas in Cancer (BLOODPAC) is focused on accelerating the development and validation of liquid biopsy assays to improve the outcomes of patients with cancer. BLOODPAC is a nonprofit consortium managed by the Center for Computational Science Research, Inc. (CCSR), which is an Illinois-based not-for-profit corporation. Today, over sixty organizations have pledged support by contributing liquid biopsy data, protocols, and expertise into an open data commons.

BLOODPAC participants include: Adela Inc., American Cancer Society (ACS), Arkansas Bioinformatics Consortium (ARBIC), Association for Molecular Pathology (AMP), AstraZeneca, Bio-Rad Laboratories, Breast Cancer Research Foundation (BCRF), Bristol Myers Squibb, C2i Genomics, the Center for Translational Data Science at the University of Chicago, The Center for Genetic Medicine Research at Children's National Medical Center (CNMC), Ceres Nanosciences, College of American Pathologists (CAP), Daiichi Sankyo, Delfi Diagnostics, Eli Lilly and Company, Exact Sciences, The Food and Drug Administration (FDA), Focused Ultrasound Foundation, Foundation Medicine Inc., Freenome, Friends of Cancer Research, GlaxoSmithKline, GRAIL, Guardant Health, Horizon Discovery, Illumina, Inivata, LGC/SeraCare, LUNGevity Foundation, Memorial Sloan Kettering Cancer Center, Merck, Movember Foundation, Natera, National Cancer Institute (NCI), Novartis, OncoRNA Lab at Ghent University, Open Commons Consortium (OCC), Personal Genome Diagnostics (PGDx), Personalis, Pfizer, Prostate Cancer Foundation (PCF), Prostate Cancer Clinical Trials Consortium (PCCTC), Quest Diagnostics, SiO2 Materials Science, Streck, Sysmex Inostics Inc., Tempus Labs, Thermo Fisher Scientific, University of Chicago, University of Southern California, U.S. Department of Veterans Affairs (VA), Windber Research Institute.

For more information on how to contribute or participate in BLOODPAC, an open consortium, please visit www.BLOODPAC.org.