

Performance specification of the Almac TP53 clinical trial assay



Assay background

The Almac TP53 clinical trial assay is a qualitative assay intended to detect genomic aberrations in Formalin Fixed Paraffin Embedded (FFPE) solid tumour, lymph node & bone marrow samples. The assay detects aberrations in DNA 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 variant 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

Performance parameter	Performance established
Accuracy: positive percentage agreement	91.14% (85.55% Lower 95% CI, 94.93 Upper 95% CI)
Sensitivity	100% (67.56% Lower 95% CI, 100% Upper 95% CI)
Specificity	100% (99.96 Lower 95% CI, 100% Upper 95% CI)
Repeatability (within batch across three batches)	100% (99.99% Lower 95% CI, 100% Upper 95% CI)
Reproducibility	100% (100% Lower 95% CI, 100% Upper 95% CI)
Limit of detection (variant frequency)	5%
Reportable range	chr17 7572905 to 7573028 chr17 7573892 to 7574036 chr17 7576836 to 7577195 chr17 7577498 to 7577624 chr17 7578142 to 7578625 chr17 7579257 to 7579592 chr17 7579699 to 7580036 chr17 7590708 to 7591470

Assay coverage

Isoform ID	Transcript ID	CDS ID	% CDS Covered	CDS not Covered
Isoform a	NM_000546.5	CCDS11118.1	100	N/A
Isoform a	NM_001126112.2	CCDS11118.1	100	N/A
Isoform c	NM_001126113.2	CCDS45605.1	95.39	Exon 10
Isoform b	NM_001126114.2	CCDS45606.1	96.78	Exon 10
Isoform d	NM_001126115.1	CCDS73966.1	100	N/A
Isoform e	NM_001126116.1	CCDS73968.1	94.76	Exon 6
Isoform f	NM_001126117.1	CCDS73967.1	92.56	Exon 6
Isoform g	NM_001126118.1	CCDS73969.1	100	N/A
Isoform h	NM_001276695.1	CCDS73970.1	94.81	Exon 10
Isoform i	NM_001276696.1	CCDS73971.1	96.37	Exon 10
Isoform j	NM_001276697.1	CCDS73963.1	100	N/A
Isoform k	NM_001276698.1	CCDS73965.1	93.99	Exon 6
Isoform l	NM_001276699.1	CCDS73964.1	91.49	Exon 6
Isoform g	NM_001276760.1	CCDS73969.1	100	N/A
Isoform g	NM_001276761.1	CCDS73969.1	100	N/A

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

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