

Abstract

Title : Method validation according to ISO 15189: application of assisted reproductive technology

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The objective of this work is to contribute to respect the requirements of ISO 15189:2012 in terms of performance verification of two techniques of medically assisted procreation (PMA), a manual qualitative technique of: morphological identification of the oocyte, the zygote and the embryo first and then the assessment of sperm concentration.

Due to the lack of internal quality control and external quality evaluation, risk control in the three pre-, post- and post-analytical stages becomes decisive, based on the 5M method.

As regards the assessment of sperm concentration, we establish a method for implementation and validation of internal quality controls samples laboratory-made and to use the control charts X bar, S bar and Bland-Altman plot for the graphical exploitation of the first results concerning the determination of the sperm concentration.

Four technicians having similar experiments in spermiology determined the sperm concentrations of two semen specimen with low and normal concentrations at $11 \times 10^6/\text{mL}$ and $43 \times 10^6/\text{mL}$ using two methods.

Repeatability of our method was established by calculating the CV for the 20 repeats of each ejaculate; our repeatability CVs are 2 times lower than the Ricos values for normal concentration (CV mean of 10.6%) and low concentration (CV mean of 15%). Our method is reproducible for both normal and low sperm concentration levels with CVs of 6.72% and 8.7% respectively and which are lower than the data of the literature (CV=13.4% for Ricos et al 1999), we can conclude that our method is precise with good intra and inter-operator reproducibility.

Comparing our method to the reference method that uses the Neubauer cell proved to us that our method is comparable for spermatic concentrations higher than 20M / ml, below this value, a control by the reference cell is recommended.

Key words: Assisted reproductive technology, validation of methods, retrospective assessment, ISO 15189:2012, sperm concentration, internal quality control, quality management, interlaboratory comparisons, statistical methods, external quality assessment.