

VitalScreen

For in vitro diagnostic use
Reagents for professional use only

IVD

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MATERIAL INCLUDED

Catalogue number

VITAL 200 tests VitalScreen

CUSTOMER-TECHNICAL SUPPORT

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VitalScreen

GENERAL INFORMATION

VitalScreen uses eosin-nigrosin staining to assess the percentage of live spermatozoa. The technique is based on the principle that dead cells take up eosin through their cell membrane, and as a result stain red. The nigrosin provides a dark background which makes it easier to evaluate the slides.

Sperm vitality should be determined when less than 40% of spermatozoa are motile. In samples with poor motility, it is important to discriminate between immotile dead sperm and immotile live sperm ⁽¹⁾.

INTENDED USE

VitalScreen is a semi-quantitative, non-automated diagnostic test to evaluate the vitality of spermatozoa in a semen sample by using an eosin-nigrosin staining. VitalScreen may help in assessing the diagnosis and management of male infertility.

VitalScreen is designed so that 200 tests can be performed with 1 kit.

MATERIAL INCLUDED WITH THE TEST

VitalScreen (product code: VITAL):

- Reagent 1 - 20ml of 1% Eosin Y in saline
- Reagent 2 - 30ml of 5% Nigrosin in saline

A certificate of analysis and MSDS are available on request or can be downloaded from our website (www.fertipro.com).

MATERIAL REQUIRED, BUT NOT PROVIDED

- light microscope (400 - 600x magnification)
- microscope slides
- cover glasses
- pipettes and fresh pipette tips
- small reagent tubes or Eppendorf tubes

METHOD

Scan barcode (or follow link on www.fertipro.com) to view the demonstration video:



SPECIMEN COLLECTION AND PREPARATION

VitalScreen should be performed on fresh, human semen samples, preferably within one hour after ejaculation.

REAGENT PREPARATION

Reagents are ready to use. Mix Reagent 2 before use.

METHOD VITALSCREEN

- 1 Add 50 µL of semen and 2 drops of reagent 1 in an Eppendorf tube. Mix gently. Avoid contact between the reagent bottle and the tube containing semen.
- 2 Within **30 seconds**, add 3 drops of reagent 2. Mix gently. Avoid contact between the reagent bottle and the tube containing semen.
- 3 Within **30 seconds** of adding reagent 2, place 20 µl of the semen-stain mixture on a microscope slide and immediately place a coverslip on top.
- 4 Read immediately under the microscope.

Note 1: Do not wait until the drop has dried out, crystals of nigrosin will form which can interfere with the interpretation of the results.

Note 2: In case nigrosin precipitates in the semen sample (which can rarely occur in viscous samples) or when analysing samples with a low sperm concentration, it is recommended to only work with eosin (Reagent 1) and not to use nigrosin (Reagent 2). In this case, after step 1, proceed to step 3.

INTERPRETATION

- Colourless spermatozoa: live spermatozoa
- Spermatozoa stained red: dead spermatozoa

Note: spermatozoa with a faint pink head staining should be assessed as dead ⁽¹⁾.

Scan the complete microscopic slide and count between 100 and 200 cells. Differentiate the living from the dead spermatozoa.

Read results immediately, waiting too long will yield lower vitality percentages.

Vitality results should be assessed in conjunction with motility results from the same semen sample. The presence of a large proportion of live but immotile cells may be indicative of structural defects in the flagellum; a high percentage of immotile and dead cells may indicate a long abstinence, epididymal pathology or an immunological reaction due to an infection.

We recommend to use the following classification:

- Viability <50%: abnormal semen sample
- Viability 50-60%: grey zone
- Viability >60%: normal semen sample

LIMITATIONS OF THE METHOD

Spermatozoa stained with VitalScreen cannot be used for any further ART procedures.

PERFORMANCE CHARACTERISTICS

Repeatability and reproducibility:
 $CV_{intra} < 15\%$, $CV_{inter} < 15\%$

STORAGE / DISPOSAL AND STABILITY

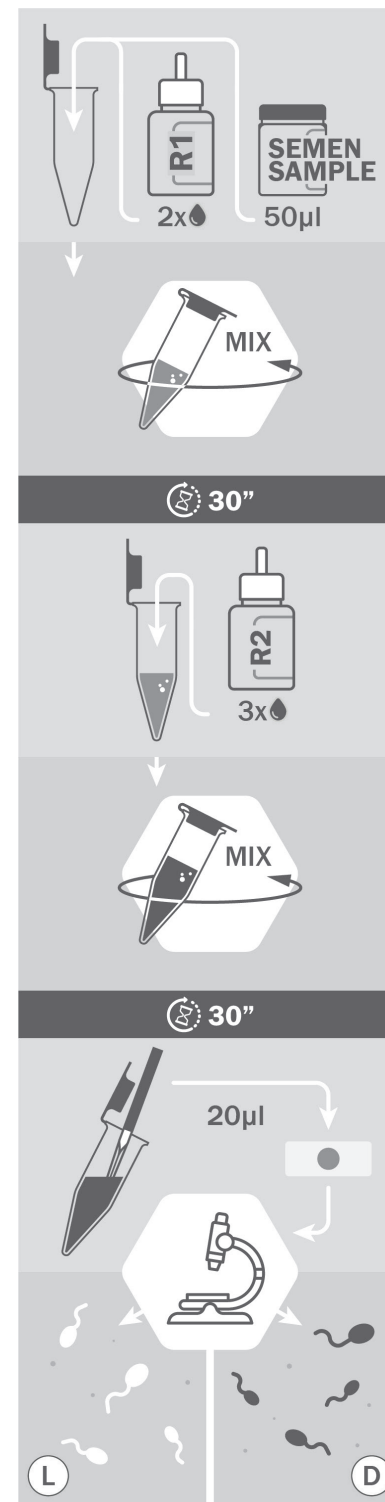
- Stable for 24 months after date of manufacture.
- Store between 2 °C and 25 °C.
- Suitable for transport or short term storage at elevated temperatures (up to 5 days at 37 °C).
- The reagents need to be disposed in accordance with local regulations for disposal of medical devices.
- Do not use after expiry date.

WARNINGS AND PRECAUTIONS

- All human, organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Reagent 1 contains eosin, which may cause an allergic skin reaction.

REFERENCES

¹ Geneva: World Health Organization. 2021. 'WHO Laboratory manual for the examination and processing of human semen', sixth edition.



SYMBOLS GLOSSARY

Symbols as defined in ISO 15223

REF Catalogue number

LOT Batch code

i Consult instructions for use

M Manufacturer

IVD In Vitro Diagnostics

25°C
2°C Temperature limit

⌚ Use-by date

Symbol as defined in IVDR 2017/746

CE CE marking

Symbol as defined in Regulation (EC)
No. 1272/2008 [CLP]

! GHS07: Health hazard: may cause an allergic skin reaction