Risks Associated with Use of Rupture of Membranes Tests - Letter to Health Care Providers

This letter corrects the previously issued Dear Health Care Provider Letter from August 8, 2018.

Dear Health Care Providers,

The FDA is reminding health care providers that tests to detect rupture of the amniotic membranes should not be used without other clinical assessments to make critical patient management decisions. Health care providers using rupture of membranes (ROM) tests should be aware of test limitations listed within manufacturer instructions. The following limitations are typically stated in ROM device labeling:

- A negative result does not assure the absence of membrane rupture.
- False negatives may result if the amniotic sac has resealed or the position of the fetus has obstructed the rupture.
- The presence of blood, meconium, anti-fungal creams or suppositories, baby powder, baby oil, or the use of lubricant with a vaginal exam may interfere with the device.
- The test may not be accurate if sample collection and testing occurs after the timeframe recommended by the manufacturer.

The FDA is concerned about misuse, over-reliance, and inaccurate interpretation of lab test results from ROM tests used to detect rupture of membranes in pregnant women. These can lead to serious adverse events, including fetal death, infection, and other health complications in pregnant women.

The FDA is aware of adverse events related to the use of ROM tests, including 13 fetal deaths and multiple reports of health complications in pregnant women*. In addition, the FDA has received information which indicates that health care providers may be over-relying on ROM test results when making critical patient management decisions, despite labeling instructions warning against this practice.

To help protect patients and reduce the chance of adverse events, ROM tests should be part of an overall clinical assessment, which may include physical examination of the patient and testing to detect leaking amniotic fluid.

REPORTING PROBLEMS:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with ROM tests. Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities). Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements (/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

FDA ACTIONS

The FDA will continue to closely monitor adverse event reports associated with ROM tests and evaluate whether additional regulatory action is needed to address the risks associated with their use.

The FDA has also released a press release related to this issue that can be found here (/news-events/press-announcements/fda-alerts-healthcare-providers-women-about-risks-associated-improper-use-rupture-membranes-tests).

CONTACT US

If you have questions about this communication, please contact CDRH's Division of Industry and Consumer Education (DICE) at DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov), 800-638-2041, or 301-796-7100.

Sincerely,
/s/
William Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration

**The previous letter issued on August 8, 2018 attributed an inaccurate number of adverse events and deaths.*