



# PIGF and sFlt-1 assays on KRYPTOR

## Thermo Scientific B·R·A·H·M·S PIGF plus KRYPTOR Thermo Scientific B·R·A·H·M·S sFlt-1 KRYPTOR

Thermo Scientific™ B·R·A·H·M·S™ PIGF plus KRYPTOR™ is an automated immunofluorescent assay for the quantitative determination of placental growth factor (PIGF) in human serum and plasma (K2 EDTA).

Thermo Scientific B·R·A·H·M·S sFlt-1 KRYPTOR is an automated immunofluorescent assay for the quantitative determination of soluble fms-like tyrosine kinase-1 (sFlt-1), also known as VEGF receptor-1 in human serum and plasma (K2 EDTA).

sFlt-1/PIGF ratio  
can be provided within  
30 minutes



B·R·A·H·M·S KRYPTOR  
compact PLUS

### Ease of handling

	PIGF plus	sFlt-1
Sample volume	70 µL	8 µL
Sample type	Serum, plasma (K2 EDTA)	Serum, plasma (K2 EDTA)
Incubation time	29 min	9 min
Linear direct measuring range	7.6 –4,000 pg/mL	315 –90,000 pg/mL
Limit of Detection	4.9 pg/mL	28.5 pg/mL
Limit of Quantitation	7.6 pg/mL	29.4 pg/mL
Kit stability on board	29 days	29 days
Calibrator	1 point	2 points
Calibration stability	15 days	15 days

### Specimen collection and storage

	Room temperature	2-8°C	Freezing
Serum, plasma (K2 EDTA)	24h	24h	6 months at -70°C

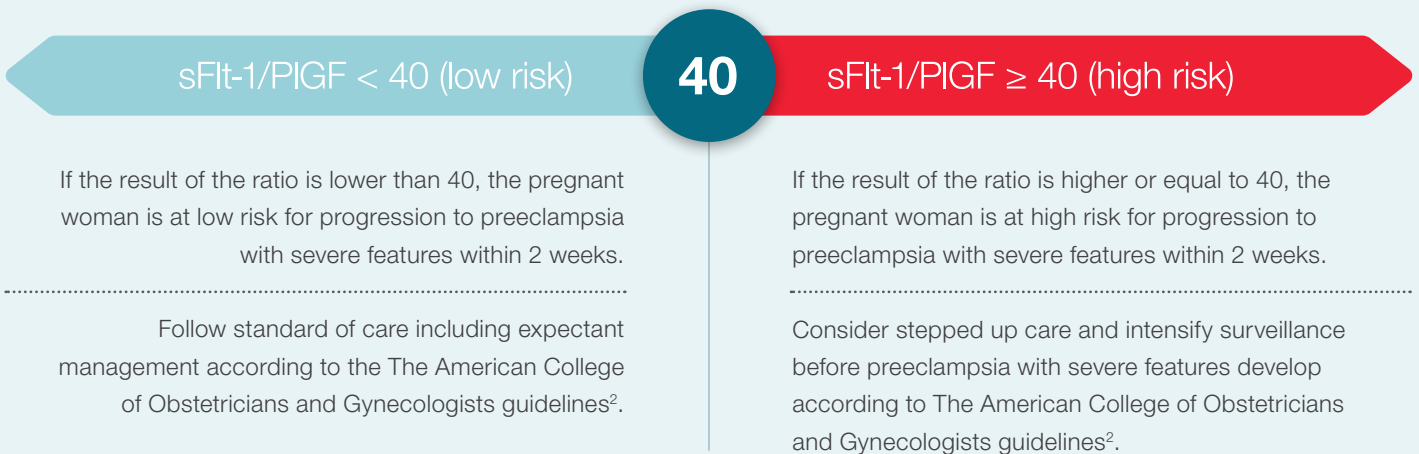
# Risk stratification of pregnant women for progression to preeclampsia with severe features

## Intended use:

The B·R·A·H·M·S PIGF plus KRYPTOR is to be used in conjunction with the B·R·A·H·M·S sFlt-1 KRYPTOR along with other laboratory tests and clinical assessments to aid in the risk assessment of pregnant women (singleton pregnancies between gestational age 23+0 to 34+6/7 weeks) hospitalized

for hypertensive disorders of pregnancy (preeclampsia, chronic hypertension with or without superimposed preeclampsia, or gestational hypertension) for progression to preeclampsia with severe features (as defined by The American College of Obstetricians and Gynecologists guidelines) within 2 weeks of presentation.

