



MEASURE THE DNA THAT MATTERS.

ASSAY FEATURES

- MEASURES THE DNA THAT MATTERS: PCR-AMPLIFIABLE DNA
- PROVIDES ACTIONABLE GUIDANCE THAT RESCUES LOW-QUALITY DNA AND HELPS ASSURE THE ACCURACY OF NGS CALLS
- A 2-IN-1 ASSAY: DISTINGUISHES LOW-QUALITY,
 UNAMPLIFIABLE DNA FROM DNA WITH SAMPLE-DERIVED
 PCR INHIBITION
- SIMPLE, HIGH-THROUGHPUT WORKFLOW USING A CONVENIENT MULTIPLEXED DESIGN

EXTENSIVELY VALIDATED IN PEER-REVIEWED PUBLICATIONS

1866 RESIDUAL CLINICAL FFPE SPECIMENS FROM 13 COHORTS

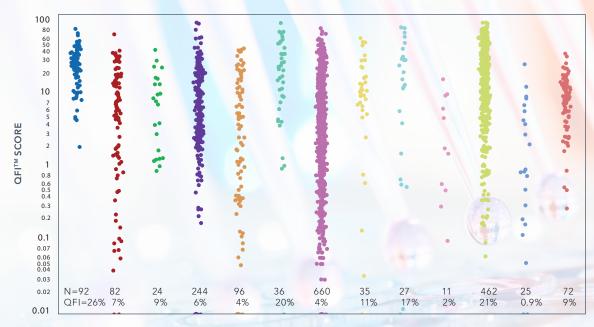


Figure 1: The QuantideX® qPCR DNA QC Assay has been assessed with >2000 FFPE and FNA tumor biopsies across more than a dozen different cohorts. Each sample is represented by its corresponding QFI™ Score.



GUIDES DNA INPUT TO IMPROVE THE ACCURACY OF NGS VARIANT CALLS AND RESCUES FALSE POSITIVE AND NEGATIVE CALLS

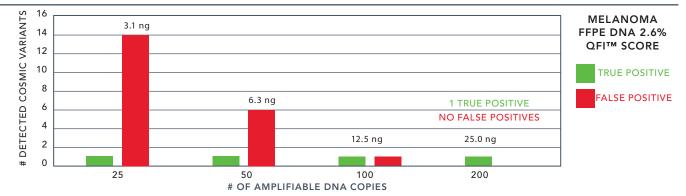


Figure 2: The specificity of NGS mutation detection can be dramatically improved by increasing the input of amplifiable DNA from a low-quality FFPE tumor biopsy (QFI Score= 2.6%). Although the expected BRAF V600E mutation is detected at all inputs, the number of false positives is significantly increased at lower copy number inputs. The QuantideX® qPCR DNA QC Assay informs an input of 200 amplifiable copies, which is associated with detection of a single variant, the expected BRAF V600E mutation. The mass inputs at the top of each bar were measured using spectrophotometry.

IDENTIFIES PCR INHIBITORS PRESENT IN THE SAMPLE

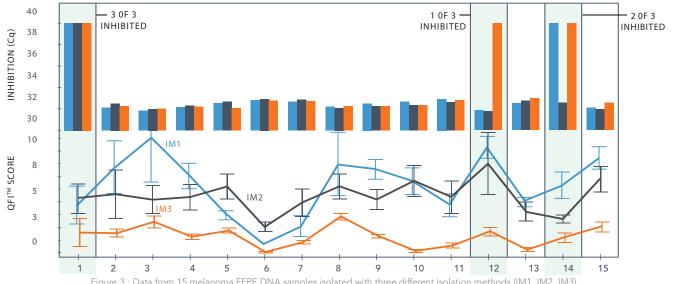


Figure 3 : Data from 15 melanoma FFPE DNA samples isolated with three different isolation methods (IM1, IM2, IM3).

A high Cq is an indicator of inhibition in a sample.

PROVIDES ACTIONABLE GUIDANCE FOR DNA INPUTS INTO DOWNSTREAM NGS ENRICHMENT STEPS

SAMPLE NAME	DNA INPUT (ng)	INHIBITION	AMPLIFIABLE COPY NUMBER PER µL	QFITM SCORE
SAMPLE A	10	PASS	300	10.0
SAMPLE B	10	PASS	856	28.5
SAMPLE C	15	FAIL	FAIL	FAIL
SAMPLE D	5	AT RISK	56	3.7
SAMPLE E	20	PASS	8	0.1

Figure 4 : Actionable results generated from the QuantideX® qPCR DNA QC Assay. The results identify PCR inhibition, reveal the DNA quality score (QFI™ Score), and prescribe volume inputs based on sample-specific DNA copy number for theoretical detection of a 5% variant.

KIT ORDERING INFORMATION

QUANTIDEX® qPCR DNA QC ASSAY [P/N 49539] 100 Reactions.

*Research Use Only. Not for use in diagnostic procedures.

REFERENCES

- Functional DNA quantification guides accurate next-generation sequencing mutation detection in formalin-fixed, paraffin-embedded tumor biopsies. Sah et al. Genome Med 2013;5(8):77
- 2. Evaluation of an integrated clinical workflow for targeted next-generation sequencing of low-quality tumor DNA using a 51-gene enrichment panel. Choudhary et al. BMC Med Genomics 2014;(7):62
- 3. Variation in pre-PCR processing of FFPE samples leads to discrepancies in BRAF and EGFR mutation detection: A diagnostic RING trial. Kapp et al. J Clin Pathol 2015;(68):111-118

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