



First trimester trisomy and pre-eclampsia screening with assays on KRYPTOR

The best solution with reliable results for the benefit of the patient



B·R·A·H·M·S KRYPTOR GOLD

Thermo Scientific™ B·R·A·H·M·S™ PAPP-A KRYPTOR™,
Thermo Scientific™ B·R·A·H·M·S™ Free βhCG KRYPTOR™,
Thermo Scientific™ B·R·A·H·M·S™ PIGF plus KRYPTOR™



B·R·A·H·M·S KRYPTOR compact PLUS

and Thermo Scientific™ B·R·A·H·M·S™ AFP KRYPTOR™
assays are used in combination with B·R·A·H·M·S™
KRYPTOR™ analyzers



Ease of handling

	PAPP-A*	Free βhCG*	PIGF*	AFP*
Sample volume	50 µl	26 µl	70 µl	14 µl
Incubation time	19 min	19 min	29 min	9 min
Linear direct measuring range	0.010-6 IU/L	0.74-150 IU/L	7.7-7000 pg/ml	1.91-700 ng/mL
Limit of Detection	0.0054 IU/L	0.09 IU/L	4.91 pg/ml	0.21 ng/mL
Limit of Quantitation	0.01 IU/L	0.74 IU/L	7.7 pg/ml	1.91 ng/mL
Kit stability on board	29 days	29 days	29 days	15 days
Calibrator	1 point	1 point	1 point	1 point
Calibration stability	15 days	15 days	15 days	15 days

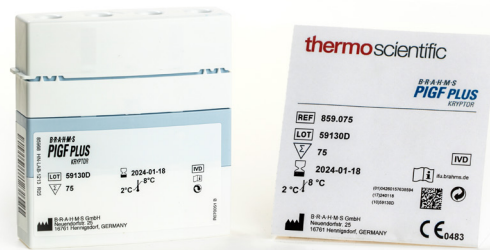
* PAPP-A = Pregnancy Associated Plasma Protein A
 Free βhCG = Free beta human Chorionic Gonadotropin Hormone
 PIGF = Placental Growth Factor
 AFP = Alpha-fetoprotein

Specimen collection and storage

Analyte	Sample matrix	Room temperature	2-8°C	Freezing	Freeze-thaw cycles
PAPP-A	Serum	24h	48h	-20°C (up to 6 years)	Not recommended
Free βhCG	Serum	8h	24h	-20°C (up to 6 years)	Not recommended
PIGF	Serum, plasma (EDTA)	24h	48h	-20°C (up to 6 years)	3
AFP	Serum, plasma (heparin), amniotic fluid	8h	24h	-20°C (up to 1 years)	Not recommended

Intended use

Risk assessment for	Trisomy 21	Trisomy 18	Trisomy 13	Pre-eclampsia
PAPP-A	√	√	√	√
Free βhCG	√	√	√	
PIGF	√			√
AFP	√			



Clinical performance

		PAPP-A + Free bhCG	PAPP-A + Free bhCG + PIGF	PAPP-A + Free bhCG + PIGF + AFP
Reference		1. Wright D et al., Ultrasound Obstet Gynecol 2011 2. Spencer K et al., Prenat Diagn 2002	Internal study (590 unaffected and 44 T21 pregnancies)	Internal study (298 unaffected and 50 T21 pregnancies)
T21 ⁽¹⁾	Sensitivity (%)	90	84	82
	Specificity (%)	97	95	95
T18-T13 ⁽²⁾	Sensitivity (%)	99.7		
	Specificity (%)	95		



Normal Values

Data for PAPP-A and Free βhCG from Study of the Fetal Medicine Foundation

Data for PIGF and AFP from self-declared healthy individuals

Gestational age*	Analyte	n	5th percentile	median	95th percentile
	PAPP-A Free βhCG PIGF AFP				
8	PAPP-A	6884	0.11	0.33	0.93
	PIGF	99	9.3	17	29
	AFP	158	2.5	4.5	10.1
9	PAPP-A	16179	0.22	0.64	1.76
	PIGF	100	12	23	38
	AFP	251	3.0	5.5	11.0
10	PAPP-A	14215	0.41	1.17	3.2
	PIGF	150	16	28	55
	AFP	177	3.6	7.3	17.1
11	PAPP-A	33512	0.79	2.18	5.62
	Free βhCG	>5000	17	45	120
	PIGF	83	19	33	61
	AFP	348	5.5	10.4	27.9
12	PAPP-A	98011	1.14	3.17	7.72
	Free βhCG	>5000	15	39	106
	PIGF	231	21	42	97
	AFP	387	7.5	15.0	30.3
13	PAPP-A	52163	1.65	4.57	11.08
	Free βhCG	>5000	11	30	81
	PIGF	122	25	55	100
	AFP	330	10.1	19.0	35.1

*completed week

Precision

Precision/Repeatability and within-laboratory precision

Repeatability and within-laboratory precision % CV were calculated from the measurement of samples over 20 days, with 2 runs per day in 2 replicates using 3 (2 for Free β hCG and AFP) reagent lots according to CLSI Guideline EP05-A3 (Evaluation of Precision of Quantitative Measurement Procedures).

Precision / Reproducibility

For reproducibility, samples were measured for 5 days, with 1 run per day on 3 instruments in 5 replicates and calculated according to CLSI Guideline EP05-A3 (Evaluation of Precision of Quantitative Measurement Procedures).

