



April 21, 2014

RE: Quality Control (QC) for ROM Plus<sup>®</sup>

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 level (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 every 30 days, or for every new lot number or shipment received, whichever comes first.

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,

A handwritten signature in black ink, appearing to read 'RWMQ', followed by a long horizontal flourish.

Ross McQuivey, M.D.  
*Medical Director*

A handwritten signature in black ink, appearing to read 'Wm. Dean Wallace', written in a cursive style.

Wm. Dean Wallace, M.D., P.h.D.  
*Senior VP of New Product Development*