Product Insert

Product Name

O **Wildtype PIK3CA-AKT1 FFPE Control**	**Part No.: D182-000**
O **5% PIK3CA-AKT1 Panel1 FFPE Control**	**Part No.: D182-001**
O **5% PIK3CA-AKT1 Panel2 FFPE Control**	**Part No.: D182-002**
O **5% PIK3CA-AKT1 Panel3 FFPE Control**	**Part No.: D182-003**
O **5% PIK3CA-AKT1 Panel4 FFPE Control**	**Part No.: D182-004**
O **5% PIK3CA-AKT1 Panel5 FFPE Control**	**Part No.: D182-005**
O **5% PIK3CA-AKT1 Panel6 FFPE Control**	**Part No.: D182-006**
O **5% PIK3CA-AKT1 Panel7 FFPE Control**	**Part No.: D182-007**

Description

The **PIK3CA-AKT1 Mutation Controls** are full-process reference materials designed for use with molecular assays that detect PIK3CA and AKT1 mutations. Each product contains **10 µm FFPE tissue slices** embedded with cellular DNA carrying either wildtype genes or one of the following mutations:

- **PANEL1**: R88Q, N345K, E542K, Q546K, G1049R
- **PANEL2**: C420R, E545K, M1043I, H1047R
- **PANEL3**: R88L, N345I, E545G, Q546L, H1047L
- **PANEL4**: N345S, C420S, E545A, Q546E, H1047Y
- **PANEL5**: C420G, Q546R, G1049S
- **PANEL6**: E545D
- **PANEL7**: AKT E17K

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:

- **~200,000 copies** of the wildtype gene
- **~5% mutant allele frequency** in mutation control samples
- An average DNA yield of **~400 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)**.

FOR RESEARCH USE ONLY

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