

QUALITY REPORT

To be completed by the patient's
clinic or participating lab.



PHONE 706-733-0130

FAX 706-736-9720

Please review the Requirements for Specimen Credit Consideration below.

Files will not be reviewed until all supplemental materials are received. Please print legibly and allow our lab up to **45 business days** to process inquiries once a complete file is received by Xytex. Remit all paperwork to info@xytex.com.

MUST INCLUDE:

- ☐ Andrology report
- ☐ Pregnancy test results
- ☐ Fertilization report if sample was used in an IVF procedure

Reporting Clinic: _____ Inseminating Physician: _____
Client Name: _____ Person Submitting form: _____
Client Email: _____ Clinic Email: _____

IS THE CLIENT PREGNANT? ☐ Yes ☐ No

Donor Vial Identification:

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

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

Specimen Handling:

Date sample received: _____ Condition of Shipper: ☐ Charged ☐ Thawed (If sample arrived thawed, contact Xytex immediately)
Date sample thawed: _____ Method of thawing? ☐ RT duration? _____
☐ 37°C H₂O bath duration? _____
☐ Other: _____ duration? _____

Specimen Analysis

Was sample evaluated on a warm counting chamber? ☐ Yes ☐ No

Was sample mixed before evaluation? ☐ Yes ☐ No If yes, describe: _____

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

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

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

INITIAL 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, PROCEED WITH THE FOLLOWING CALCULATION:

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

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: _____

Reason for quality report submission: _____

Additional comments: _____

I attest to the accuracy of the above information:

Submitter's Signature

Date

REQUIREMENTS FOR SPECIMEN CREDIT CONSIDERATION

- Supporting documentation must be submitted *within 45 days of sample thaw*, including specimen processing/andrology report and pregnancy test results. If sample was used in an IVF procedure, please include the fertilization report.
- Specimen must be thawed and handled according to Xytex protocols (included with each shipment).
- Specimens stored at the clinic longer than **60 days** 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 having achieved fertilization with a Xytex donor sperm specimen will not be considered.
- Quality Reports submitted for units shipped to locations other than a clinic (i.e. home shipments or other cryo storage facilities) 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., & Shamoni, 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