

LGC SeraCare: A Global Partner for NGS Reference Materials and Controls

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[InstandNGS4P](#)

Partnerships and Collaborations Advancing Development and Adoption



CRADA, Biosynthetic solid tumor, MATCH, ctDNA



ccfDNA amplification and analysis



PDX, ctDNA, Exosomes



ctDNA standardization, CTC reference materials



Solid tumor, Fusions, Interlab, iQ NGS software, QC metrics



Tumor mutational burden, NGS assay harmonization



CRADA, ctDNA performance testing, dPCR vs NGS, DNA methylation



ctDNA reference material commutability, NGS analytical validation, clinical validation of 14 biomarkers, FDA



Assay validation, CAP CLIA certification



ctDNA NGS assay standardization & data commons



TMB Working Group, NGS assay standardization, validation, clinical support



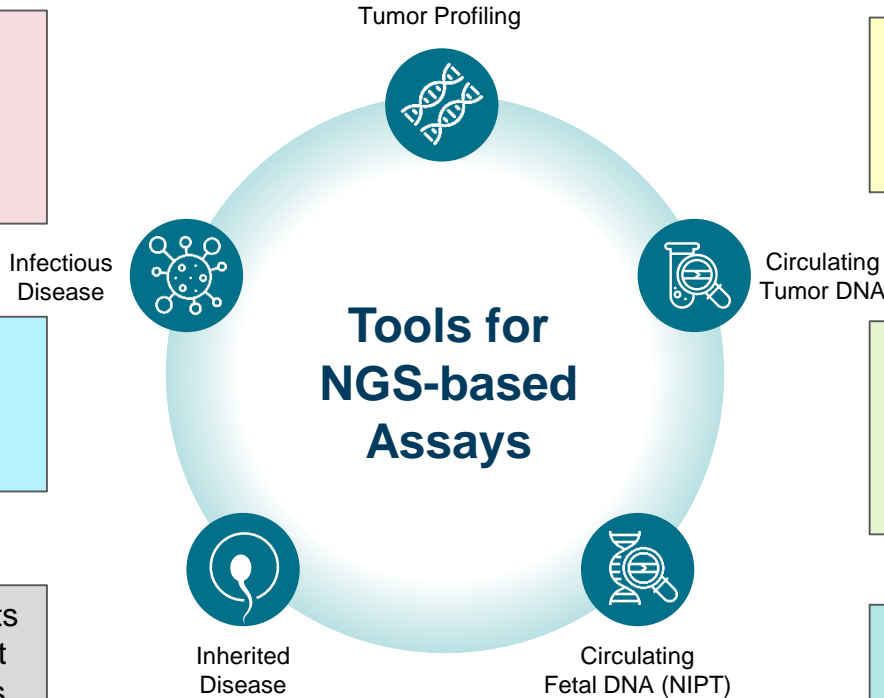
LGC-SeraCare Capabilities



Biosynthetic spike-in technology for any clinically relevant variant (and variant type) of interest

Multiplex controls provide rich source of data in a single run at low cost

Library of >350 variants across different variant types – SNVs, INDELS, CNVs, SVs, and RNA Fusions.