PAPP-A

Precision	Conc (IU/L)	Repeatability CV%	Within - lab precision CV%	Reproducibility CV%
Sample 1	0.065	1.7	3.1	-
Sample 10	0.26	-	-	3.1
Sample 6	0.34	-	2.5	-
Sample 2	0.35	1.0	-	-
Sample 11	1.5	-	-	3.6
Sample 7	1.7	-	3.6	-
Sample 12	2.7	-	-	3.3
Sample 8	4.4	-	4.1	-
Sample 3	5	1.5	-	-
Sample 13	8.1	-	-	4.3
Sample 4	24	1.3	-	-
Sample 9	45	-	3.9	-

Free β hCG

Precision	Conc (IU/L)	Repeatability CV%	Within - lab precision CV%	Reproducibility CV%
Sample 1	0.56	8	17.7	-
Sample 9	1	-	-	10.8
Sample 2	2.9	2.1	5.8	-
Sample 10	11	-	-	4.3
Sample 7	35	-	3.8	-
Sample 11	67	-	-	4.5
Sample 3	97	0.7	-	-
Sample 12	193	-	-	1.2
Sample 4	1000	1.9	3.6	-

PIGF

Precision	Conc (pg/mL)	Repeatability CV%	Within - lab precision CV%	Reproducibility CV%
Sample 6	7.5	-	16.4	-
Sample 1	8.7	14.6	-	-
Sample 11	15	-	-	11.1
Sample 2	17	7.6	8.6	-
Sample 12	20	-	-	7.4
Sample 3	21	6.0	7.0	-
Sample 4	47	3.1	6.6	-
Sample 13	238	-	-	2.6
Sample 5	411	1.7	-	-
Sample 14	894	-	-	4.6
Sample 10	928	-	4.6	-

AFP

Precision	Conc (ng/mL)	Repeatability CV%	Within - lab precision CV%	Reproducibility CV%
Sample 1	2.85	2.9	-	-
Sample 5	5.29	-	8.3	-
Sample 9	5.35	-	-	4.7
Sample 2	11.1	1.2	-	3.6
Sample 6	11.2	-	3.8	-
Sample 7	68.6	-	2.7	-
Sample 3	511	1.2	-	-
Sample 8	1096	-	2.9	-
Sample 11	1149	-	-	3.0
Sample 4	335142	1.4	-	-

Calibration

Analyte	Units	International Standard
PAPP-A	IU/L	WHO IRP 78/610
Free β hCG	IU/L	NIBSC 75/551
PIGF	pg/ml	No international standard available
AFP	ng/ml	1st NIBSC 72/225



Reagents overview

Kits

	Content	Shelf life (2-8°C)	Stability after opening onboard the instrument (2-8°C)
B·R·A·H·M·S PAPP-A KRYPTOR	75 tests Ready for use	15 months	29 days
B·R·A·H·M·S Free βhCG KRYPTOR	75 tests Ready for use	12 months	29 days
B·R·A·H·M·S PIGF plus KRYPTOR	75 tests Reconstituted on the instrument	18 months	29 days
B·R·A·H·M·S AFP KRYPTOR	75 tests Reconstituted on the instrument	12 months	15 days

Calibrators

	Content	Target concentration	Shelf life	Stability after opening at room temperature (18-25°C)
B·R·A·H·M·S PAPP-A KRYPTOR CAL	6 vials Ready for use	3 IU/L	16 months	2h
B·R·A·H·M·S Free βhCG KRYPTOR CAL	6 vials Ready for use	40 IU/L	12 months	2h
B·R·A·H·M·S PIGF plus KRYPTOR CAL	6 vials Reconstituted manually with 0.85 mL of distilled water	330 pg/ml	24 months	5h
B·R·A·H·M·S AFP KRYPTOR CAL	6 vials Ready for use	150 ng/mL	12 months	2h

Controls

Content	Target concentrations	Shelf life* (2-8°C)	Stability after opening		
			Room temperature	2-8°C	Freezing
B·R·A·H·M·S GM KRYPTOR QC (PAPP-A + Free βhCG + AFP)	PAPP-A Level 1: 0.3 IU/L Level 2: 1.5 IU/L Level 3: 4 IU/L Free βhCG Level 1: 80 IU/L Level 2: 20 IU/L Level 3: 8 IU/L AFP Level 1: 10 ng/mL Level 2: 35 ng/mL Level 3: 100 ng/mL	24 months	8h	24h	1 month at -20°C
B·R·A·H·M·S PIGF plus KRYPTOR QC	Level 1: 30 pg/mL Level 2: 100 pg/mL Level 3: 400 pg/mL	24 months	5h	24h	1 month at -20°C

* from date of production

References

1. IFU B-R-A-H-M-S PAPP-A KRYPTOR
2. IFU B-R-A-H-M-S Free β hCG KRYPTOR
3. IFU B-R-A-H-M-S PIGF plus KRYPTOR
4. IFU B-R-A-H-M-S AFP KRYPTOR



Advantages/Benefits

Safe results

KRYPTOR assays are not impacted by biotin and other unknown interferences

Fast results

Short incubation time for PAPP-A (19 minutes) and Free β hCG (19 minutes), suitable for OSCAR program*. 29 and 9 minutes are required for PIGF and AFP, respectively

Optimized workflow

Self-determining dilution factor for out-of-range samples (dilution is not possible for PIGF)

Optimal CV

Outstanding precision in term of low CV% confirmed by UKNEQAS long-term data, since 2003

High Specificity

Low B-R-A-H-M-S PIGF plus KRYPTOR cross reactivity with other isoforms

Assays compliance

IVDR compliant and FMF approved assays
In routine use by Fetal Medicine Foundation since 1999

*OSCAR = One Step Clinical Assessment of Risk

Clinical Diagnostics

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