

## FFPE DNA Reference Standard (Sections)

**IMPORTANT:** Centrifuge tube prior to opening to prevent loss of product

### PRODUCTION INFORMATION

<b>Manufacturing QMS Status</b>	ISO 9001 and ISO 13485
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### PROPERTIES

<b>Format</b>	15 µm section
<b>Storage Conditions</b>	+4°C
<b>Use By</b>	Stable for 48 months from date of manufacture

### QUALITY CONTROL

TEST	TEST METHOD	ACCEPTANCE CRITERIA	PASS/FAIL
Allelic Frequency	Droplet Digital™ PCR+	<ul style="list-style-type: none"> <li>0%, accepted range = ≤0.1%</li> <li>1 - 5%, accepted range = ±30%</li> <li>&gt;5% - ≤20% accepted range = ±20%</li> <li>&gt;20% accepted range = ±10%</li> </ul>	Pass
Genotype			
Quality	Agarose gel electrophoresis	Bright band of high molecular weight	Pass
Quantification	QuantiFluor® assay (Promega) *	≥ 400 ng*	Pass
+Acceptance criteria example, 1- <5%, accepted range = ±30%, for 1% this represents a range of 0.7 – 1.3%. * DNA extraction performed using Maxwell® 16 FFPE plus LEV DNA Purification Kit (Promega)			

### CUSTOMER SUPPORT

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