## Cut-off



## Clinical performance<sup>1</sup>

N=556	Sensitivity*	Specificity*	PPV*	NPV*
<b>PE with severe features within 2 weeks</b>	<b>93.5%</b> (89.1- 96.3)	<b>74.9%</b> (70.2 - 79.0)	<b>65.2%</b> (59.3- 70.6)	<b>95.8%</b> (92.9 - 97.6)

\* 95% CI

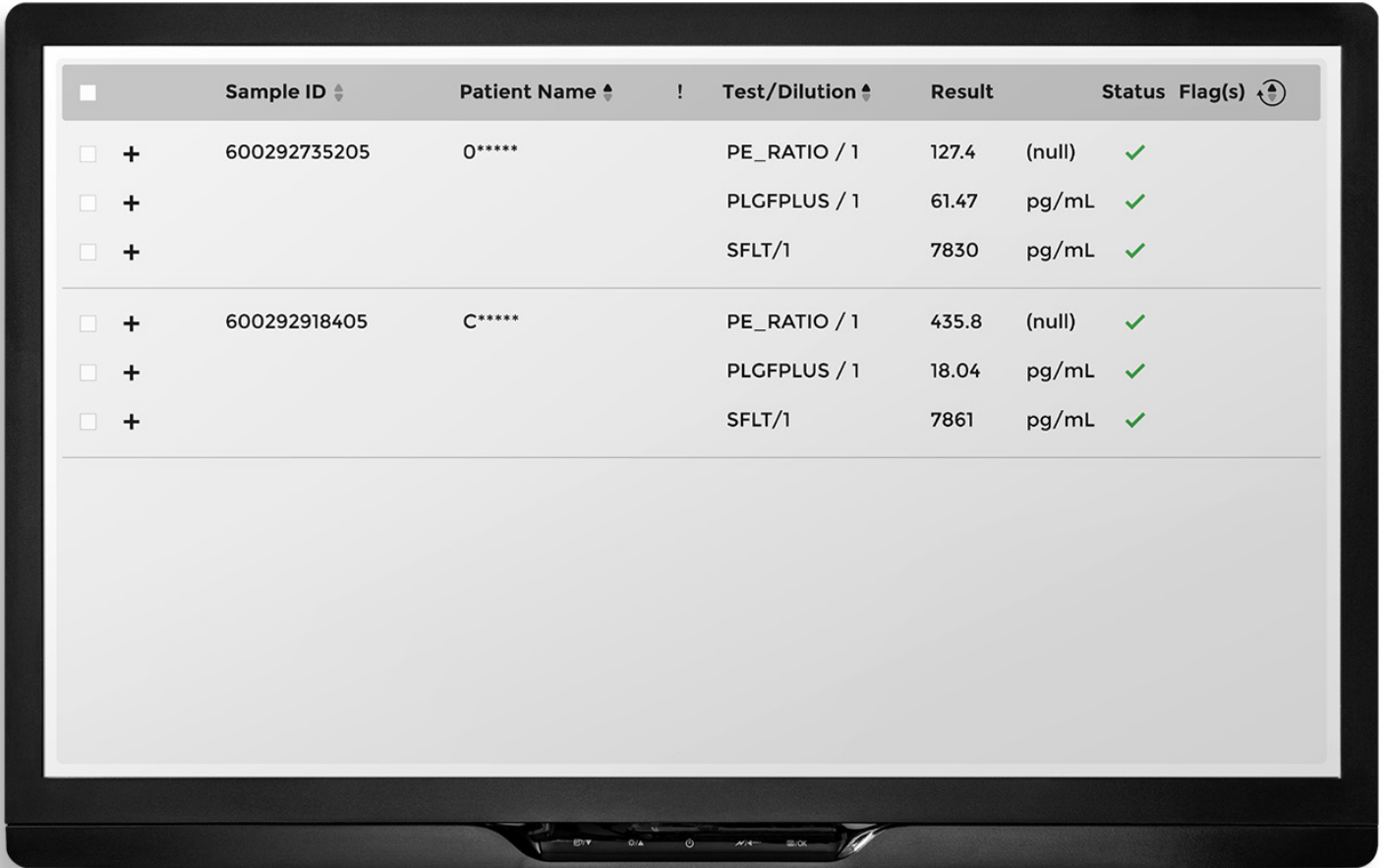
## Reference Range

Established in a population of 166 healthy pregnant women between week 23+0 up to week 34+6.

	2.5th percentile	Median	97.5th percentile
<b>PIGF (pg/mL)</b>	87	450	1,202
<b>sFlt-1 (pg/mL)</b>	526	1,299	5,140
<b>Ratio</b>	0.84	3.16	31.1

# Recommendations for Laboratory Reports

sFlt-1/PIGF ratio is calculated and displayed by the instrument



	Sample ID	Patient Name	!	Test/Dilution	Result	Status	Flag(s)
<input type="checkbox"/> +	600292735205	O*****		PE_RATIO / 1	127.4	(null)	✓
<input type="checkbox"/> +				PLGFPLUS / 1	61.47	pg/mL	✓
<input type="checkbox"/> +				SFLT/1	7830	pg/mL	✓
<input type="checkbox"/> +	600292918405	C*****		PE_RATIO / 1	435.8	(null)	✓
<input type="checkbox"/> +				PLGFPLUS / 1	18.04	pg/mL	✓
<input type="checkbox"/> +				SFLT/1	7861	pg/mL	✓

Quantitative results for PIGF, sFlt-1, and sFlt-1/PIGF ratio are individually reported by the instrument. These results for PIGF and sFlt-1 should only be used by laboratories to assess assay performance as part of a quality control program, and are not intended for interpretation of results.

