

ESR1 Control Kit**PRODUCT DESCRIPTION:**

ESR1 Control Kit is formulated with synthetic ESR1 DNA containing 16 different ESR1 mutations at a 1% allele frequency in TE buffer (10 mM Tris pH 8.0, 0.1 mM EDTA) as listed in **Table 1**.

INTENDED USE:

ESR1 Control Kit (0860016) can be used as reference material for various ESR1 mutation detection assays. It has been designed for use in the following applications.

- Run control for PCR- and NGS-based ESR1 mutation assays
- Verification/Validation control
- Reference material for ESR1 assay development
- ESR1 spike-in experiments

MATERIALS SUPPLIED:

- 4 x 20 µL vials and 1 x 100 µL vial of wt cfgDNA control.

ADDITIONAL CONTROL (sold separately):

- 0860005 cfgDNA Normal Female Standard Background (1µg in TE buffer)

WARNINGS AND PRECAUTIONS:

- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- Store at ≤ -10°C.

INSTRUCTIONS FOR USE:

- Thaw the tubes on ice or at room temperature.
- Centrifuge briefly to collect liquid in the bottom of the tube.
- Mix by pipetting up and down 10 times or by gently flicking the tube.
- The DNA is ready for use, no DNA purification is required.
- Vial 5, the wt control, may be used to reduce the allele frequency to 0.5%. If a lower allele frequency is desired, ZeptoMetrix 0860005 cfgDNA Normal Female Standard Background (1µg in TE buffer) is recommended.

LIMITATIONS:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- Optimal DNA concentration and allele frequency may vary depending on the ESR1 assay being performed. While ESR1 mutations and allele frequency have been determined using ddPCR, variation may be observed due to differences in assay characteristics.
- This product is not intended to replace the manufacturer's controls provided with the assay.

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EXPECTED RESULTS:

Each laboratory must evaluate the control and establish their own performance criteria.

Table 1

Catalog Number	Vial	ESR1 Mutation	Expected Result
0860016	1	S463P	S463P is detected
		L536H	L536H is detected
		Y537S	Y537S is detected
		D538G	D538G is detected
	2	E380Q	E380Q is detected
		P535H	P535H is detected
		L536P	L536P is detected
		Y537C	Y537C is detected
	3	S463C	S463C is detected
		L536R	L536R is detected
		Y537N	Y537N is detected
		K303R	K303R is detected
	4	S463F	S463F is detected
		V534E	V534E is detected
		L536Q	L536Q is detected
		V422del	V422del is detected
5	None	No ESR1 mutations detected	

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		