

QwikCheck™ Beads

Quality Control Material for Sperm Counting Systems

QwikCheck™ Beads are an FDA approved quality control material for use in automated and manual sperm counting systems. The beads are for in-vitro use only and can be used to assess the accuracy and precision of the laboratory's sperm counting methods by providing a known target value.

The beads are assayed for use on the following automated and manual systems:

- SQA-V / SPERMALITE™ automated systems
- SQA-V visualization system (standard slide)
- Neubauer hemacytometers
- Makler counting chambers
- Fixed cover slip chambers (like MicroCell™)



QwikCheck™ Beads

OVERVIEW

Each kit of QwikCheck™ Beads contains:

- Two 5 ml. vials of latex beads of a known concentration plus one 5 ml. vial of a NEGATIVE (ZERO) control.
- A product insert with a sample table of target values and +/- ranges.
- Instructions describing how to run the assayed beads on the SQA-V and standard laboratory counting chambers in the same manner the laboratory runs sperm counts.

Sample Table for All Control Levels:

| Counting Method | Level 1 (Million/mL) | | | Level 2 (Million/mL) | | | Level 3 Negative Control | |
|-----------------------------------|----------------------|-----------|-------------|----------------------|-----------|-------------|--------------------------|------|
| | Target Value | Range +/- | Between | Target Value | Range +/- | Between | Conc. | MSC |
| SQA-V Automated | 45 | 6.4 | 38.6 - 51.4 | 23 | 3.2 | 19.8 - 26.2 | 0.0 | 0.0 |
| SQA-V Visualization | 46 | 11.6 | 34.4 - 57.6 | 24 | 5.9 | 18.1 - 29.9 | 0.0 | 0.0 |
| Hemocytometer (Neubauer) | 45 | 11.1 | 33.9 - 56.1 | 21 | 5.2 | 15.8 - 26.2 | 0.0 | N.A. |
| Counting Chamber (Makler) | 47 | 11.9 | 35.1 - 58.9 | 25 | 6.2 | 18.8 - 31.2 | 0.0 | N.A. |
| Fixed Coverslip (like Micro-Cell) | 44 | 10.9 | 33.1 - 54.9 | 22 | 5.4 | 16.6 - 27.4 | 0.0 | N.A. |

According to CLIA, "...for most moderately complex tests, the general requirement is to analyze two levels of QC materials on each day of testing" (Quest Essay Quality Regulations – 2002 Update).

QwikCheck™ Beads can be ordered directly from the Medical Electronic Systems website @ <http://www.mes-ltd.com> by selecting the "Products" tab or through your local SQA-V distributor by calling 310 557-9066.



Medical Electronic Systems

www.mes-ltd.com

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