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Viscosity-CH

reagent for
hyper viscous semen

REF SP/SFT/VS-001-A

IVD

User Manual

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product



Turnaround time for test: 15-18min



Store at: 2°C - 8°C after receiving

Concept

After ejaculation, semen normally coagulates into a gelatinous mass & then liquefies within 60 min at room temperature or 37°C.

Proteins originating from seminal vesicle **cause coagulation** while **proteases** originating from prostate cause the coagulum to **liquefy**.

Viscosity measures **friction** between various seminal fluid components as they slide by one another. Usually viscosity & liquefaction time go hand in hand. i.e. if liquefaction time is more, then viscosity is increased.

High viscosity combined with poor sperm motility can lead to a marked **decrease in fertilization capacity** due to **problems with delivery** i.e. the poor or total absence of sperm-release into the cervical mucus. Therefore, its viscosity must be made normal before performing semen analysis & sperm function tests.

Viscosity can be **evaluated** by performing '**String Test**' or by using '**Modified Pipette Method**'. It is measured in **millimeters (mm)** by the length of '**Spinnbarkeit**' or '**Threadiness**'.

If an **average length (mm)** of a string or a drop is :

- < 40 mm - **Normal Viscosity**
- 40 - 60 mm - **Equivocal**
- > 60 mm - **Abnormal (Highly Viscous)**

Highly viscous sample should be **treated** with **Chemotrypsin** or **Bromelain**. Both treatments do not affect the sperm function tests.

Viscosity - CH™ should be used only for semen analysis & Sperm Function Test. Viscosity - BR™ for semen processing.

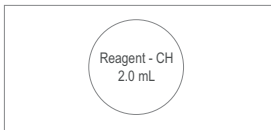
Specimen Preparation

- Semen sample is collected with :
 - **Abstinence period** of **2-7 days**.
 - **Ideal collection** through **masturbation** in sterile container.
 - **Non-spermicidal polyurethane semen collection pouch (Sperm Collect™)** can be used when required.
- Semen sample is allowed to liquefy and then wellmixed for performing test.
- Ideally test is to be performed within 30 to 60 min of collection.

Kit Contents

- Reagent - CH : 2.0 mL

Content Box Diagram :



Storage Conditions:

- The kit should be stored in dark at 2°C - 8°C after receiving.
- Bring all the reagents to room temperature before use.
- Once opened, store reagents in the fridge protected from light.
- Expiry date is printed on the out side of the box.

Equipments

REQUIRED BUT NOT PROVIDED IN KIT

- Controlled Temperature 37°C Dry bath (Sperm Warmer™ / Water bath)
- Pipettes Set
- Stopwatch
- Microtip Box

Disposable Materials

REQUIRED BUT NOT PROVIDED IN KIT

- Hand gloves
- Semen Collection Container
- Non-spermicidal Semen Collection Pouch (Sperm Collect™)
- Microtips
- Pasteur Pipettes
- Test Tubes
- Filter Papers

Procedure

Step 1 : Label plastic ware & disposable material with appropriate **Patient ID & Sample ID.**

Step 2 :

- Use freshly collected semen (liquefied & well mixed) sample to perform the '**String Test**'. (Ideally use sample within **30 to 60 min** after collection).
- **Confirm hyper-viscosity** of semen sample by performing the '**String Test**'.
- Label the semen sample as 'Hyper-viscous' if the thread is more than 4 cm in length.

Step 3 :

Measure the volume (approx.) of semen.

Step 4 :

Add 10 µL/mL of Reagent - CH to semen sample & mix well.

Step 5 :

Keep sample (well mixed) at **37°C** for about **10 - 15 min** (max 30 min).

Quick Glance

Viscous semen sample with **approx. volume**



Add 10µL/ml of Reagent - CH to semen sample



Keep semen sample at **37°C for 10 - 15 min**



Mix Well semen sample & perform **String** test

Examination

- Perform string test on reagent added sample to **recheck viscosity**.
- Note the **length** of the 'string'.

Result

- If length of string is **less than 4 cm**, **viscosity** of sample should be considered as **normal**.

Precautions

- All patient samples & reagents should be treated as potentially infectious & the user must wear protective gloves, eye protection & laboratory coats when performing the test.
- The kit should be discarded in a proper biohazard container after testing.
- Do not eat, drink or smoke in the area where specimens & kit reagents are handled.
- Do not use beyond the expiration date which appears on the package label.
- It is recommended to use of gloves & face mask.

Safety & Environment

- Do not release the products used into the environment. Follow centre guidelines for the storage & disposal of toxic substances.
- Biological samples must be handled as potentially infectious.

Description of Symbols



consult instructions of use



product reference



lot number



use by



manufacturer



health surveillance device
for in-vitro diagnostic



contains sufficient for 'n' tests



temperature limitation



keep dry




CE mark (Conformité Européene)


Accreditations & Registered Certificates

- **ISO 13485 : 2003** Certified
- **CE** Certified
- **GMDN** Registered
- **US FDA** Registered

For more information & procedure videos

 www.spermprocessor.com/sft-viscosity.html



 www.youtube.com/watch?v=EnYbcMIPsAg

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