



September 3, 2019

RE: Quality Control (QC) for ROM Plus®

To Whom It May Concern:

ROM Plus is a rapid qualitative immunoassay test used to assist in the diagnosis of ruptured membranes (ROM) in pregnant patients, manufactured by Clinical Innovations.

Each ROM Plus test cassette contains Internal Quality Control, which verifies the integrity of the test procedure, verifies proper assembly of the test strip and that the test has been appropriately stored (not exposed to extreme temperature). The positive control, demonstrated by the appearance of the control line(C), assures that the reagent is functioning properly, an adequate sample volume was applied to the cassette and adequate capillary migration (lateral flow) occurred. The negative control is represented by the lack of color along the entire strip length assuring no inappropriate binding occurred.

Because this test contains two levels (positive and negative) of internal quality control and is a qualitative, moderately complex test, it is the company's recommendation that external QC be completed for each new lot number or shipment of test material or if there is suspicion of improper storage and as required by regulatory or accrediting agencies.

We understand that local, state, federal regulations or accrediting bodies may require more stringent requirements and thus we acquiesce to those regulations/guidelines.

If you have any questions regarding Rom Plus don't hesitate to contact us.

Sincerely,

Ross McQuivey, M.D.
Chief Medical Officer