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ILLUMINA TruSight Oncology 500 Sequencing Panel Validation at A Large Community Based Hospital

Sandeep Kumar

John Schwartz

Mitual Amin

Jennifer Kilbourn

Hlee Vue

See next page for additional authors

Authors

Sandeep Kumar, John Schwartz, Mitual Amin, Jennifer Kilbourn, Hlee Vue, Susan Daraiseh, and Kausar Jabbar

Conclusions: Multiplex chromogenic IHC is a powerful high-throughput tool that preserves tissue. It makes possible the precise assessment of more than one marker per section with the ability to reveal exact spatial context and proximity between cells and/or certain molecules. The automated platform in our use works based on simultaneous and sequential cycles using chromogens with broad absorbance spectra without destaining steps and does not need the integration of a scanner, imaging microscope, or analytic software. Evaluation of the staining can be easily performed with a conventional bright field microscope. Chromogenic multiplex IHC, as exemplified by our IO pentaplex and lung cancer triplex panels, is a powerful companion diagnostic for immune checkpoint inhibitor therapy guidance.

894 ILLUMINA TruSight Oncology 500 Sequencing Panel Validation at A Large Community Based Hospital

Sandeep Kumar[1], John Schwartz[1], Mitual Amin[2], Jennifer Kilbourn[1], Hlee Vue[1], Susan Daraiseh[1], Kausar Jabbar[1]
[1]Beaumont Health, Royal Oak, Royal Oak, MI, [2]William Beaumont Hospital, Royal Oak, MI

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Background: With growing efficacy of targeted therapy, it is critical to have comprehensive tumor profiling. TruSight Oncology 500 (TSO500) is a hybrid capture based next generation sequencing (NGS) assay that enables comprehensive genomic profiling of tumor samples. TSO500 includes 523 cancer-related genes which provides identification of pertinent single nucleotide variants (SNV), insertions and deletions (Indels), splice variants, fusions, copy number variants (CNV), tumor mutational burden (TMB) and microsatellite instability (MSI), from genomic DNA and RNA.

Design: We evaluated the performance of TSO500 using a combination of 102 formalin fixed paraffin embedded (FFPE) tumor types, 41 hematologic samples and 27 reference standard samples (Images 1A and 1B). The clinical samples were previously tested by reference laboratories using NGS. Test performance considered optimal with specimens containing at least 10% tumor cells, and nucleic acid concentration of at least 3.3 ng/µL for DNA and 4.6 ng/µL for RNA. Library preparation performed using hybrid capture based TruSight Oncology 500 Library Preparation Kit and sequenced on Nextseq 550/500. Sequenced data analyzed using TSO500 local app and analysis pipeline customized in collaboration with PierianDX.

Results: For clinical samples, SNVs with at least 3 % allele frequency and at least 100X depth of coverage detected with 97% sensitivity. Indels with 3% allele frequency and depth of coverage at least 100X detected with 95% sensitivity. CNVs with 3 or greater copies detected with 94% sensitivity. RNA fusions detected with 72% sensitivity. TMB values determined without the need for matched normal DNA. (Table 1)

Variant Type	Clinical Samples Only	Reference Standards & Clinical Samples
	Sensitivity	Sensitivity
SNV	97%	99%
Indels	95%	98%
CNVs	94%	98%
RNA Fusions	72%	92%

Figure 1 - 894

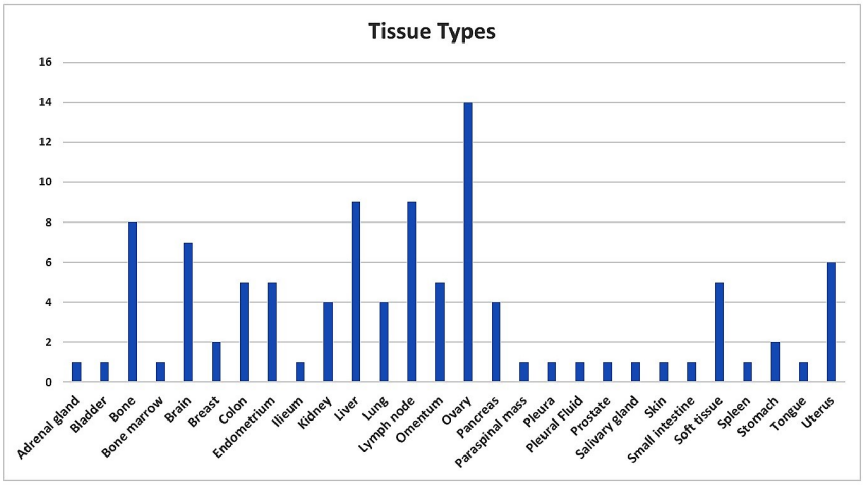

Image 1A: Solid Tumor Tissue Source of Extracted DNA and RNA used for TSO500 Assay.

Figure 2 - 894

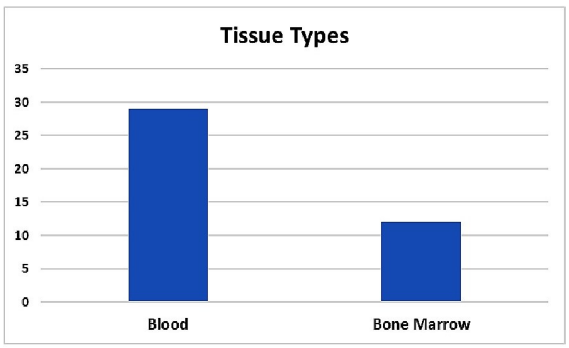

Image 1B: Hematologic Tissue Source of Extracted DNA and RNA used for TSO500.

Conclusions: Use of a large cancer panel, like TSO500, allows detailed and simultaneous assessment of SNVs, fusions, CNVs, in a single assay at low variant allele frequencies (VAFs) with a high degree of sensitivity and specificity. This comprehensive oncology panel can also assess biomarkers such as TMB and MSI, both of which are helpful in patients stratification for targeted and immune therapy.

895 FIBI: Novel, Direct-to-Digital, Slide-Free Histology for Rapid, High-Quality Imaging of Tissue Specimens

Richard Levenson[1], Farzad Fereidouni[2], Taryn Morningstar[1]
[1]UC Davis Health, Sacramento, CA, [2]University of California, Davis, Sacramento, CA

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Background: The traditional histology workflow in pathology, based on formalin-fixation, paraffin-embedding, microtomy, mounting on glass slides, staining and delivery for review, is now recognized as a logistical challenge, especially if the process has to be followed by whole-slide scanning to create a digital image. Frozen sections used for rapid tissue imaging, come with their own drawbacks. A method that can go directly from thick (unsectioned) tissue specimens, either fresh or fixed, to diagnostic-quality histology while skipping most of histology workflow,