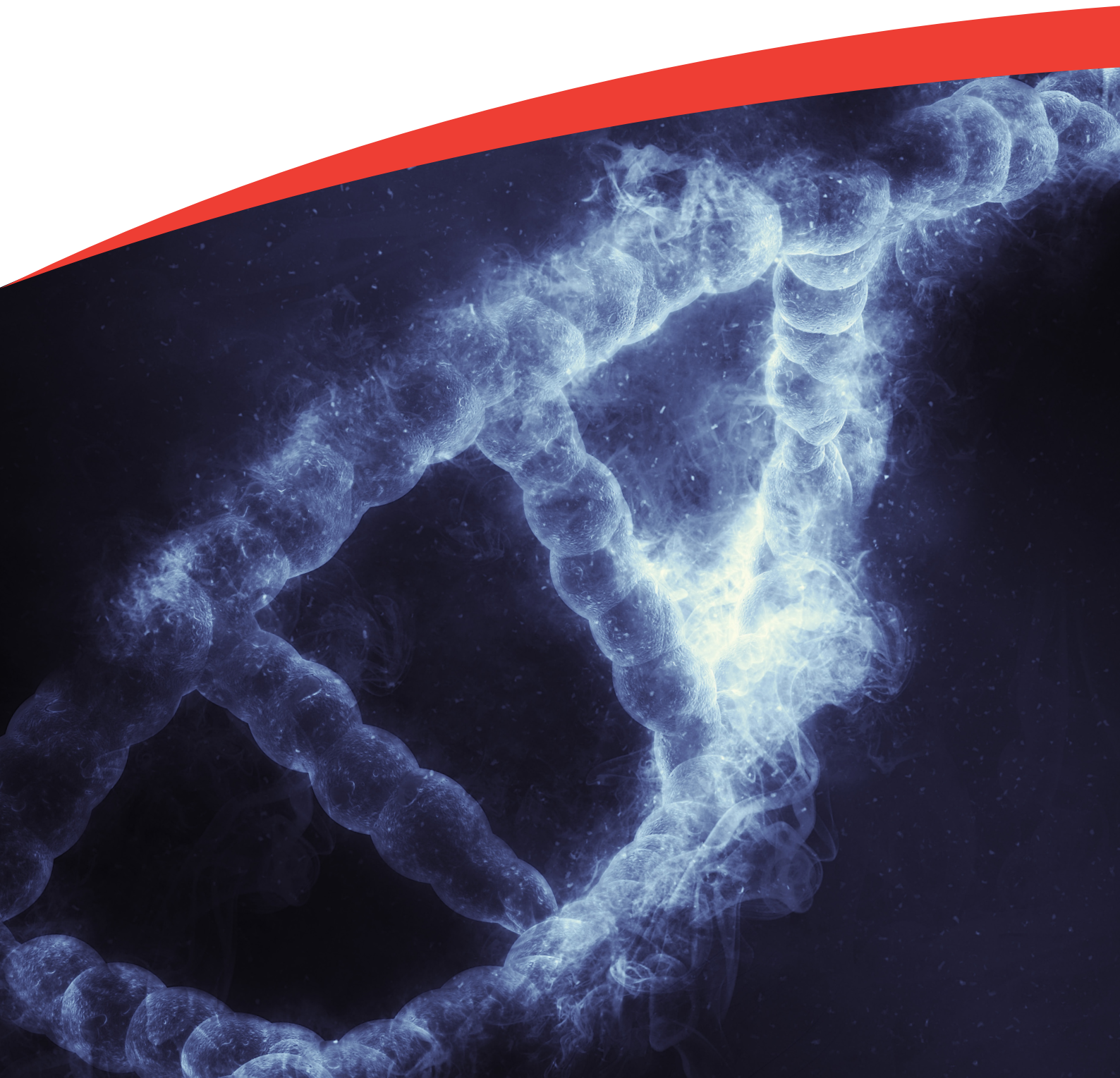




Partnering to Advance Human Health

# Performance specifications of the Almac Illumina TruSight<sup>®</sup> Tumor 170 clinical trial assay



## Assay background

The Almac Illumina TruSight® Tumor 170 clinical trial assay is a qualitative assay intended to detect genomic aberrations in formalin fixed paraffin embedded (FFPE) solid tumour tissue. The assay detects aberrations in both DNA and RNA enabling determination of molecular eligibility to facilitate clinical trial enrolment.

## Analytical validation

The Almac assay has been analytically validated in accordance with CLIA requirements. The validated assay is suitable for use in prospective clinical testing for the determination of molecular eligibility for small variants and fusion calls.

In accordance with regulatory guidance, an appropriate quality model has been established in addition to the development of process controls ensuring the validity of data output by the assay.

## Performance specification

Small variant calling	Upper 95% Confidence Interval		
	Insertions	Deletions	SNV
Accuracy: positive percentage agreement (germline and somatic calls combined)	97.08	96.09	97.16
Sensitivity (germline calls)	100	98.34	99.99
Specificity (germline calls)	99.72	99.72	99.69
Repeatability (within batch across three batches)	94.37-99.58	96.31-99.87	99.63-99.87
Reproducibility	98.74	99.01	99.88
Limit of detection (variant frequency)	5%	5%	5%

DNA panel coverage	
Detection power at 100X coverage	88% power to detect variant at 10% allele frequency
Detection power at 288X coverage	99% power to detect variant at 5% allele frequency
Panel coverage at 100X	93.21
Panel coverage at 288X	88.22

Fusion Calling	Upper 95% Confidence Interval
Accuracy: positive percent agreement	94.79
Accuracy: negative percent agreement	99.53
Positive repeatability (within batch across three batches)	98.728-100
Negative repeatability (within batch across three batches)	99.998-99.999
Positive reproducibility	99.578
Negative reproducibility	99.998
Limit of detection (variant frequency)	15 fusion copies per cell equivalent of total RNA

The full analytical validation report is available on request from Almac Diagnostic Services

[Visit the website](#)