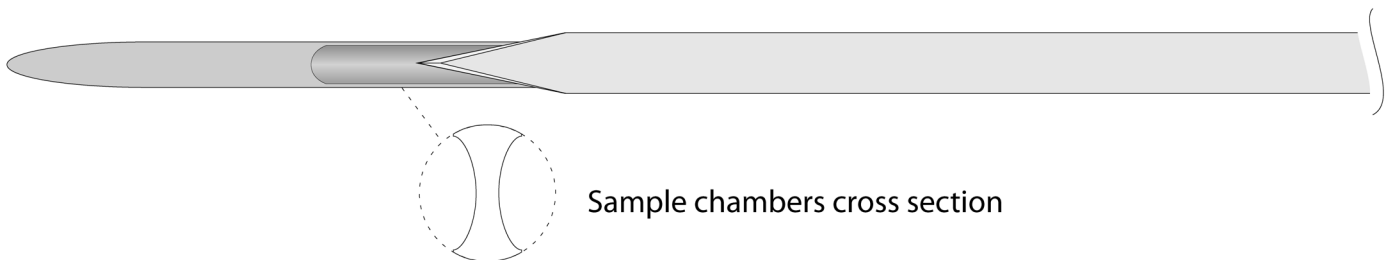


## Tissue collection for molecular assays

The Twin Sample™ needle collects two biopsy samples in one pass. One sample is processed in the normal fashion in formalin and satisfies the pathologist. The second can be reserved for molecular assays and also serves as a back-up sample. The sharp edge of the stylus point splits the tissue; the two samples on opposite sides of the stylus were joined and their architecture is comparable. Therefore, tumor-rich areas identified in the first sample by the pathologist can be isolated in the second sample, provided the tissue orientation is preserved.

The second tissue sample will reduce sample inadequacy as a cause of assay failure, currently reported for 15 – 20% of patients when the remaining tissue block from a biopsy is the only source of analyte. Although analysis of mRNA extracted from formalin-fixed, paraffin-embedded (FFPE) samples has improved, this mRNA is still degraded. Currently, assay developers have to compromise on signal clarity and intensity because they are limited to working with the left-overs from a single biopsy. A full fresh-frozen biopsy will deliver more and better quality mRNA, protein, miRNA or whatever analyte is being tested in the molecular assay.

The needle design mimics a conventional Tru-cut biopsy needle, but with two sample chambers and two cutting beaks on the cannula. Since it delivers more tissue, the Twin Sample™ needle is two gauges larger than its comparable single sample needle; a 12G Twin Sample™ needle replaces the 14 G conventional needle, and a 16 G Twin Sample™ replaces the 18G conventional needle. The 30% increase in diameter is compensated by the smoother point of the Twin Sample™, which is designed to minimize damage and will also travel straighter than the angled point of a conventional Tru-cut needle.



The Twin Sample™ biopsy needle will feature echo location marks, compatibility with biopsy guns (or semi-automatic actuator) and MRI compatibility.

Twin sampling provides a separate biopsy sample for RNA extraction or other diagnostic test. The second sample can be forwarded directly to a central lab; the work of tracking a single biopsy through a series of tests is eliminated. Sample inadequacy is eliminated as a cause of assay failure. Making high quality tissue available in sufficient quantity will improve molecular assay results and foster personalized medicine.