### Quality Control of Reproductive Products

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<th>Assay</th>
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| Mouse Embryo Testing MET     | Fresh one-cell mouse embryos are cultured in test and control media for 96 hours and the % blastocyst (fully expanded) development is determined. | - Game and Embryo Culture Media  
- Oil for Embryo Culture  
- Water for ART Use  
- Protein Supplements  
- Sperm Washing Media  
- Embryo Biopsy Medium  
- Hyaluronidase Solution |
| (B1C3F1 X B4D2F1)           | Modified MET: For some products the embryos are exposed for a limited time (up to 2 hours) to the solution, washed and then cultured in growth control medium to blastocysts (fully expanded) by 96 hours. | - Embryo Freeze Media  
- Embryo Thaw Media  
- Blastocyst Freeze Media  
- Blastocyst Thaw Media  
- Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Embryo Recovery Assay*       | Fresh one-cell mouse embryos are sequentially exposed to freeze media, frozen, then thawed and exposed sequentially to thaw media. The thawed one-cell embryos are then cultured in growth medium to determine % blastocysts (fully expanded) by 96 hours. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Blastocyst Recovery Assay*   | Fresh mouse blastocysts are sequentially exposed to freeze media, frozen, then thawed and exposed sequentially to thaw media. The thawed blastocysts are then cultured for 24 hours in growth medium to assess survival (re-expansion and viability). | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Sperm Survival Assay (human) | Sperm specimens are processed in test and control media, then washed and the % motility is determined after 24 hours of incubation in sperm washing medium. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Sperm Motility Recovery Assay | Sperm Motility Recovery Assay is a modification where sperm are exposed to the solution for up to 60 minutes, then washed and the % motility is determined. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Sperm Cryo-Survival Assay*    | Semen is cryopreserved according to product’s directions for use, then thawed, washed and the % motility is determined. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Rabbit Pyrogen tested        | In vivo pyrogen testing by evaluation of vaginal irritation in rabbits following intravaginal administration of Isolate. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Formulation Verification     | HPLC quantitation of energy substrates and amino acids (as appropriate) to verify concentrations within formulation specifications. | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Enzymatic Activity Assay     | A standard turbidimetric assay is used to quantify the specific activity of hyaluronidase raw material and finished product | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |
| Other Assays                 | pH, Osmolality and Endotoxin (USP <85>)  
Sterility (USP <71> and CFR Title 21 part 610.12)  
Appearance, Bioburden and Moisture | - Isolate*-Sperm Separation Media  
- PVP Lyophilized  
- PVP Solution  
- Refrigeration Medium-TYB  
- Freezing Medium-TYB  
- Sperm Maintenance Medium  
- Gamete and Embryo Culture Media  
- Hyaluronidase Solution  
- All products  
- Powder media |

Quality defines the beginning and the end of product manufacture at Irvine Scientific. It begins with stringent supplier qualification standards and confirmation of incoming raw materials. Quality objectives and standards direct the detail of our manufacturing processes and protocols. In-process testing and confirmation ensures quality through each product’s manufacture and end-stage testing confirms that a product can be released into finished goods inventory. Quality of process at Irvine Scientific delivers confidence in performance and outcomes for our customers.

*Customized QC assay utilized by Irvine Scientific to emulate the intended use of the product. For more information on all of our Reproductive Products, call 1 (800) 437 5706.

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