

Systematic review of PCR performance in amniotic fluid, for congenital toxoplasmosis diagnosis

| Section 1: Identifying text | | |
|--|-------------------------------------|------------------|
| 1. Identifier number: | 2. Name of reviewer: | |
| 3. Date of review: | 4. First author's name: | |
| 5. Year of publication: | 6. Journal: | |
| 7. Volume: | 8. Number: | 9. Page (first): |
| Section 2: Eligibility full text | | |
| 10. This study approaches women who have suspected acute toxoplasmosis during pregnancy? | 1. Yes 0.No -7.No information | P 10: |
| 11. This study evaluates the accuracy of PCR in amniotic liquid? | 1. Yes 0.No -7.No information | P 11: |
| 12. This study evaluates the accuracy of PCR in cord blood? | 1. Yes 0.No -7.No information | P 12: |
| 13. This study evaluates the accuracy of PCR in maternal blood? | 1. Yes 0.No -7.No information | P 13: |
| 14. This study presents the outcome measures, sensitivity, specificity, predictive values? | 1. Yes 0.No -7.No information | P 14: |
| 15. This study compares the results of the PCR test with a reference test? | 1. Yes 0.No -7.No information | P 15: |
| 16. This study is written in Portuguese, English, French, Spanish or Italian? | 1. Yes 0.No -7.No information | P 16: |
| 17. This study was included for data extraction from full text? | 1. Yes 0.No | P 17: |
| Section 3: assessment of risk of bias by QUADAS 2 | | |
| <i>Regarding the selection of patients:</i> | | |
| A. Risk of bias | | |
| 18. The sample of patients was consecutive or random? | 1. Yes 0.No 9.It is not clear | P 18: |
| 19. A case-control design was avoided? | 1. Yes 0.No 9.It is not clear | P 19: |
| 20. The study avoided inappropriate exclusions? | 1. Yes 0.No 9.It is not clear | P 20: |
| 21. What is the risk of selection of patients have introduced bias? | 1. Yes 0.No 9.It is not clear | P 21: |
| B. Concern about the applicability | | |
| 22. There is concern that the patients included did not correspond to the review question? | 1.High 0.Low 9.It is not clear | P 22: |
| <i>As to the test index</i> | | |
| A. Risk of bias | | |
| 23. The result of the index test was interpreted without knowledge of the results of the reference test? | 1. Yes 0.No 9.It is not clear | P 23: |
| 24. If a decision threshold (cutoff) was used, it was pre-specified? | 1. Yes 0.No 9.It is not clear | P 24: |
| 25. What is the risk of the conduct or interpretation of the index test may have introduced bias? | 1. Yes 0.No 9.It is not clear | P 25: |
| B. Concern about the applicability | | |
| 26. There is concern that the index test, your driving, your interpretation is different from review of the matter? | 1.High 0. Low 9.It is not clear | P 26: |
| <i>As for the reference test</i> | | |
| A. Risk of bias | | |
| 27. The standard reference test correctly classifies the condition of interest? | 1. Yes 0.No 9.It is not clear | P 27: |
| 28. The results of the reference test was interpreted without knowledge of the index test result? | 1. Yes 0.No 9.It is not clear | P 28: |
| 29. What is the risk of the conduct or interpretation of the reference test have introduced bias? | 1.High 0.Low 9.It is not clear | P 29: |
| B. Concern as to the applicability | | |
| 30. There is concern that the condition of interest, as defined by the reference test does not correspond to question of the revision? | 1.High 0.Low 9.It is not clear | P 30: |
| <i>As the flow of patients and time</i> | | |

| A. Risk of bias | | | |
|--|--|----------------------|---------------------|
| 31. There was an appropriate time interval between the index test and reference? | 1. Yes 0.No 9.It is not clear | P 31: | |
| 32. All patients underwent a test reference? | 1. Yes 0.No 9.It is not clear | P 32: | |
| 33. All patients were subjected to the same test reference? | 1. Yes 0.No 9.It is not clear | P 33: | |
| 34. All patients were included in the analysis? | 1. Yes 0.No 9.It is not clear | P 34: | |
| 35. What is the risk of patient flow have introduced bias? | 1.High 0.Low 9.It is not clear | P 35: | |
| Section 4: Characteristics of the study or sample | | | |
| 36. This study is a multicenter? | 1. Yes 0.No 9.It is not clear | P 36: | |
| 37. Nationality of volunteers or country where the research was conducted: | P 37: | | |
| 38. Average or median age of the sample of voluntary pregnant? | P 38: | | |
| 39a. Proportion of pregnant women in the first trimester diagnosis of acute maternal toxoplasmosis: | P 39a: | | |
| 39b. Proportion of pregnant women in the second trimester diagnosis of acute maternal toxoplasmosis: | P 39b: | | |
| 39c. Proportion of pregnant women in the third trimester diagnosis of acute maternal toxoplasmosis: | P 39c: | | |
| 40. What is the average gestational age of acute maternal infection, in weeks? | P 40d: | | |
| 41. Was explicit assessment of research by research ethics committee? | 1. Yes 0.No -7.No information | P 41: | |
| 42. Mean / Median time in weeks between diagnosis of maternal infection and fetal research: | P 42: | | |
| 43. Proportion of pregnant women who received treatment for toxoplasmosis before fetal research: | P 43: | | |
| 44. Average time / average between start of treatment for toxoplasmosis and fetal research: | P 44: | | |
| 45. There is evidence that pretreatment of pregnant women influenced the result of the index test? | 1. Yes 0.No -7.No information | | |
| 46. Ratio diagnosis of acute maternal infection IgM: | P 46: | | |
| 47. Proportion of diagnosis of acute maternal infection avidity test: | P 47: | | |
| 48. Proportion of diagnosis of acute infection by maternal fetal U.S.: | P 48: | | |
| 49. Proporção de diagnóstico da infecção aguda materna por PCR: | P 49: | | |
| 50. Proportion of diagnosis of acute maternal infection clinic: | P 50: | | |
| 51. Study of HIV-infected pregnant women: | 1. Yes 0.No -7.No information | P 51: | |
| 52. Proportion of HIV-infected pregnant women in the sample: | P 52: | | |
| Section 5: Test data | | | |
| 53. Testing in-house? | 1. Yes 0.No -7.No information | P 53: | |
| 54. Name of the commercial test: | | | |
| 55. Manufacturer of commercial test: | 1. Yes 0.No -7.No information | P 55: | |
| 56. Qualitative / Quantitative PCR | 1. Qualitative 2. Quantitative | P 56: | |
| 57. Name of the probe or primer: | P 57: | | |
| 58. Amplified region: | P 58: | | |
| 59. Reported detection limit and analytical sensitivity: | | | |
| 60. Cutoff used in the test, if quantitative: | | | |
| 61. Biological sample used: | 1. Amniotic fluid 2. Cord Blood 3. Maternal Blood 4. Other | P 61: | |
| 62a. Test performance in the first quarter: | P 62a: | | |
| 62b. Test performance in the second quarter: | P 62b: | | |
| 62c. Test performance in the third quarter: | P 62c: | | |
| 63. This paper proposes a prediction model? | Yes 0.No -7.No information | | |
| 64. Test used as reference: | 1. Follow 2. Inoculation 3. Placenta 4. Other | P 64: | |
| 65. Sample size: | | | |
| 66a. True positive: | 66b. False Negative: | 66c. False positive: | 66d. True negative: |

Notes: