halotech®

Every life is unique. **So are we.**

Innovative Specialist **Visionary**

Halotech DNA, based in Madrid, is a leading international biotech company, uniquely dedicated to the analysis of male sterility.

We understand that clinicians and couples need information before assessing the best reproductive process for their situation. Semen analysis is vital, and using Halotech DNA's patented SCD system, the all-important genetic quality of the sperm can easily and quickly be tested.

A Unique **Approach**

There is no shame in infertility. It affects 15% of people. It is essential to know the facts in each case.

The male component

The male factor in infertility is responsible for about 50% of the cases of pregnancy failure. The success rate of Assisted Reproductive Technology in specialised centres is still relatively low and the male contribution is frequently ignored.

"An exhaustive semen analysis can identify potential problems and is strongly recommended before embarking on painful and expensive technological processes."

DNA Solutions

We facilitate the analysis of the DNA quality in sperm cells to provide essential information that aids correct clinical decision making.

Our unique process is the patented Sperm Chromatin Dispersion (SCD) test. It simply and easily measures DNA Fragmentation without the need for complex laboratory equipment.

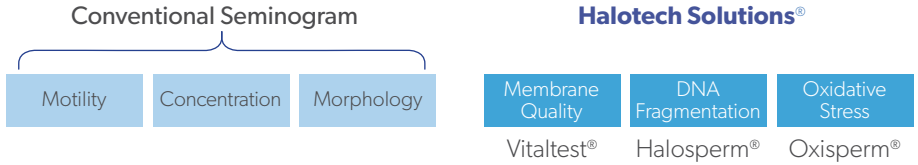
Halotech DNA's testing solutions, by directly analysing the male sample, provide data on the DNA quality of the sperm cells.

CSQ MED ISO 13485

CE

Innovative **Solutions**

Introducing tests that are simple, cost-effective, fast and reliable. An advanced process that produces better results.



1. The Quality Issue

Diagnosis of male infertility is driven by the World Health Organization (WHO) recommendations based on conventional semen parameters. However, none of these are reliable markers for the fertility potential of an individual.

2. The SDF Factor

Sperm DNA Fragmentation correlates with low fertilisation rate and with zygote development failure. Eight percent of infertile men have a high level of Sperm DNA Fragmentation despite exhibiting normal semen parameters. *(Kodama et al. 1997; Spano et al. 2000, Zina et al. 2001, Fortunato et al. 2013)*

3. New, Improved Solutions

Halotech DNA's solutions provide rapid, reliable and independent data complementary to conventional seminogram laboratory testing results.

Our international network of contacts amongst clinicians and fertility centres, as well as with gynaecologists, embryologists and scientists from all over the world, has led us to a deep understanding of what issues surround male fertility.

This has informed our research, leading to a set of unique, patented test kits that do not require complex laboratory equipment or lengthy analysis.

Halosperm®

Versatile, easy and cost effective

Halosperm® allows the measurement of Sperm DNA Fragmentation in an easy and quick manner, with no need of complex laboratory equipment.

Halosperm® offers a better evaluation of semen quality since a traditional seminogram fails to take into account the most important parameter, which is the quality of the genetic material supplied by the male as a 50% factor of importance to give pregnancy.

Halosperm® empowers clinicians in their decision-making about which assisted reproductive treatment is best suited to the couple's history.

