

INTENDED USE

QC-Beads™ are used as controls in counting sperm manually using a microscope or automatically using computer assisted semen analysis instruments. QC-Beads cannot be used to validate the accuracy of manual and automated methods of counting moving sperm.

SUMMARY

Standardized counting of sperm is an important part of routine semen analysis. QC-Beads have been developed to monitor the accuracy of sperm counting methods and 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. This kit contains:

Hi QC-Beads: 4 ml bead suspension of known concentration with 0.1% sodium azide. See Expected Values for the number of beads/ ml.

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

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

PRECAUTIONS

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

STABILITY AND STORAGE

The reagents are stable to the stated expiration date when stored at the required temperature. Store reagents at room temperature. Do not freeze.

USER QUALITY CONTROL

This product is a white opaque liquid. Any product showing discoloration should be discarded.

SPECIMEN COLLECTION AND PREPARATION

Semen should be collected in a clean collection cup. The semen sample can be stored at room temperature until the time of use.

PROCEDURE

Materials Provided with QC-Beads (#0006020): Hi QC-Beads, Lo QC-Beads.

Materials Not Provided: Hemacytometer or counting chambers, automated counting equipment, microscope.

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.

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 to ensure a 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- μ m 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.

EXPECTED RESULTS

QC-Beads should yield the expected counts when using the methods contained in these instructions for use.

LIMITATIONS OF PROCEDURES

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

BIBLIOGRAPHY

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

CONTACT

Alpha-Tec Systems, Inc. offers a complete line of reagents, stains, and QC1™ Quality Control Slides for AFB, Parasitology, Bacteriology, and Mycology processing. Alpha-Tec also provides O&P collection systems and concentration devices for Parasitology, as well as products for the evaluation of male fertility. For Technical Assistance, email Technical@AlphaTecSystems.com, and for Customer Service, email Sales@AlphaTecSystems.com, or call either [+1] 800.221.6058 (USA) or [+1] 360.260.2779 between 8AM and 4PM Monday through Friday, Pacific Time.

WARRANTY

This product is warranted by Alpha-Tec Systems, Inc. to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

TRADEMARKS:

QC-Beads™ is the trademark of Alpha-Tec Systems, Inc., a CalibreScientific Company. 1311 SE Cardinal Court, Suite 170, Vancouver, WA 98683 USA.

PRODUCT CODES:

0006020 QC-Beads, 2 x 4 ml



Manufactured by Alpha-Tec Systems, Inc.
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GLOSSARY OF SYMBOLS

- LOT** Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote
- REF** Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog number / Het aantal van de catalogus / Kataloška številka / Número de catálogo
- IVD** In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro
- EC REP** Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Gemachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeu Autorizado
-  Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada
-  Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante
-  Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / laktag försiktighet / Previdno / Atenção
-  Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperatura comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas
-  Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenido suficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebinsa zadostuje za <n> testov / Contém quantidade suficiente para <n> testes
-  Consult instructions for use / Consulter la notice d'utilisation / Consulte las instrucciones para el uso / Consultare le istruzioni per l'uso / Bitte beachten Sie die Anwendungsvorschriften / Raadpleeg instructies voor gebruik / Konsultera bruksanvisningen innan användning / Glej navodila za uporabo / Consulte instruções para o uso
-  Do not reuse / Ne pas réutiliser / No reutilizar / Non riutilizzare / Nicht wiederverwenden / Niet hergebruiken / Återanvänd inte / Ne uporabljajte znova / Não reutilize