

**Issue date**  
8 May 2024

**Distributed to:**

Chief Executives  
Directors of Clinical Governance  
Director, Regulation and Compliance Unit

**Action required by:**

Chief Executives  
Directors of Clinical Governance  
Pregnancy Connect Care Coordinators and Medical Leads

**We recommend you also inform:**

Directors, managers, and staff of maternity services

**Content reviewed by:**

Health and Social Policy Branch, MoH  
Clinical Excellence Commission  
NSW Health Pathology

**Ministry of Health – Health and Social Policy Branch**

[Email](#)

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**Review date**  
January 2025

**Updated: Supply disruption: Rapid Fetal Fibronectin (fFN) 10Q cassettes**

**What is updated in the Safety Notice from 029/23?**

This notice has been updated to advise of ongoing supply disruption.

**Situation**

There continues to be supply disruption of Rapid Fetal Fibronectin 10Q cassettes due to ongoing manufacturing issues. Limited supply is expected until the end of 2024. Stock for regional and remote facilities will continue to be prioritised. An alternative product, Actim Partus, remains available for ordering.

**Background**

Fetal Fibronectin is a biomarker test used to help diagnose the risk of premature labour and birth. This assists in clinical decision making to determine if a pregnant woman requires transfer for higher-level care. Rapid Fetal Fibronectin tests are quantitative, providing a numerical result that can improve the accuracy of risk assessment for preterm birth.

The test is used as part of the decision-making tool (Appendix 2 – page 14) in the NSW Health Policy Directive *Tiered Networking Arrangements for Perinatal Care in NSW* ([PD2023\\_035](#)) and NSW Health Guideline *Management of Threatened Preterm Labour* ([GL2022\\_006](#)).

**Assessment**

There is a small amount of stock available within NSW Health maternity facilities. This stock may not be sufficient for demand levels.

**Clinical Recommendations**

Assessment and management of women who present with signs and symptoms of threatened preterm labour should continue as per NSW Health Guideline *Management of Threatened Preterm Labour* ([GL2022\\_006](#)).

**Conservation Measures:**

Pregnancy Connect Care Coordinators and Medical Leads are to ensure that:

- available stock is appropriately allocated across their Tiered Perinatal Network (TPN) - considering service capability levels, regional and rural locations and stock expiry dates.
- stock levels are communicated between TPNs as required.
- Rapid Fetal Fibronectin 10Q cassettes are not used in asymptomatic women.

**Utilisation of Actim Partus tests:**

As Actim Partus tests provide a qualitative result only care must be taken when utilising the *Maternal Transfers Decision Making Tool* (Appendix 2 - [PD2023\\_035](#)). Consultation with the Tiered Perinatal Network should occur to assist with care planning and decision making regarding the need for transfer.

**Required actions for the Local Health Districts/Networks**

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where pregnant women at risk of premature birth receive care.
2. Include this Safety Notice in relevant handovers and safety huddles.
3. Report any associated incidents into [ims+](#)