

## Oncology

# AcroMetrix Hotspot Frequency Ladder

A next generation sequencing (NGS) validation ladder featuring **555 hotspots** representative across various cancers at varying tumor burden levels. For use in **analytical validation** of various oncology NGS assays.

As oncology testing expands in the clinical setting, laboratories are challenged with finding highly characterized, standardized, and reproducible quality control materials to support validation or verification of new assays.

Prior to reporting patient results, validation or verification is required to establish or verify the performance characteristics of a new assay.

The Thermo Scientific™ AcroMetrix™ Solid Tumor product line now includes a new product developed for research use only.

Product	Regulatory Classification	SKU	Variants	7 Levels
AcroMetrix Hotspot Frequency Ladder	Research Use Only	10026229	555 Hotspots	50%, 25%, 15%, 10%, 5%, 2.5%, Variant Allele Frequency and Negative Control

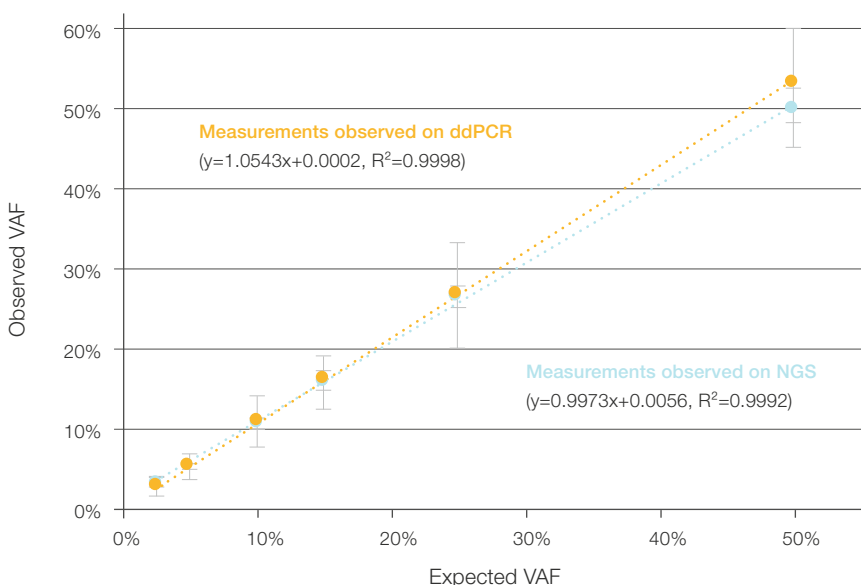


**Table 1. Core targeted genes:** 555 mutations including 504 SNV, 2 MNV, 29 DEL, 19 INS and 1 complex indel all in one control sample.

ABL1	CTNNB1	FLT3	JAK2	NOTCH1	SMARCB1
AKT1	EGFR	FOXL2	JAK3	NRAS	SMO
ALK	ERBB2	GNA11	KDR	PDGFRA	SRC
APC	ERBB4	GNAQ	KIT	PIK3CA	STK11
ATM	EZH2	GNAS	KRAS	PTEN	TP53
BRAF	FBXW7	HNF1A	MET	PTPN11	VHL
CDH1	FGFR1	HRAS	MLH1	RB1	MAP2K1
CDKN2A	FGFR2	IDH1	MPL	RET	NPM1
CSF1R	FGFR3	IDH2	MSH6	SMAD4	

**Table 2. Analytical validation data generated:** The AcroMetrix Frequency Ladder can be used to generate data for the listed analytical validation metrics.

<b>Reproducibility</b> <ul style="list-style-type: none"> <li>Inter-operator</li> <li>Intra-run</li> <li>Inter-run</li> <li>Inter-instrument</li> </ul>	<b>Cross-sample contamination</b> <ul style="list-style-type: none"> <li>On-instrument</li> <li>Cross-library prep</li> </ul>
<b>Accuracy</b> <ul style="list-style-type: none"> <li>Sensitivity</li> <li>Specificity</li> </ul>	<b>Limit of Detection</b> <ul style="list-style-type: none"> <li>Coverage</li> <li>Frequency</li> <li>DNA Input</li> </ul>



Expected VAF%	Observed ddPCR VAF%	Observed NGS VAF%
50.0%	50.0%	52.5%
25.0%	26.3%	26.7%
15.0%	15.8%	15.8%
10.0%	10.6%	10.9%
5.0%	5.1%	5.1%
2.5%	2.8%	2.4%

**Figure 1. AcroMetrix Hotspot Frequency Ladder ddPCR results:** AcroMetrix MegaMix™ technology containing 550+ variants was used to prepare highly multiplexed samples at six different allelic frequencies.

## Clinical Diagnostics

**USA**  
 46500 Kato Road  
 Fremont, CA 94538 USA  
 Tel. 800-232-3342 / +1 510-979-5000  
 sales.diagnostics.fmt@thermofisher.com

**Asia Pacific**  
 Tel. +65 6499 9999  
 cdd.asia.info2@thermofisher.com

**Australia**  
 Tel. +61 1800 333 110  
 auinfo@thermofisher.com

**Canada**  
 Tel. +1 905-286-4290  
 CDD.Canada@thermofisher.com

**China**  
 Tel. +86 400 650 5118  
 sales.china@thermofisher.com

**France, Belgium (Brussels / Wallonia) & Luxembourg**  
 Tel. +33 (0) 1 40 86 65 00  
 cdx.fr.info@thermofisher.com

**Germany**  
 Tel. +49 (0) 3302 883 608  
 cdx.de.info@thermofisher.com

**Hong Kong**  
 Tel. +852 3107 7600  
 sales.hk@thermofisher.com

**Italy**  
 distributor.cdd@thermofisher.com

**Japan**  
 Tel. +81 (0) 120 489 211  
 JPYOK-CDD.QC@thermofisher.com

**Netherlands & Belgium (Flemish)**  
 Tel. +49 3302 883 660  
 Info.benelux.cdd@thermofisher.com

**New Zealand**  
 Tel. +61 0800933 966  
 nzinfo@thermofisher.co.nz

**Nordic**  
 Tel. +46 8 594 691 30  
 info.nordic.cdd@thermofisher.com

**Russia**  
 Tel. +7 495 739 76 41  
 info.btd.moscow@thermofisher.com

**South Africa**  
 Tel. +27 11 792 6790  
 support-za.idd@thermofisher.com

**Spain & Portugal (Iberia)**  
 Tel. +34 93589 8338  
 CDD.Info.ES@thermofisher.com

**Switzerland & Austria**  
 Tel. +41 26 663 86 70  
 cdx.ch.info@thermofisher.com

**United Kingdom & Ireland**  
 Tel. +44 1442 868 940  
 cdx.UK.info@thermofisher.com

**For Countries Not Listed**  
 distributor.cdd@thermofisher.com

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