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## Sperm Confirm

test to confirm sperms in a smear

REF SP/SFT/SC-014

IVD



User Manual



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Turnaround time for test: 6-7min



Store at: 2°C - 8°C after receiving

## Concept

Azoospermia is defined as absence of sperm in the ejaculate (given as the limit of quantification for the assessment method employed). Cryptozoospermia is defined as sperm absent from fresh preparations but observed in a centrifuged pellet.

During microscopic examination, absence of sperm is known to occur. **Azoospermia diagnosis** should be made **only after** an undiluted ejaculate is centrifuged, & the **complete absence** of sperm in the **centrifuge pellet is microscopically confirmed** in not less than two ejaculates.

**Sperm confirm test** is used on the **pellet sample** to confirm presence of sperm. If sperm is present, condition is called as Cryptozoospermia & if sperm is absent it is called as Azoospermia.

## 1 Specimen Preparation

- Semen sample is collected with :
  - **Abstinence period of 2-7days.**
  - **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 well mixed for performing test.

### Special Instructions :

- **Hyperviscous** semen sample should be processed to bring towards normal viscosity. (**Viscosity-CH™** or **Viscosity-BR™** kit can be used)

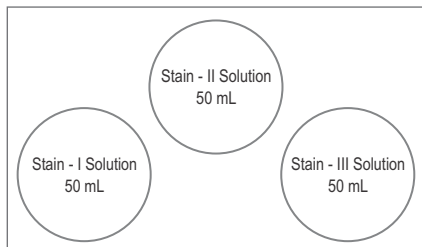
## 2 Kit Contents

- Stain - I Solution : 50 mL
- Stain - II Solution : 50 mL
- Stain - III Solution : 50 mL

### **Other Reagents (Required But Not Provided In Kit) :**

- Distilled Water
- Xylene (Neoclear)
- Mounting Solution
- Immersion Oil

### 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.

**REQUIRED BUT NOT PROVIDED IN KIT**

- Microscope
- Controlled Temperature 37°C Dry bath (Sperm Warmer™ / Water bath)
- Pipette Set
- Centrifuge Machine (Androspin™)
- Slide Warmer™
- Stopwatch
- Semen Analysis Chamber (Sperm Meter™)
- Microtip Box
- Staining Tray
- Glass Slide Stand
- Glass Slide Tray
- Coplin Jar

**REQUIRED BUT NOT PROVIDED IN KIT**

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

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

**Step 2 :** After initial microscopic examination, if **no sperm** is **observed**, then **centrifuge** the liquefied semen sample at **2000 rpm** for **5 min**.

**Step 3 :** **Discard supernatant & pellet** is **ready** for microscopic examination.

**Step 4 :** Place **10 µL** of pellet sample (obtained after centrifugation) on glass slide.  
**Form smear.**



**Step 5 :** Allow smear to **air dry** (use Slide Warmer™).

**Step 6 :** Lay dried smear horizontally & **cover** entire smear with **1 mL Stain - I** solution. Keep it for **5 min**.



**Step 7 :** **Drain off Stain - I** solution & **rinse** smear in **distilled water (DW)**.



**Step 8 :** Lay smear horizontally & **cover** entire smear with **1 mL of Stain - II** solution. Keep it for **3 - 5 sec.**



**Step 9 :** **Drain off Stain - II** solution.



**Step 10 :** **Rinse** smear in **Stain - III** solution.

**Step 11 :** **Dry** smear on Slide Warmer™.

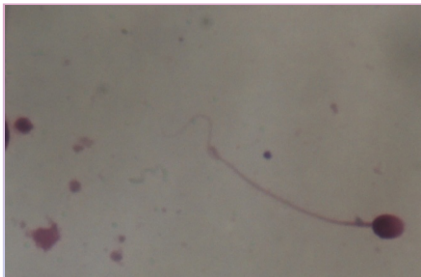
## Quick Glance



Examine  
under **100x** objective lens

- Put a **drop** of **immersion oil** on dry smear.
- **Examine** smear under the microscope with the help of **100x** objective lens.
- If **sperm** or **immature sperm** are present in the smear, then they appear as **stained red bodies**.
- **Acrosomal cap** stains **less intensely red** than the nuclear protein of the sperm head.
- If present, the **mid-piece & tail** sections are stained **green** or **blue – green**.
- **Background** material is stained **blue** or **green**.

#### Reference Image :



#### **Semen Smear Examination (Centrifuged Sample)**

- Microscopic Examination of Stained Smear
  - Sperm Found
  - No Sperm Found
- Number of sperm present as per the field :
  - 1 +** : Few sperm seen in smear
  - 2 +** : Presence of sperm more than 2 - 3 per microscopic field.
  - 3 +** : Presence of sperm more than 5 per microscopic field
  - 4 +** : Presence of sperm is almost in each microscopic field.

(As per **Fifth Edition** of **WHO Laboratory manual** For Examination And Processing Of Human Semen.)

#### Limitations :

- This test provides presumptive quantitative information of sperm.
- This parameter should be analyzed by a specialist.
- The result should be evaluated taking into account all clinical & laboratory findings related to the same sample.

**Permanent Stained Slide :**

- Dip dried stained - slide into Xylene (Neoclear) solution just prior to coverslipping.
  - Place the mounting media on the slide.
  - Place the coverslip on to the slide as quickly as possible to avoid air-drying & air bubbles.
- 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.

- 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-sperm-confirm.html](http://www.spermprocessor.com/sft-sperm-confirm.html)

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