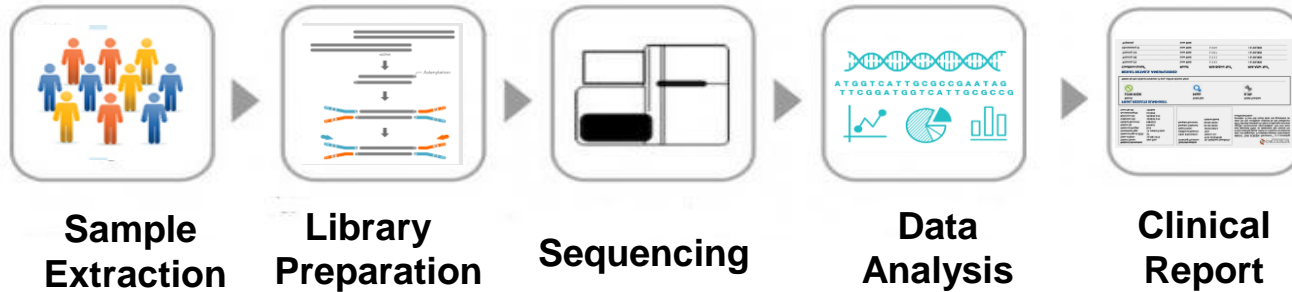


Patient-like reference materials in multiple formats - gDNA/RNA/ FFPE/Plasma

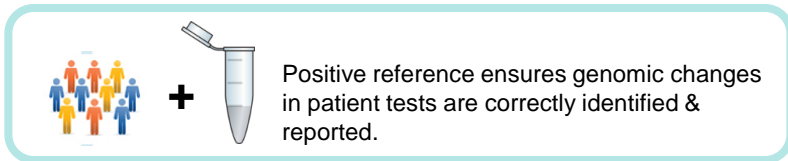
Unique immuno-oncology reference portfolio supports cutting edge research and patient stratification based on complex signatures

Customizable and well characterized to expedite NGS assay development, validation, QC and proficiency testing (EQA)

Next Gen Sequencing needs Next Gen Quality Controls - Seraseq[®] Oncology Products



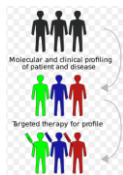
- Developed specifically for NGS platforms
- Well-characterized GIAB GM24385 genomic background
- cGMP manufactured to ISO 13485 standards
- US-FDA audited manufacturing facilities
- Global IVD product manufacturer for >30 years



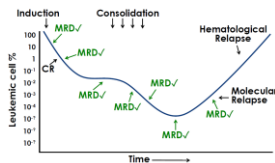
Clinical Oncology NGS Applications & LGC Solutions



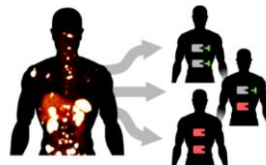
Profiling Diagnosis/Prognosis



Disease/Treatment Monitoring



Immuno-Oncology / Treatment Response



Regulated NGS assays (CDx / IVD)



Solutions Offered

Tumor profiling

- Tumor DNA/FFPE
- CNVs DNA/FFPE
- Myeloid DNA/RNA
- Lymphoma DNA/FFPE
- Fusion RNA/FFPE
- WT (FFPE/TNA)
- Whole Transcriptome RNA-Seq

Solutions Offered

Liquid biopsy

- ctDNA v2 & Complete™
- cfTNA (cfDNA + cfRNA)
- ctDNA MRD
- Me-ctDNA

Solutions Offered

TMB: Tumor Mutational Burden

- gDNA/FFPE
- TMB Reference Panel (Score 3-to-40)
- Blood TMB
- Transcriptome eTMB

MSI: MicroSatellite Instability

- gDNA/FFPE
- MSI Reference Panels
- MSI-High

Solutions Offered

- Custom solutions for solid tumor and liquid biopsy assays
- Support analytical validation for FDA/CE-IVD submission
- QC controls for kit release
- In-kit controls to NGS OEMs

Seraseq[®] Reference Materials are NGS Platform Agnostic and Support All Major NGS Assays



Assay	DNA variants	RNA fusions	TMB / MSI
Illumina TruSight Oncology 500	☑	☑	☑
Illumina TruSight RNA Fusion		☑	
Illumina Ampliseq myeloid	☑	☑	
Thermo Oncomine	☑		
Thermo Oncomine cfDNA/cfTNA	☑	☑	
Archer Reveal / VariantPlex / FusionPlex	☑	☑	
Agilent SureSelect / MASTR	☑	?	
Qiagen QIASeq	☑	☑	
Roche AVENIO ctDNA	☑		
FoundationOne CDx	☑		☑
Guardant 360 CDx	☑	☑	
SOPHiA Genetics STS			☑

Contacts



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Thank you!

Science for a safer world

