

PRONTO® kits for clinical* analysis of genetic variations PRODUCT LIST

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CE IVD

Manufactured under ISO
PRONTO DIAGNOSTICS LTD.
www.prontodiagnostics.com

Distributor: Bionicum sp. z o.o.
www.bionicum.com.pl



PRONTO™ Procedure

1. DNA Extraction

Pronto Diagnostics' DNA Extraction kit features a rapid method for isolating DNA from whole blood ready for direct use in DNA amplification reactions. Other methods that isolate DNA from whole blood have been validated for use with the PRONTO™ kit.

2. Template Amplification

The PRONTO™ kit functions over a range of template DNA concentrations (50-300 ng/μl) and with validated DNA polymerases. The targeted gene sequences are simultaneously amplified using a multiplex DNA Amplification Mix.

3. Post Amplification Treatment

An alkaline phosphatase (AP) catalyzed reaction inactivates free nucleotides which remain after the amplification step.

4. Primer Extension

Each mutation is tested in two wells: one for the mutant and one for the wild-type allele. The wells are coated with a 5' labeled primer and a single biotinylated nucleotide, which matches the complementary nucleotide at the test site. The primer extension reaction takes place during a short thermal-cycling incubation.

5. Detection by ELISA

Reaction products are transferred to a 96-well ELISA plate, where biotin-labeled primers bind to the streptavidin-coated wells. Following a routine ELISA procedure, results are determined either visually (blue color) or colorimetrically (yellow color).

6. Result Interpretation

Numerical results can be obtained using an ELISA reader. Optical density readings (OD) are analyzed according to standard cut-off and *mut/wt* ratio values.

Pronto Diagnostics Ltd.

3 Habosem St.
77610 Ashdod Israel

Carrier Screening and Prenatal Diagnosis

Cat. No.	Product Name	Associated Disease	Gene (Mutations)	Mutations/ Sampe	Tests/ Kit
9901	CF Basic	Cystic Fibrosis	CFTR (F508del, G542X, W1282X, N1303K, 3849+10KbC>T)	5	24
9943	CF Basic+	Cystic Fibrosis	CFTR (F508del, G542X, W1282X, N1303K, 3849+10KbC>T, D1152H)	6	24
9946	CF Euro I	Cystic Fibrosis	CFTR (F508del, G542X, W1282X, N1303K, 1717-1G>A, R1162X)	6	24
9920	CF Open **	Cystic Fibrosis	CFTR (S549R, G85E, D1152H, W1089X, 1717-1G>A, 405+1G>A, Q359K/T360K, 4010delTATT)	8	96
9945	CFTR 5T	Cystic Fibrosis CBAVD - congenital bilateral absence of the vas deferens	CFTR (5T/7T/9T)	1	48

* Supplied with PrTaq™

** CF Open kit (9920) - choose desired mutations (from one to eight) from those listed here.

Differential Diagnosis

Cat. No.	Product Name	Associated Disease	Gene (Mutations)	Mutations/ Sampe	Tests/ Kit
9971	AAT	Alpha-1 Antitrypsin deficiency	SERPINA1 [AAT] (PiZ)	1	144
9965	ProntoPlex™ AAT	Alpha-1 Antitrypsin deficiency	SERPINA1 [AAT] (PiZ and PiS)	2	96
9968	Connexin™	Deafness	GJB2 connexin 26 (35delG, 167delT) GJB6 connexin 30 (del[GJB6-D13S1830])	3	48
9945	CFTR 5T	Cystic Fibrosis CBAVD - congenital bilateral absence of the vas deferens	CFTR (5T/7T/9T)	1	48

Genetic Predisposition to disease

Cat. No.	Product Name	Associated Disease	Gene (Mutations)	Mutations/ Sampe	Tests/ Kit
9971	AAT	Alpha-1 Antitrypsin deficiency	SERPINA1 [AAT] (PiZ)	1	144
9903	ApoE	Predisposition to hypercholesterolemia, cardiovascular disease	APOE (ε2, ε3, ε4)	2	48
9907	APC	Predisposition to colorectal cancer	APC (3920T>A)	1	96
9911	BRCA	Predisposition to breast and ovarian cancer	BRCA1 (185delAG, 5382insC) BRCA2 (6174delT)	3	48
9949	Hemochromatosis	Hereditary hemochromatosis	HFE (C282Y, H63D, S65C)	3	32
9923	ThromboRisk™	Predisposition to thrombosis	F5 / Factor V (1691G>A) F2 / Factor II (20210G>A) MTHFR (677C>T)	3	32
9905	Factor V	Predisposition to thrombosis	F5 / Factor V (1691G>A)	1	96
9909	Prothrombin	Predisposition to thrombosis	F2 / Factor II (20210G>A)	1	96
9910	MTHFR	Predisposition to thrombosis	MTHFR (677C>T)	1	96

Pharmacogenetics

Cat. No.	Product Name	Associated Disease	Gene (Mutations)	Mutations/ Sampe	Tests/ Kit
9984	5FU	5-Fluorouracil sensitivity	DPYD (IVS14+1G>A)	1	144
9985	ClopidRisk™	Clopidogrel metabolism	CYP2C19 (*2,*3,*4,*5) ABCB1 (3435C>T)	5	24
9978	MorphiRisk™	Morphine dosage	OPRM1 (118A>G) COMT (472G>A)	2	72
9983	TamoxiRisk™	Tamoxifen metabolism	CYP2D6 (*2, *3, *4,*10,*17,*41)	6	24
9979	WarfaRisk™	Warfarin dosage	CYP2C9 (*2 [430C>T], *3 [1075A>C]) VKORC1 (-1639G>A)	3	48
9980	WarfaRisk+™	Warfarin dosage	CYP2C9 (*2 [430C>T], *3 [1075A>C]) VKORC1 (-1639G>A, 5417G>T)	4	36