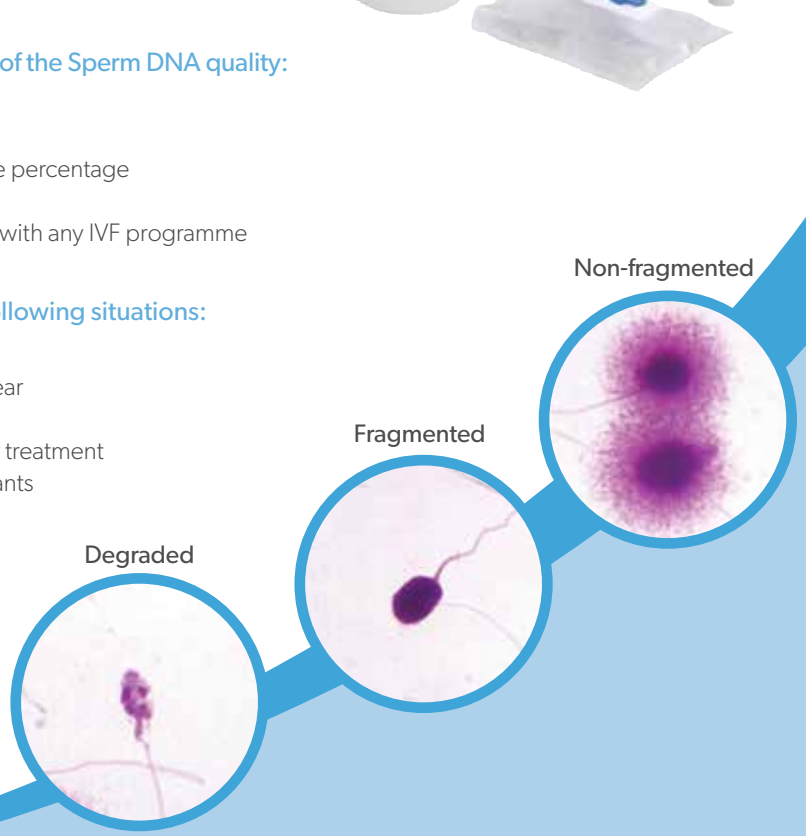
"Therefore, before incurring expensive and frustrating IVF processes for the couple, the evaluation of the Sperm DNA Fragmentation is highly recommended."

A recent survey has confirmed that clinicians use the information of the Sperm DNA quality:

- The information is incorporated within our decision tree process
- The information contributes in deciding to opt for IVF with ICSI
- The information is taken into consideration within our IVF programme percentage risk failure calculation
- We consider proposing some specific treatment before proceeding with any IVF programme

Most of our customers already incorporate this analysis in the following situations:

- Couples with a history of spontaneous miscarriages
- All couples with unexplained infertility for more than 6 months to 1 year
- Selection of the best donor
- Selection of the best seminal sample prior to vasectomy or oncology treatment
- Men over 40 years old; smokers; those exposed to toxics and pollutants
- Men treated for cancer; on certain prescription medications
- Men with infectious disease, fever and varicocele indicators
- Poor embryo quality on second egg donation cycles
- Idiopatic male factor



Halosperm® belongs to the Halosperm Kits Family® and Halotech Solutions®

Halosperm G2®

Quick, user-friendly, reduced-odour process

Halosperm G2® provides a fast, simple and hood-free method to measure Sperm DNA fragmentation.

Halosperm G2® has been developed in response to specific needs expressed by users of the first-generation **Halosperm®** kit. This new generation of kits supplies IVF laboratories with all the key materials to successfully assess DNA fragmentation in a simple, timely and cost-effective manner.

The key advantage of the **Halosperm G2®** kit is that there is no need to work in an extraction hood. It partially eliminates the typically bad smell of the lysis solutions derived from the use of disulphide bond reductors. Using a few drops will give you the same reliable results as the current **Halosperm®** kit in a user-friendlier environment.

Halosperm G2® also includes staining reagents making it easier to stain with bright field microscopy and so avoid inter-laboratories staining differences.

Halosperm G2®** belongs to the **Halosperm Kits Family®** and **Halotech Solutions®

Dynhalosperm®

Enhanced DNA fragmentation analysis

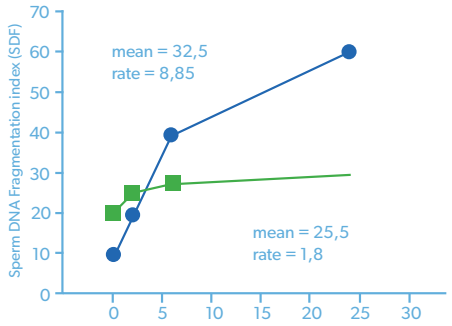
Dynhalosperm® has been developed in response to the users´ needs to assess the kinetic aspects of Sperm DNA damage.

Sperm DNA fragmentation is present from the first moment of ejaculation and sperm damages increase over time. DNA longevity differs among patients; those presenting a high rate of DNA fragmentation after ejaculation need to be identified adequately to avoid extra iatrogenic sperm damage.

Dynhalosperm® operates just like the **Halosperm®** test and allows the study of Sperm DNA fragmentation over time, helping clinicians to decide if using an ART strategy ensures short periods of in vitro manipulation and a rapid fertilization of the oocyte.

