MICROFLUIDIC SPERM SORTING CHIPS

FERTILE® PLUS

Device Components:
- FERTILE PLUS® Microfluidic Sperm Sorting Chips (10 pcs)
- Instructions for Use
- ID Card (10 pcs)

Materials/Equipment Required, But Not Supplied:
- Sperm washing solutions: bicarbonate or HEPES-buffered
- 37ºC incubator
- 1 mL Luer-tip syringes (3 pcs)
- Capped tubes

Learn more at www.fertilechip.com

CE 1984

Instruction for Use

Please read all instructions below prior to beginning use of this device.

1. Incubate semen sample to allow for liquefaction (15 minutes).

2. Carefully open the device package from corner.

3. Use a 1 mL syringe to draw an 850 µL aliquot of liquefied semen specimen. If there is insufficient volume, add sperm washing solution to give 850 µL.

4. Take approximately 850 µL of semen sample from the sample container with the help of an injector. Be careful not to get air bubbles into the syringe while taking samples due to its dense structure. These air bubbles will cause volume loss and affect the performance of the product (Figure 1).

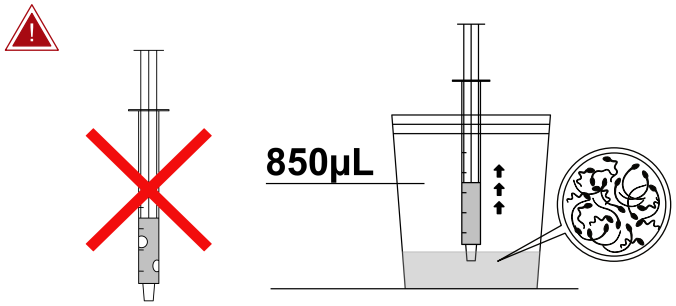

Figure 1. Draw 850µL of the sample.

5. Hold the syringe in a vertical position, carefully insert the tip into the inlet and apply gentle pressure to achieve a seal. Be careful to avoid the formation of bubbles under the membrane (Figure 2).

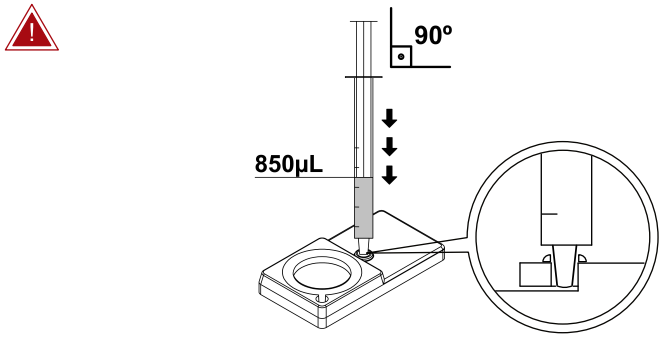

Figure 2. Fill the bottom chamber with 850 µL semen sample.

6. Prepare a fresh syringe with 750 µL of sperm wash solution. Cover the entire upper collection chamber. Ensure an uninterrupted flow of media over the membrane and the outlet port (Figure 3).

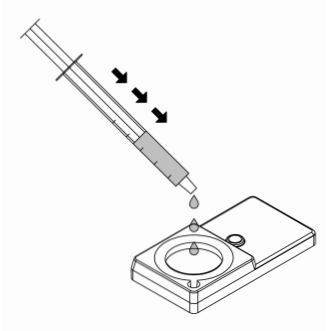

Figure 3. Cover the membrane surface with 750 µL sperm wash solution.

7. Incubate the prepared device at 37°C for 30 minutes. If you are using HEPES buffered media you don't need CO_2 incubator. If you use bicarbonate buffered media, you have to use 5% CO_2 incubator. (Figure 4).

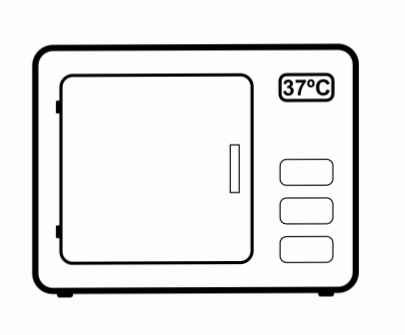

Figure 4. Incubate the prepared device at 37°C for 30 minutes.

8. After 30 minutes incubation, insert a fresh 1 mL syringe into the outlet port of device.Slowly aspirate a maximum of 500 µL of the sperm-containing fluid (Figure 5).

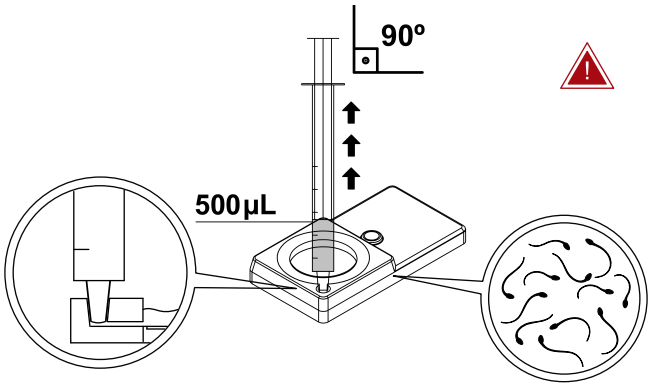

Figure 5. Slowly aspirate a maximum of 500 µL.

