

TECHNICAL SHEET IDYLLA™ ctESR1 MUTATION ASSAY

The **Idylla™ ctESR1 Mutation Assay** is a fully automated real-time PCR test for the qualitative detection of **12 mutations in exons 5, 6, 7 and 8** of the *ESR1* gene.

The Idylla™ ctESR1 Mutation Assay is optimized for **plasma**, derived from whole blood collected in Streck Cell-Free DNA BCT® collection tubes, Roche Cell-Free DNA collection tubes or K2-EDTA collection tubes. The Assay covers the entire process from **plasma sample to result**, including fully integrated sample preparation, ctDNA extraction, real-time PCR amplification and detection, data analysis and result reporting.

FEATURES

ESR1 mutation detection			Genotype call
Exon 5	E380Q	c.1138G>C	E380Q
Exon 6	V422del	c.1265_1267del	V422del
Exon 7	S463P	c.1387T>C	S463P
Exon 8	P535H	c.1604C>A	L536R/Q/H/P; P535H
	L536R	c.1607T>G	
	L536Q	c.1607_1608delinsAG (TC>AG)	
	L536H	c.1607T>A	
	L536P	c.1607T>C	
	Y537C	c.1610A>G	Y537C
	Y537S	c.1610A>C	Y537S
	Y537N	c.1609T>A	Y537N
	D538G	c.1613A>G	D538G

Minimum specimen requirements

Sample type	4 ml of plasma
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Supported blood collection tubes

Streck Cell-Free DNA BCT® collection tubes

Roche Cell-Free DNA collection tubes

K2-EDTA collection tubes (blood must be centrifuged within 4 hours after collection)

Total turnaround time

Time Approx. 135 minutes

Result reporting

Report Qualitative genotype call, multiple mutations can be simultaneously reported.

Catalog number

Idylla™ ctESR1 Mutation Assay A0151/6

Regulatory status

Regulatory status RUO



Idylla™ ctESR1 Mutation Assay is currently under development and will be for Research Use Only (RUO), not for use in diagnostic procedures. Idylla™ Platform is CE-marked in Europe in compliance with EU IVD Regulation 2017/746, listed as a class II device in the US under establishment registration 3009972873, and registered in many other countries. Biocartis and Idylla™ are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis. Idylla™ is available for sale in Europe, the US and many other countries. Please check availability with the local Biocartis representative.
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