Poster 74

The Fern Test Compared with ROM Plus® for the Detection of Amniotic Fluid in the Diagnosis of Ruptured Fetal Membranes

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Background: Accurate and timely diagnosis of rupture of amniotic membranes (ROM) in the pregnant patient is of critical importance to clinicians in order to provide appropriate interventions to optimize outcome for both mother and neonate. Diagnostic tests are based on the detection of amniotic fluid in vaginal secretions. Conventional diagnosis is made by a microscopic slide evaluation of a collected specimen for evidence of ferning/crystallization. The fern test is subjective and labor intensive with questionable sensitivity and specificity. Qualitative immune-chromatographic tests, have been developed to provide more accurate and objective results and can be used at the point of care (POC). The ROM Plus® (Clinical Innovations) is a device that uses a unique monoclonal/polyclonal antibody approach to detect two different proteins, Placenta Protein (PP12) and Alpha-Fetoprotein (AFP). Both proteins are found at high concentrations in amniotic fluid
Objective: We have compared the results of the fern test with the ROM Plus device for 75 patients with suspected rupture of membranes. Both tests were collected at the point of care and performed in the clinical laboratory, although the ROM Plus test can easily be performed at the point of care.. An outside laboratory performed confirmatory testing with the Amnisure® (Qiagen) device and quantification of PP12 and AFP levels by an ELISA method.
Results: 49 patient samples were positive and 11 negative with the both the fern and ROM Plus tests. There were 14 discrepant results. Patients were classified as true positive or true negative if all confirmatory tests were consistently positive or negative, respectively. Of 67 patients with confirmatory testing we found 12 false positives and 2 false negatives with the fern test for a sensitivity of 77.8% and specificity of 79.3%, due to the large number of false positives. We found 3 false positives and 0 false negatives with ROM Plus with a sensitivity of 100% and specificity of 94.8 %
Conclusion: The fern test has been shown to provide inaccurate results with false positives due to contamination and false negative due to technical errors. We found both in this study. We found the ROM Plus device to be a more objective and accurate test for the identification of amniotic fluid for the diagnosis of ruptured membranes. Slide preparation and quality and the competency and training of the technologist reading the slide greatly affect the results of the fern test.