ORIGINAL RESEARCH

The use of latex beads in external quality assurance and internal quality control for routine semen analysis

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SUMMARY

The usefulness of latex beads of defined concentration was assessed as a substitute for sperm in the performance of External Quality Assurance (EQA) and Internal Quality Control (IQC) of semen analysis. Within the EQA programme, mean±SEM bias (%) was significantly reduced in 2007 compared to 2002 for both specialist (6.0%±5.4% vs. 55.0%±5.9%) and non-specialist (18.4%±5.9% vs. 90.9%±13.4%) laboratories (both $p<0.0001$), indicating improved accuracy over time. Within the IQC programme, the beads were used in the appraisal of two scientists, one experienced and one inexperienced, against a known standard. Beads were also used to calibrate eleven counting chambers, resulting in one old chamber being discarded due to its poor performance. The present study has shown that the use of a defined concentration of beads is an excellent adjunct to IQC and EQA programmes enabling the performance of both people and equipment to be assessed in an objective manner. *Reproductive Biology 2011 11 3: 264-275.*
Key words: quality control, semen analysis, latex beads

INTRODUCTION

Assisted Reproductive Technology (ART) laboratories, including diagnostic andrology laboratories, in many countries require the mandatory adoption of a Quality Management System (QMS) which is clearly visible to users of the services provided [25]. As part of this process, accuracy and precision of any medical laboratory test must be validated through Internal Quality Control (IQC) and External Quality Assurance (EQA) programmes, and measurements of uncertainty be quantified. Australia is just one example where the process is required if payment is to be secured for recognized tests through the government's Medicare system [17-19].

Manuals for the performance of semen analysis have been made available from the World Health Organization and these have proved valuable in standardizing practice, evolving with increased detail and complexity and culminating in the recent 5th edition [28]. Checking the performance of both equipment and personnel is covered extensively in the current edition and will no doubt be beneficial to laboratories in providing an acceptable professional standard. However, methods for quality control need not be confined to those set out in the WHO manual. The use of latex beads to assess the accuracy and precision of methods for counting sperm can complement the measures recommended in the manual. Whilst the evaluation of methods or personnel in estimating sperm concentration is limited by not knowing the true value, latex beads of a known concentration have long been recognized as a useful tool in the quality control of counting sperm [21], comparing the accuracy of different counting chambers [23, 24], and identifying sources of error associated with counting chambers [15].

The current study describes the usefulness of latex beads in the quality control of semen analysis. The beads were used in an internal quality programme of an andrology laboratory in two ways, namely 1/ checking the performance of the counting chambers and using the data to remove from service chambers that were sub-standard, and 2/ the evaluation of an inexperienced technician relative to an experienced counterpart. The beads were also employed in an EQA programme so that bias could be calculated from a known target value rather than a mean of the participants, and the value of the scheme was gauged by the change in average bias seen over a five year period.