Classification: Official-Sensitive: Commercial

Publication reference: PR00100

To:
- All trusts and foundation trusts:
  - heads/directors of midwifery
  - obstetric clinical directors
  - neonatal clinical directors
- Regional:
  - chief midwives
  - obstetricians and neonatologists

cc.
- Trust and foundation trust pathology incident directors
- Regional heads of EPRR

NHS England
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23 December 2022

Dear colleagues,

Hologic fetal fibronectin cassettes

NHS England and the Department of Health and Social Care (DHSC) have been alerted to a supply disruption of Hologic fetal fibronectin (FFN) cassettes used as a preterm birth marker at point of care. These tests are carried out in maternity units on symptomatic women and in preterm birth clinics for high-risk asymptomatic women. They are considered a point of care test.

The disruption is due to a quality control issue with the raw material used to make the cassettes and this is temporarily disrupting their manufacture and supply. Hologic estimates recovery for this product to be March 2023.

We are recommending the below adjustments to clinical practice based on a number of assumptions for women presenting with threatened preterm labour. These adjustments are supported by both the in-utero transfer and optimisation of the preterm infant (provision of antenatal corticosteroids). An alternative product is available to support these clinical adjustments.

These adjustment in clinical practice have been discussed with the Royal College of Midwives and Royal College of Obstetricians and Gynaecologists, NHS England Pathology Transformation team and point of care test national experts, and they are supportive of the changes in clinical care.

Assumptions

Current national recommendations are:

- to use quantitative FFN tests for women presenting with threatened preterm labour to assess risks of labour and potential need for in-utero transfer and optimisation of the preterm infant (provision of antenatal corticosteroids)
- to use quantitative FFN tests to support the management of asymptomatic women at risk of preterm birth (see in preterm birth clinics)
- the current recommended cut-off for recommending in-utero transfer or optimisation of a preterm baby is 50ng/ml or a risk above 5% using an app such as QUIPP
- alternative tests only provide qualitative results (Actim® Partus).

Clinical decision-making adjustments

1. While stocks of quantitative FFN are low or absent, the use of this test on asymptomatic women should be avoided:

    a. Within preterm birth clinics the swabs should be taken prior to assessment of cervical length but only analysed if there is concurrent cervical length shortening or this will significantly affect management (eg if considering insertion of cervical suture, etc).

2. Women presenting in threatened preterm birth can be assessed with an alternative test (Actim® Partus):

    a. If this test is negative, the woman can be assumed to be at low risk of preterm birth and as such would not require in-utero transfer or optimisation medications.

    b. If the test is positive, the woman should be recommended to deliver in an appropriate unit and receive optimisation medications.

3. Laboratory operations:

    a. All services to rapidly assess their stock holding of Hologic FFN and compare this to workloads to understand service demands.

    b. Support the implementation of an alternative biomarker, the Abbott Actim® Partus test, as required.

    c. Sites affected should order these direct from Abbott Rapid Diagnostics UK Ltd as quickly as required by local stock levels.

d. Laboratories should engage with maternity units and support them to rapidly implement this test.

e. There is a strong likelihood that departments will be limited in their ability to perform significant pre-implementation verification. Data sharing across networks, regions and nationally is encouraged.

Further details about the Actim® Partus test can be found via this link: https://www.actimtest.com/actim-partus/#how-to-use-it

Trusts which are unable to source supply of either test through their normal supply routes or via mutual aid should call the National Supply Disruption Response on 0800 915 9964 (UK free phone number) between 9am and 6pm Monday to Friday (excluding bank holidays).

For queries, clinical guidance, and training regarding the Actim® Partus test, please contact ctosupport@abbott.com (with Actim Partus in the subject line of the email).

Yours sincerely,

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