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SECTION 16

MATERNAL SCREENING

Maternal Screening Controls

Maternal screening controls are essential in diagnostics for accurately assessing the health of pregnant individuals and identifying potential risks to the developing fetus. These controls consist of standardised samples with known concentrations of biomarkers, such as hormones and proteins, used to validate the performance of screening assays. By incorporating these controls, laboratories ensure the reliability and accuracy of test results, which are crucial for detecting conditions like gestational diabetes, preeclampsia, and chromosomal abnormalities, thereby informing timely clinical interventions.

The role of maternal screening controls also extends to maintaining quality assurance in laboratory processes, ensuring consistent and reproducible results across different tests. Reliable maternal diagnostics are critical for guiding prenatal care and enabling informed decision-making for expectant parents. Regular use of these controls helps identify any potential issues with reagents or equipment, ultimately supporting effective patient management and improving health outcomes for both mothers and their babies. The Fortress Maternal Screening Controls are available in a lyophilised format offering enhanced stability and are 100% human serum based to negate matrix effects.

Lyophilised | Liquid Frozen | Liquid Stable | 100% Human Serum | Assayed Target Values Provided

Anti-Mullerian Hormone (AMH) Calibrators & Controls

- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.
- Compatable with all AMH assays.

Description	Size	Cat No.	Type
Anti-Mullerian Hormone (AMH) Calibrators & Control Set	Calibrator Set: 2 x 1x0.5ml ; Control Set: 2x1x0.5ml	BXC0999A	Lyo.

Maternal Screening Control

For screening of Down's syndrome & Spina Bifida compatible for use on most clinical chemistry systems including immunoassay systems.

- Screening Controls are multi analyte controls intended for use in monitoring accuracy and precision for assays used in first and second trimester screening of Downs Syndrome and Spina Bifida.
- The Controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8 °C.
- 100% human serum.

Analytes

AFP	Inhibin A	Total hCG
Free beta hCG	PAPP-A	Unconjugated Estriol

Description	Size	Cat No.	Type
Maternal Screening Control (Level 1)	2 x 1 ml	BXC0695A	Lyo.
Maternal Screening Control (Level 2)	2 x 1 ml	BXC0695B	Lyo.
Maternal Screening Control (Level 3)	2 x 1 ml	BXC0695C	Lyo.
Maternal Screening Control Tri-Level	3 x 1 x 1 ml	BXC0699A	Lyo.

PAPP-A & f-beta-hCG Controls

- The Controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- 100% human serum.
- Reconstituted stability of 7 days at 2-8 °C.

Description	Size	Cat No.	Type
PAPP-A & f-beta-hCG Control (Level 1)	1 x 0.5 ml	BXC0337A	Lyo.
PAPP-A & f-beta-hCG Control (Level 2)	1 x 0.5 ml	BXC0338A	Lyo.
PAPP-A & f-beta-hCG Control (Level 3)	1 x 0.5 ml	BXC0339A	Lyo.
PAPP-A Control	1 x 0.5 ml	BXC0240A	Lyo.

Peadiatric Control

- L
- R
- C

Description	Details	Size	Cat No.	Type
Paediatric Control	**ALP, Bilirubin, Calcium, Chloride, Magnesium, In. Phosphorous, Potassium, Sodium**	3 x 1ml	BXC0807A	Lyo.

Pre-eclampsia

Pre-eclampsia is a disorder of pregnancy that is associated with new-onset hypertension most often after 20 weeks' gestation and frequently near term. During the 2nd and 3rd trimesters soluble fms-like tyrosine kinase 1 and Placental Growth Factor (PLGF) are both predictive and diagnostic for pre-eclampsia. It has been shown that increased levels of sFlt-1 and decreased levels of PlGF in maternal serum can predict the subsequent onset of pre-eclampsia..

Determining serum PlGF concentration, used as a single marker, or sFlt-1 and PlGF, used as a ratio, improve the clinical management and decision making (risk stratification) with women showing signs and symptoms of pre-eclampsia.

PlGF Testing will be valuable:

- For testing women with signs and symptoms of pre-eclampsia after week 20 of gestation
- To help Rule-out and Rule-in suspected pre-eclampsia
- To monitor women that are at high risk for pre-eclampsia
- To confirm clinical suspection of pre-eclampsia with symptomatic women and/or to confirm unclear diagnosis of pre-eclampsia
- Serum concentrations of sFlt-1 and PlGF can differentiate healthy women from women with pre-eclampsia. Changes in sFlt-1 and PlGF levels reflect the severity of the disease.

PlGF as a single marker or sFlt-1/PlGF ratio. PlGF alone compared to sFlt-1/PlGF ratio for pre-eclampsia rule-in and rule-out has a comparable performance, and both options are equally recommended for clinical use. In addition to SFlt-1/PlGF ratio, PLGF alone, with concentration based cut-offs, could provide more simpler and affordable alternative to dual biomarker testing. Using PlGF has additional advantages. Studies have shown that PlGF is a good marker (decreased serum PlGF level) for identifying pregnancies with placental insufficiency including fetal growth restriction and/or stillbirth

PLGF Controls

For screening of Down's syndrome & Spina Bifida compatible for use on most clinical chemistry systems including immunoassay systems.

Description	Details	Size	Cat No.	Type
Placental Growth Factor (PLGF) Control Level-1	**Target: 30pg/ml**	3 x 2 ml	BXC0700A	LS.
Placental Growth Factor (PLGF) Control Level-2	**Target: 100pg/ml**	3 x 2 ml	BXC0700B	LS.
Placental Growth Factor (PLGF) Control Level-3	**Target: 600pg/ml**	3 x 2 ml	BXC0700C	LS.

Pre-eclampsia Control

Description	Details	Size	Cat No.	Type
Pre-eclampsia Control Level-1	**s-FLT-1 (soluble fms-like tyrosine Kinase-1)**	3 x 1 ml	BXC0704A	Lyo.
Pre-eclampsia Control Level-2	**s-FLT-1 (soluble fms-like tyrosine Kinase-1)**	3 x 1 ml	BXC0704B	Lyo.