It is recommended to only provide the sFlt-1/PIGF ratio on the laboratory report for healthcare practitioners. For a guided interpretation of the test result the laboratory report should

include a link to the following training program for healthcare practitioners: [www.thermofisher.com/brahms-pe-training](http://www.thermofisher.com/brahms-pe-training). Alternatively the laboratory report may provide such interpretative criteria directly (as found on the website above) together with the sFlt-1/PIGF ratio result.

# Precision

## PIGF and sFlt-1 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 reagent lots according to CLSI Guideline EP05-A3 (tables 1 & 2).

**Table 1: PIGF**

Sample	PIGF plus average (pg/mL)	Repeatability CV (%)	Within-Laboratory CV (%)
LOQ3	8.7	14.6	15.2
P02	10.6	12.3	13.7
P04	20.7	6.0	7.0
P08	79.8	2.3	4.3
P12	364	1.1	3.5
P15	973	0.8	2.2

**Table 3: PIGF**

Sample	PIGF plus average (pg/mL)	Repeatability CV (%)	Within-Laboratory CV (%)	Reproducibility CV (%)
PRE02	15.2	9.5	10.9	11.1
PRE03	19.7	7.2	7.2	7.4
PRE05	238	1.4	1.7	2.6
PRE06	894	1.0	2.0	4.6

**Table 5: sFlt-1/PIGF ratio**

sFlt-1 Sample	PIGF Sample	Average Ratio (sFlt-1 / PIGF)	Repeatability CV (%)	Within-Laboratory CV (%)	Reproducibility CV (%)
PRE11	PRE05	7.1	1.3%	2.4%	3.4%
PRE15	PRE06	12.7	1.9%	3.5%	4.5%
PRE17	PRE06	44.6	1.3%	4.1%	4.1%
PRE15	PRE05	47.9	1.7%	3.0%	3.3%
PRE11	PRE03	86.6	7.5%	7.5%	8.4%
PRE17	PRE05	168	1.5%	3.4%	3.5%
PRE15	PRE03	582	7.9%	7.9%	8.4%
PRE17	PRE03	2,041	7.7%	8.2%	9.3%

# Calibration

The PIGF and sFlt-1 results are given in pg/mL, international reference preparations are not available.

## Reproducibility

For reproducibility, samples were measured for 5 days, with 1 run per day in 5 replicates using 1 reagent lot in 3 different sites (different instruments). Repeatability, within-laboratory and reproducibility were calculated according to CLSI Guideline EP05-A3 (tables 3, 4 & 5).

**Table 2: sFlt-1**

Sample	sFlt-1 average (pg/mL)	Repeatability CV (%)	Within-Laboratory CV (%)
PRE11	1,605	0.6	2.7
PRE15	10,453	0.6	2.8
PRE18	50,452	0.9	3.5
PRE19	68,944	0.7	3.8

**Table 4: sFlt-1**

Sample	sFlt-1 average (pg/mL)	Repeatability CV (%)	Within-Laboratory CV (%)	Reproducibility CV (%)
PRE11	1,697	0.8	2.3	3.0
PRE15	11,401	1.7	3.2	3.3
PRE17	40,067	0.7	3.8	5.1

# Reagents overview

## Kits

	Content	Shelf life* (2-8°C)	Stability after opening onboard the instrument (2-8°C)
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 sFit-1 KRYPTOR	75 tests Ready for use	18 months	29 days

## Calibrators

	Content	Target concentrations (pg/mL)	Shelf life* (2-8°C)	Stability after opening at room temperature (18-25°C)
B-R-A-H-M-S PIGF plus KRYPTOR CAL	6 vials Reconstituted manually with 0.85 mL of type II water	330	24 months	5h
B-R-A-H-M-S sFit-1 KRYPTOR CAL	2*6 vials Reconstituted manually with 0.65 mL of type II water	CAL 1: 360 CAL 2: 36,000	24 months	5h

## Controls

	Content	Target concentrations (pg/mL)	Shelf life* (2-8°C)	Stability after opening		
				Room temperature (18-25°C)	2-8°C	Freezing
B-R-A-H-M-S PIGF plus KRYPTOR QC	6 vials Reconstituted manually with 2 mL of type II water	Level 1: 30 Level 2: 100 Level 3: 400	24 months	5h	24h	1 month at -20°C
B-R-A-H-M-S sFit-1 KRYPTOR QC	6 vials Reconstituted manually with 2 mL of type II water	Level 1: 1,500 Level 2: 3,000 Level 3: 10,000	24 months	5h	24h	1 month at -20°C

\* from date of production

## References

1. Thadhani et al (2022). NEJM; <https://doi.org/10.1056/EVIDoa2200161>  
B-R-A-H-M-S PIGF plus KRYPTOR and B-R-A-H-M-S sFit-1 KRYPTOR IFU USA
2. ACOG practice bulletin 222 (2020)
3. US IFU B-R-A-H-M-S sFit-1 plus KRYPTOR
4. US IFU B-R-A-H-M-S PIGF plus KRYPTOR
5. US IFU B-R-A-H-M-S sFit-1/PIGF KRYPTOR
6. B-R-A-H-M-S KRYPTOR compact PLUS manual

## Clinical Diagnostics

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