Reviewer's report

Title: Evaluation of procalcitonin for diagnosis of neonatal sepsis of vertical transmission

Version: Date: 27 September 2006

Reviewer: Lucia Pacifico

Reviewer's report:

General

-----------------------------------------------------------------------------------

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

My major concerns with this revision are:

A. Authors' response to item #1 of my previous review is still inappropriate since "over a wide range of sensitivity and specificity Youden's index does not change very much";

B. Authors' response to item #2 of my previous review is still inappropriate. Group C is most likely to comprise the uncertain or ill-defined subset of patients. In the real world we have these kinds of neonates. Thus, all data from this group should be included in the ROC analysis. It goes without saying, sentence on page 11, lines 3-4, should be deleted;

C. Authors' responses to items #4 and #5 of my previous review are still inappropriate. The reader of the Journal needs to know the limit of quantification (rather than the detection limit) to quantify the precision of the method as well as the reliability of the diagnostic marker (PCT). Query to Authors: according to the manufacturer, what is the limit of quantification of LUMItest? In a few words, according to the manufacturer, what is the lowest PCT measured concentration with CVs (i.e. coefficients of variations) less than 10%? Thus, Authors should report as undetected values not those read as 0.04 ng/mL, but those falling below the limit of quantification (i.e. ......);

D. Authors' response to item #7 of my previous review is still flawed;

E. Authors' response to item #8 of my previous review is still flawed;

F. Authors' response to item #9.d of my previous review is still inappropriate. Reference #25 includes infants with increased risk of infection (premature PROM > 12 hours, discoloring of amniotic fluid, or clinical signs of maternal or neonatal infection). Indeed, Authors of reference #25 state "Our data ..... give a more detailed picture of the time course of PCT in infants without infection...... We cannot rule out subclinical infection in these infants". On which grounds can these neonates labelled as "healthy" neonates? It goes without saying, reference #25 is misleading since it does not report at all on the PCT "physiologic" (in neonates without any evidence of an abnormal state) peak. Yet, reference #26 is inappropriate since Monneret et al. did not provide evidence that the postnatal course of the 32 "healthy" neonates was unremarkable throughout the neonatal period, implying therefore no need of any management throughout this period.

-----------------------------------------------------------------------------------

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

-----------------------------------------------------------------------------------

Discretionary Revisions (which the author can choose to ignore)

-----------------------------------------------------------------------------------

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published

Statistical review: Yes