11/3/04

QC-BEADS™

For Use as Controls in Counting Sperm Using Manual and Automated Methods

Intended Use:

QC-Beads™ are intended for use as controls in counting sperm manually using a microscope or automatically using computer assisted semen analysis instruments.

Summary and Explanation:

Standardized counting of sperm is an important part of routine semen analysis. QC-Beads™ has been developed to monitor the accuracy of sperm counting methods. QC-Beads™ is used in the same manner routinely used within the laboratory for counting sperm, as described in the *WHO Manual*. In accordance with CLIA regulations, QC-Beads™ are supplied as two different levels of controls.

It is recommended that the researcher perform a quality control check using the two levels of controls each day prior to counting sperm samples.

Reagents: For in vitro diagnostic use only.

Hi QC-Beads™: 4 ml bead suspension of known concentration with 0.1% sodium azide. See **Expected Values** for the number of beads/ml. Ready to use.
Lo QC-Beads™: 4 ml bead suspension of half the concentration of the Hi QC-Beads™ with 0.1% sodium azide. See **Expected Values** for the number of beads/ml. Ready to use.

Precaution:

Keep reagent bottles tightly capped at all times to prevent evaporation. Warning: Contains 0.1% sodium azide. Dispose of with care.

Storage and Stability:

Store the reagents at room temperature. They can be used until the expiration date on each label. The expiration date is one year from the date of manufacture. Do not freeze.

Limitation:

The QC-Beads™ cannot be used to validate the accuracy of manual and automated methods of counting moving sperm.

Procedure for Manual Counting of QC-Beads™:

Count the beads using a standard counting procedure for counting sperm.

1. Invert the bottle several times to resuspend the Hi QC-Beads™.
2. Using a pipette, remove the volume recommended for the counting chamber you are using. (If using a hemacytometer, dilute the Hi QC-Beads™ before counting.)
3. Pipette the bead suspension into the counting chamber.
4. Immediately recap the bottle.
5. Wait about 5 minutes to allow the beads to stop moving and then observe using a microscope.
6. Count at least 200 beads.
7. Calculate the concentration of beads according to the counting chamber manufacturer's instructions.
8. Repeat steps 1- 7 using a fresh aliquot of beads.
9. Compare the two results. If the results are within 10% of each other, then average the two counts.
10. The average count should be within the range of the **Expected Values**. If the results are not within this range, then repeat steps 1-9.
11. Repeat steps 1-10 using the Lo QC-Beads™.

Procedure for Automated Counting of QC-Beads™:

Count the beads using a standard counting procedure for counting sperm.

1. Invert the bottle several times to resuspend the Hi QC-Beads™.
2. Using a pipette, remove the volume recommended for the counting chamber you are using.
3. Pipette the bead suspension into the counting chamber.
4. Immediately recap the bottle.
5. Place the counting chamber in the automated analyzer and follow the directions for performing a sperm count.
6. Count at least 5 fields so as to count a total of at least 200 beads.
7. Record the concentration of beads.
8. Repeat steps 1-7 using a fresh aliquot of beads.
9. Compare the two results. If the results are within 10% of each other, then average the two counts.
10. The average count should be within the range of the **Expected Values**. If the results are not within this range, then repeat steps 1- 9.
11. Repeat steps 1-10 using the Lo QC-Beads™.

Expected Values:

Counting chamber of 0.1-mm thick, such as a hemacytometer:

Hi QC-Beads™ between 34 - 46 million beads/ml.
Lo QC-Beads™ between 16 - 24 million beads/ml.

Counting chamber of 20-µm thick, such as a Cell-Vu, Micro-Cell, or Standard Count:

Hi QC-Beads™ between 30 - 40 million beads/ml.
Lo QC-Beads™ between 15 - 21 million beads/ml.

Makler Chamber:

Hi QC-Beads™ between 53 - 67 million beads/ml.
Lo QC-Beads™ between 25 - 34 million beads/ml.

References:

World Health Organization. 1992, 1999. *WHO laboratory Manual for the examination of human semen and sperm-cervical mucus interaction.* Cambridge University Press.

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