

# Predictive Marker for Pre-Term Birth

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## Technology description

A small antimicrobial peptide (elafin) predicts risk of developing a short cervix and spontaneous pre-term birth (sPTB) relatively early pregnancy (~ 12-14 weeks of pregnancy)

Elevated elafin concentrations in cervico-vaginal fluid (CVF) predict cervical shortening from 14 weeks' and remain high when cervical shortening is first detected.

Raised elafin concentrations <24 weeks' are associated with SPTB <37 weeks

## Technology Overview

Preterm birth (<37 weeks' gestation) is responsible for over 15 million births and a million neonatal deaths annually. A growing body of evidence emphasises the role of infection and inflammation in the pathogenesis of early spontaneous preterm birth (i.e. < 34 weeks' ) with these births accounting for the majority of neonatal death and morbidity.

To date, detection of a shortened cervix using transvaginal ultrasound ( $\pm$  CVF fetal fibronectin) has been proven to be useful and widely used in high resource settings for prediction of sPTB and as an indicator for progesterone prophylaxis or cervical suture. However, optimal predictive capability occurs relatively late in gestation (> 20 weeks' ), providing only a small window for intervention. Prophylactic treatments such as progesterone can then only 'treat' but not prevent a short cervix. There is a need for a test which accurately predicts a short cervix and risk of early SPTB as a valuable screening tool.

To address this need, we have recently identified a small antimicrobial peptide (elafin) that predicts risk of developing a short cervix and also sPTB in cervical vaginal secretions of women much earlier in pregnancy (~12-14 weeks of pregnancy). Elafin concentrations are substantially raised in women most at risk and could indicate either the presence of asymptomatic infection or a genetic predisposition to spontaneous preterm birth.

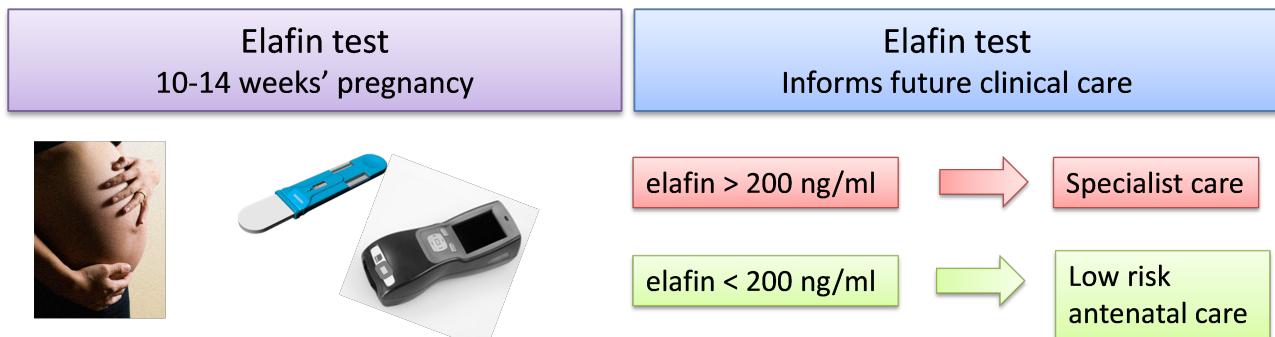
## Opportunity

A predictive test for raised elafin levels would provide clinicians extra time to intervene much earlier in pregnancy and have an increased opportunity to prevent preterm birth, whether that is in a low or high resource environment.

We have set out to develop a point of care test that can be used in a variety of clinical settings.

Development of reliable elafin based pregnancy test, which identifies women at risk of early spontaneous premature labour may substantially reduce neonatal deaths.

Currently, we are validating our findings in a large (2000 women) clinical study which also addresses how elafin levels correlate to response to clinical interventions such as vaginal progesterone, cervical stitch or pessary.



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