

Comparing 0.9% sterile saline to phosphate buffered saline as a transport media for *Tritrichomonas foetus* RT-qPCR testing

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Introduction

The limit of detection for *T. foetus* RT-qPCR is 1 organism/extraction in phosphate buffered saline (PBS) without prior culture. The objective of this study was to determine if 0.9% sterile saline (SAL), a readily available media, was not inferior to PBS as a transport media for *T. foetus* RT-qPCR testing at that concentration.

Materials and methods

Smegma was collected via 10 weekly preputial washings from known *T. foetus* negative bulls. Each week, 1.3 mL of PBS with smegma (n = 60) and 1.3 mL of SAL with smegma (n = 60) were prepared. For each media, 30 samples were inoculated with *T. foetus* to a concentration of 1 organism/100 μ L to evaluate sensitivity (Sn), 30 were left uninoculated to evaluate specificity (Sp). A total of 1200 (Sn_{PBS} = 300, Sn_{SAL} = 300, Sp_{PBS} = 300, Sp_{SAL} = 300) samples were tested by RT-qPCR. Differences in Sn and Sp between SAL and PBS were tested in logistic regression models, with week as a random effect. The Farrington-Manning test for noninferiority was used to evaluate the difference between diagnostic parameters with $\Delta=2.5\%$.

Results

For PBS, Sn = 70.7% (95%CI: 65.2-75.8%), and Sp = 99.7% (95%CI: 98.2-100%); for SAL, the Sn = 73.3% (95%CI:68.0-78.3%), and the Sp = 100% (95%CI: 98.8-100%). No statistical differences between SAL and PBS were detected for Sn or Sp. The Sp_{SAL} was not inferior to Sp_{PBS} (P = 0.008), however, noninferiority of Sn_{SAL} to Sn_{PBS} was inconclusive (P = 0.08).

Significance

The Sn for samples with very low concentration of *T. foetus* in SAL was similar to, and Sp was as good as PBS, suggesting either would be acceptable as transport media.

