

QUALITY REPORT FORM

Please fax or email completed form within 45 days of sample thaw to info@xytex.com to be considered for replacement

Clinic Information:

Reporting Clinic: _____

Inseminating Physician: _____

Patient Name: _____

Person Submitting form: _____

Donor ID number: _____ Lot number: _____ Vial Date: _____

Product Type: Unwashed(ICI) WASHED(IUI) ART ICSI

Specimen Handling:

Date sample received: _____ Condition of Shipper: Charged Thawed (if sample arrived thawed, contact Xytex immediately)

Date sample thawed: _____ Method of thawing? RT how long? _____

37°C H₂O bath how long? _____

Other: _____ how long? _____

Was sample mixed before evaluation? Yes No

Was any processing performed prior to evaluation? Yes No If yes, describe _____

Was sample evaluated on a warm counting chamber? Yes No

Counting chamber used: Makler Hemocytometer Disposable slide (Leja, MicroCell, Cell-Vu, etc)

Counting method used: Manual CASA Kinetics: (4) Excellent (3) Good (2) Fair (1) Poor

Makler/Hemocytometer Calculation:

$$\frac{\text{Volume (mL)}}{\text{Volume (mL)}} \times \frac{\text{Sperm Concentration (M/mL)}}{\text{Sperm Concentration (M/mL)}} \times \frac{\text{Motility (\%)}}{\text{Motility (\%)}} = \frac{\text{Total Motile Concentration in vial (M)}}{\text{Total Motile Concentration in vial (M)}}$$

IF DISPOSABLE COUNTING CHAMBER USED:

$$\frac{\text{Total Motile Concentration in vial (M)}}{\text{Total Motile Concentration in vial (M)}} \times 1.3 \text{ (Conversion factor*)} = \frac{\text{Corrected Total Motile Concentration in vial (M)}}{\text{Corrected Total Motile Concentration in vial (M)}}$$

Was the unit used for insemination: Yes No

Was any processing performed on the semen after evaluation by your lab prior to insemination? Yes No

If yes, describe _____

Is the patient pregnant? Yes No Too early to test; expected pregnancy test date: _____

Type of assisted reproduction: ICI IUI IVF ICSI

Comments: _____

I attest to the accuracy of the above information: _____

Submitter's Signature

Date

REQUIREMENTS FOR CREDIT CONSIDERATION

- Supporting documentation must be submitted, including specimen processing report and pregnancy test results. If sample was used in an IVF procedure, please include the fertilization report.
- Specimen must be thawed according to Xytex protocols (included with each shipment).
- Specimens stored longer than 90 days at clinic prior to thawing will not be considered.
- Specimen must be evaluated with a quantitative analytical method upon a warmed counting chamber prior to any processing or manipulation being applied; Xytex acknowledges up to a 25% variation between laboratories.
- Quality Reports for inseminations with Xytex donor sperm specimens resulting in a positive pregnancy test will not be considered.
- Quality Reports for IVF cycles without a transfer having achieved fertilization with a Xytex donor sperm specimen will not be considered.

*conversion based on evidence that disposable slides display reproducible results 30% lower than Makler Chamber

Selected conversion factor literature review:

Peng, N., Zou, X. & Li, L. (2015) Comparison of different counting chambers using a computer-assisted semen analyzer, Sys Biol Reprod Med, 61:5, 307-313

Schiewe, M.C., Rothman, C., Sims, C.A., & Shamonki, J. (2018) Understanding inter-laboratory variation in post-thaw assessments of human sperm concentration and motility: counting chamber effect and other variables. JSM Sexual Med, 3(1):1015