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A selection of Amnicator® Citations and References for the diagnosis of Premature Rupture of Membranes during Pregnancy.

Citation	Source
"If you are unsure whether fluid loss is liquor, use an **Amnicator®** and observe the colour change from orange to blue. Liquor gives an immediate distinct colour change. Blood and meconium cause false positives."	*Prelabour Rupture of Membranes* Primary Clinical Care Manual 2001 Royal Flying Doctor Service (Queensland) Queensland Health, Australia
"The woman who gives a history of a sudden gush of fluid from the vagina followed by uncontrollable leaking is correctly self-diagnosing 90% of the time (Garite 1995). If doubt exists, the history can be confirmed with an **Amnicator®** and speculum if necessary."	*Pre-Labour Rupture of Membrane at Term* Evidence Based Midwifery Jane Munro & Helen Spiby, November 2000 Guidelines for midwifery led care in labour The Central Sheffield University Hospitals, England
"Examination of vagina and cervix in the event of: 1.Premature rupture of membranes 2.Premature labour 3.Antepartum haemorrhage 4.Vaginal Infection. Requirements: 1 X medium or large Bi-Valve Speculum 1 x KY Jelly or Normal Saline Sachet Sterile Gloves Torch or Spotlight 2 x Swab Sticks for H.V.S. dependent on indication 1 x Chlamydia Swab examination Hibitane Cream (optional) for digital examination **Amnicator®** (suspected rupture of membranes)"	*Speculum Examination* Delivery Suite Procedures, Protocols and Guidelines for Practice April 2002 John Hunter Hospital, NSW, Australia
"CONFIRM DIAGNOSIS: Sterile speculum examination (if scant liquor ½ hr bed rest prior to speculum to produce pool). **Amnicator®** Visualise cervix if possible assess state. HVS for MC&S Avoid digital examination"	*PRETERM RUPTURE OF MEMBRANES< 37 weeks* A Report by the Health and Disability Commissioner (Case 99HDC11166) Health and Disability Commissioner, Te Toihau Hauora, Hauatanga, New Zealand

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Reference	Source
Service de Gynecologie-Obstetrique A, Hopital Pellegrin, Bordeaux. "The authors set out to assess the three diagnostic methods available which can detect early breaking of the membranes: radio-enzymatic assay of diamine-oxidase (DAO), radioenzymatic assay of alpha-fetoprotein (AFP), colorimetric method for determining pH (**Amnicator®**). Between June 1991 and March 1992, 114 samples of vaginal secretions were taken from 104 pregnant patients being followed up at Maternity Unit A, Bordeaux (France). The results of the assays were expressed in quantitative terms (microU/ml for DAO and ng/ml for AFP); ROC (Receiver Operating Characteristic) curves were used to determine the positivity threshold in terms of the sensitivity and specificity (20 microU/ml for DAO and 15 ng/ml for AFP). The sensitivity of the pH test was **97.5%**, which was significantly better than that of DAO (90.2%) and even that of AFP (82.9%). However, there was no difference between the specificities of the pH, DAO and AFP tests (**93.3%**, 96.6% and 93.5% respectively). The data were compared with those in the literature. The problems in collecting the vaginal secretions probably accounts for the better results of the colorimetric test. **This is a reliable, fast and easily reproducible test; these qualities make it the preferred test in EBM, and it can be completed using a radioenzymatic method (DAO) or immunoradiometric test (AFP)**."	*Evaluation of 3 diagnostic methods in premature rupture of membranes: diamine-oxidase assay, alpha-fetoprotein assay, colorimetric method evaluating the pH* Filet JP, More N, Librati C, Ruffie A, Delouis P, Cluzeau MH, Hocke C, Leng JJ. Rev Fr Gynecol Obstet 1994 Mar;89(3):123-8
Service de Gynecologie, Obstetrique et Medecine de la Reproduction, Hopital Jean-Bernard, CHU, Poitiers. "OBJECTIVES: To compare the sensitivity (Se), specificity (Spe), positive predictive (PPV) and negative predictive (PNV) values of 2 tests used routinely for suspected premature rupture of the membranes (PROM) and their implication in the management of such cases. PATIENTS AND METHODS: From 1 November 1995 to 31 July 1996, 87 patients: 16 with obvious PROM on physical examination (group I) and 71 with suspected PROM (group II) were tested with both DAO and **Amnicator®** . PROM was arbitrary confirmed in group II when delivery occurred within 48 hours after the diagnosis was suspected. The corrected chi 2 test was used to compare both tests results in group II. RESULTS: In case of obvious PROM, the sensitivity of the DAO and **Amnicator®** tests were 75 and **87.5%** respectively. Eleven patients from group II delivered within 48 hours following admission and the 2 tests results were respectively: Se 90.9 and 81.81%, Spe 100 and 83.33%, PPV 100 and 52.63% and PNV 98.36 and 96.15%. DAO gave better results in terms of Spe and PPV ($p < 0.05$). COMMENTS: The DAO test remains a reference test when PROM is suspected but when it is not available (during night or weekend), the quite good negative predictive value of **Amnicator® could avoid unnecessary hospitalisation** and permit later DAO test."	*Biological diagnosis of premature rupture of membranes: respective values of diamine oxidase activity compared to vaginal fluid pH (**Amnicator®**)* De Meeus JB, Sima Ole B, Bascou V, Magnin G. J Gynecol Obstet Biol Reprod (Paris) 1997;26(7):730-3

The above citations and references describe the use of and performance of **Amnicator®.** They are offered as evidence for the efficacy of the **Amnicators®** product.

Bold type, where used above, is not in the original, but added for emphasis.

The above references are all taken from reputable and freely available sources.