August 16, 2018

Dear Valued Customer,

On August 8 2018 the FDA alerted women and healthcare providers about adverse events related to the improper use of tests intended as an aid in detecting rupture of membrane (ROM). These events are in connection with the improper use of ROM tests. You can read the letter here: Risks Associated with Use of Rupture of Membranes Tests - Letter to Health Care Providers (www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm616128.htm)

From the FDA letter:

> "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 membrane (ROM) tests should be aware of test limitations listed within manufacturer instructions.
>
> 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."

As a provider of such a ROM test (ROM Plus®), Clinical Innovations (CI) shares this concern. As stated in the ROM Plus Instructions for Use, "*the test is for prescription use by health care professionals to aid in the detection of ROM in pregnant women in conjunction with other signs and symptoms,*" and "*ROM diagnoses should not be based on any single test*." ROM Plus should be used as one part of the clinical assessment in evaluating patients presenting with signs and symptoms of ROM. To date, there have been no fetal deaths reported to CI or the FDA associated with the use of ROM Plus, however we are aware of two reported false negatives that resulted in maternal infections. In addition, the ROM Plus product has not been involved in any recall.

CI recommends assessing the entire clinical picture of patients complaining of ROM. If the clinical picture is not in alignment with the result of the ROM Plus test, additional testing (e.g., ultrasound assessment, etc) should be utilized. In addition, patients discharged after a negative result should be provided the usual clinical precautions of returning if they experience continued leakage of fluid, symptoms of infection or bleeding[1].

[1]Prelabor rupture of membranes. ACOG Practice Bulletin No. 188. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;131:e1–14.

Finally, while using ROM Plus, if you suspect a discrepant result, please maintain the patient sample for potential additional testing and notify CI by contacting your local sales representative or sending an email to complaints@clinicalinnovations.com or by calling 888-268-6222.

As valued customers, we are happy to provide additional in-servicing and training support tools to ensure your staff is up to date with the ROM Plus IFU and FDA statement. We strive to provide the highest quality products to care for your patients and appreciate your use of ROM Plus.

If you have any questions regarding this communication, please contact Clinical Innovations by calling 888-268-6222.

Sincerely,

Ross W. McQuivey, M.D.
Chief Medical Officer