9. Transfer the collected material to a capped tube. Store for later use according to lab practice (Figure 6).

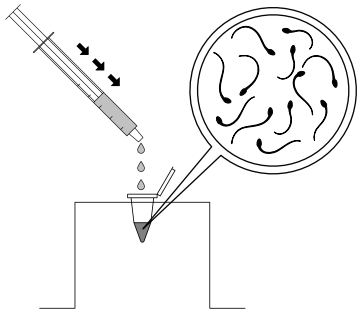

Figure 6. Transfer the collected material for later use.

Tips, Warnings and Precautions:

• Device should be used only by properly trained operators; by or on the order of a physician.

• Avoid over- or under-filling the device.

• Keep the device level during use – do not tip or rock.

• Do not use if the packaging is damaged.

• Device is single-use only and should be restricted to a single individual per device. It may not be reused.

• Practice universal precautions when handling human body fluids.

Device Description:

FERTILE®, FERTILE PLUS® and FERTILE ULTIMATE® are microfluidic sperm sorting chips used to prepare motile sperm for assisted reproductive technology (ART) procedures. Both devices separate sperm based on motility. The FERTILE®, the FERTILE PLUS® and the FERTILE ULTIMATE® are sterile and single use only. The mechanism of action for both is separation of sperm based on motility within a microenvironment created by the micro channels of the FERTILE® or the micropores in the filter of the FERTILE PLUS® and the FERTILE ULTIMATE®. The primary difference between the devices is the processing volume. The FERTILE® has a processing volume of 2µL per micro channel. The FERTILE PLUS® has a processing volume of 850µL per device and FERTILE ULTIMATE® has 3mL.

The FERTILE PLUS® and FERTILE ULTIMATE® have an inlet port that communicates with the lower sample chamber. The sample chamber is separated from the upper collection chamber by a microporous filter. Untreated semen is added through the inlet port. After 30 minutes, the separated sperm are collected from the upper chamber through the outlet port.

Indications for Use:

The FERTILE PLUS® Microfluidic Sperm Sorting Chip is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intrauterine insemination (IUI) procedures.

Contraindication:

There is no known absolute and / or relative contraindication defined in the use of the device.

Minimum Knowledge and Education Level:

The product is used in embryology and andrology laboratories for assisted reproductive treatments. For its use, it has to be someone who can use pipettes such as biology, biochemistry, medicine, laboratory technician and can perform routine procedures in embryology laboratories.

Residual Risk:

Not available.

Sterilization:

The sterilization method used for the FERTILE PLUS® chip is gamma radiation, at a dose level of 5kGy to 40kGy by the VD_{max}^{25} method to meet a Sterility Assurance Level of 10^{-6}.

Storage:

Store at 15ºC - 25ºC.

Disposal:

Discard the used device and pipette tips as medical waste.

NOTIFIED BODY

Kiwa Turkey Istanbul Branch Office

Address: ITOSB Tepeoren District 34957 Tuzla / Istanbul TURKEY

Phone: +90 216 593 25 75

Fax: +90 216 593 25 74

E-Mail: info@kiwa.com.tr

KIWA CE MARK

CE 1984

WARNING DESCRIPTION

Manufacturer Information	Breakable, Carefully Move
Manufacturing Date	Store in a Dry Place
Expiration Date	Storage Temperature
LOT Number	Do not re-use
REF Catalogue Number	Please, read the Instruction for Use, before use
STERILE R Sterilization Method	Observe Alerts
Do not re-sterilize	Suitable for 93/42/EEC Standards.
Do Not Use If The Packaging Is Corrupted	

Licenses, Patents and Trademarks:

KOEK Biotechnology is an exclusive sublicensee of DxNow, Inc., And a manufacturer of DxNow's sperm separation devices. These devices are manufactured and sold under the terms of DxNow Inc.'s exclusive worldwide patent license from The Brigham & Women's Hospital, Inc., Boston, Massachusetts, USA.

EU Patent EP2710139B1. Additional USA and international patents pending. FERTILE®, FERTILE PLUS® and FERTILE ULTIMATE® are trademarks of KOEK Biotechnology Inc.

MANUFACTURER

Manufacturer Name: KOEK Biotechnology Bioengineering and Medical Services Industry and Trade Inc. Aegean Freezone Branch Office

Manufacturing Address: Zafer Sb. District Nilufer Str. Aegean Freezone ESBAS B Block Apt. No:29/4 Gaziemir / IZMIR - TURKEY

Phone: +90 232 503 37 08

E-Mail: info@koekbiotech.com

R&D: KOEK Biotechnology Bioengineering and Medical Services Industry and Trade Inc.

Address: Inciraltı District. Mithatpasa Str. Dokuz Eylul Hospital Building. Morfoloji Apt. No:56-20/Z Balcova / IZMIR - TURKEY

Phone: +90 232 236 78 14

E-Mail: info@koekbiotech.com

KOEK BIOTECHNOLOGY

KK-02EN - First Published Date: 01.04.2020 - Revision No: 01 - Date: 20/05/2020