

# Diagnostic to Predict Paternal Premature Birth Risk Factors: Therapy can Reduce Risk

## Summary

Premature birth is the leading cause of neonatal death worldwide, affecting 13% of US infants (500,000 babies/year). Of great concern, premature birth cannot currently be reliably predicted or prevented. Existing risk factors and interventions for premature birth focus solely on maternal factors, thereby overlooking paternal factors that influence an infant's development. Vanderbilt researchers have now identified a missing piece of the puzzle and are developing a diagnostic test to predict premature birth risks conferred to infants by their fathers. Of key importance, the test offers meaningful clinical guidance, as risk factors measured by the diagnostic can be modified before conception via supplementation.

## Competitive Advantages

- Easily incorporated into current workflow: 5.1% of the U.S. population undergoes testing to identify causes of infertility. The diagnostic test measures semen biomarkers, thus can be easily incorporated into current clinical procedures to diagnose male fertility problems.

- Recurring diagnostic testing: For individuals at high-risk undergoing therapy, the diagnostic would be performed at intervals to assess improvement, generating recurring revenue.

- Flexibility: can measure either nucleic acid or protein.

- Opens additional market opportunities: Semen biomarkers may offer additional information about infant development risks, or general male wellness.

### Factors in Prenatal Health:

#### The Father's Contribution is an Unexplored Opportunity

	Mother	Father	Opportunity
General wellness recommendations	Avoid toxins, illicit drugs, smoking, alcohol		Diagnostic predicts these risks
Scholarly articles on preconception nutrition and impact on fertility*	223	14	
Specific preconception nutrition recommendations**	Folic Acid Calcium Essential Fatty Acids Adequate Iron Adequate Iodine	Essential Fatty Acids	Modify risk with fish oil supplementation

\* Pubmed search conducted on June 16, 2013, \*\* U.S. Center for Disease Control and Prevention

Table 1. Paternal influence on premature birth

Experimental Group (Males)	Number of Mice	Pregnancy Success Rate	Birth Outcome	
			Full-term	Premature
Exposed to environmental toxin	53	25/53 (47%)	61%	39%
Exposed to environmental toxin and supplemented with fish oil	11	9/11 (81%)	100%	0%

## Description of the Technology

The placenta is largely a paternally-derived tissue. Vanderbilt inventors have demonstrated that inflammatory changes in the male reproductive tract are a modifiable risk factor in premature birth. In a mouse model with an inflammatory trigger, preconception sperm analysis can identify males with an epigenetic or protein expression profile which predicts placental inflammation. Providing a therapeutic intervention to animals prior to mating normalizes the numbers and morphology of sperm and reduces placental inflammation, thereby improving fertility and eliminating premature birth (Table 1). A similar preconception analysis in men would allow appropriate intervention prior to pregnancy, potentially improving pregnancy outcomes for women and infants. Vanderbilt is seeking a partner to develop this diagnostic assay.

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