

## Product Insert

### Product Name

|                                      |                    |
|--------------------------------------|--------------------|
| ○ Wildtype POLE-POLD1 FFPE Control   | Part No.: D181-000 |
| ○ 5% POLE p.P286R FFPE Control       | Part No.: D181-001 |
| ○ 5% POLE p.F367S FFPE Control       | Part No.: D181-002 |
| ○ 5% POLE p.V411L (G>C) FFPE Control | Part No.: D181-003 |
| ○ 5% POLE p.S459F FFPE Control       | Part No.: D181-004 |
| ○ 5% POLD1 p.S478N FFPE Control      | Part No.: D181-005 |

### Description

The **POLE/POLD1 Mutation Controls** are full-process reference materials designed for use with molecular assays that detect POLE and POLD1 mutations. Each product contains **10 µm FFPE tissue slices** embedded with cellular DNA carrying either wildtype genes or one of the following mutations:

- **POLE:** p.P286R, p.F367S, p.V411L (G>C), p.S459F
- **POLD1:** p.S478N

Each mutation is present at approximately **5% allele frequency**.

### Instruction for use

1. Allow the product vial to reach **room temperature** before use.
2. Process single or multiple curls using the **same extraction protocol** as for patient samples.

### Expected Results

Each 10 µm FFPE curl typically contains:

- **~100,000 copies** of the wildtype gene
- **~5% mutant allele frequency** in mutation control samples
- An average DNA yield of **~200 ng**

Refer to the product's **Certificate of Analysis (CoA)** for exact values.

### Storage

- Store at **2–8°C** or lower for optimal DNA stability.
- Shelf life: **2 years** from the date of manufacture when stored under recommended conditions.

### Quality Control

1. DNA quantity is measured using the **DeNovix High Sensitivity DNA Assay**.
2. Copy numbers of wildtype and mutant DNA are determined by **droplet digital PCR (ddPCR)**.

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