Dynhalosperm® is extremely useful for identifying the optimal time to carry out an ART cycle, for assessing the quality of semen samples and for providing answers to cases of unexplained infertility and repeated abortions.

Choosing the optimal moment to carry out an ART cycle



Blue line: patient with low basal SDF but high rate of Sperm DNA fragmentation

Green line: patient with higher basal level of SDF but lower rate of Sperm DNA fragmentation

Dynhalosperm®** belongs to the **Halosperm Kits Family®** and **Halotech Solutions®

Oxisperm®

Detection of oxidative stress excess

Oxisperm® allows the detection and quantitation of oxidising substances, such as reactive oxygen species (ROS) that are generated in the sperm metabolism.

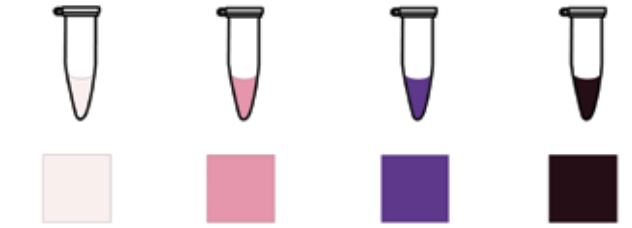
Mammalian spermatozoa are rich in polyunsaturated fatty acids and are thus susceptible to ROS attack, resulting in a decrease in sperm motility and in carrying significant levels of oxidative damage in their DNA.

Thus, ROS decrease the fertilizing capacity of the sperm by reacting with the DNA, oxidising and fragmenting its structure

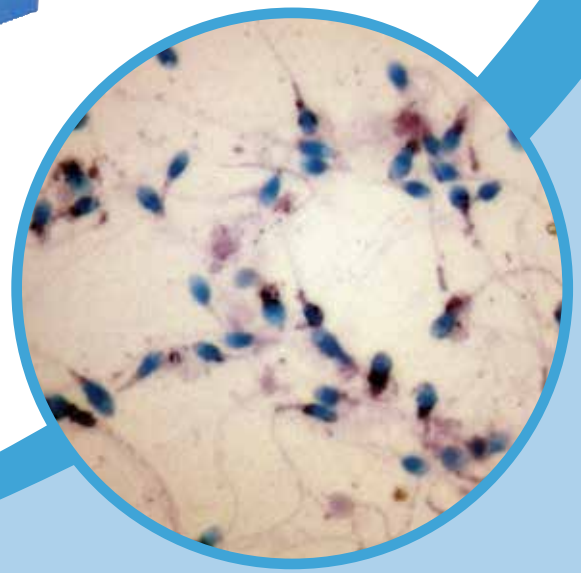
The advantage of **Oxisperm®** is that it is an easy method for the assessment of the presence of oxidative stress in neat ejaculated sperm samples, which is performed in 45 minutes. The test uses a Reactive Gel that has the capacity to change colour and the intensity of the colour is related to the level of oxidative stress in the sample *(Iommiello et al. 2015)*.

Applications of Oxisperm®

- Easy detection of oxidative stress excess in a single ejaculate using a minimum sperm volume
- Determination of ROS level in an ejaculate and re-analysis after treatment with antioxidants
- Assessment of ROS variation within each patient to select the best sperm sample



Diagrammatic representation of the colour intensity level according to amount of ROS present in the sample



Oxisperm®** belongs to **Halotech Solutions®

Vitaltest®

Fast and easy-to-use sperm vitality testing method

Vitaltest® differentiates between live and dead sperm cells by identifying those with an intact cell membrane.

Fast, inexpensive, reliable techniques to quantify cell populations in culture are crucial for laboratory experiments and diagnosis. Sperm viability is a concept linked to the presence of sperm with, or without, altered membranes in the ejaculate.

Compromised sperm motility is highly dependent on sperm viability. In cases of low motility it is imperative to determine the presence of live sperm vs. dead sperm since the massive presence of dead sperm - the so-called necrozoospermia produces severe sterility.

While using Vitaltest®, live cells appear green and dead cells appear red under a fluorescence microscope. For a high-throughput analysis, the results may be measured by a flow cytometer.

For patients with less than about 40% progressively motile spermatozoa, assessing the number of live and dead sperm cells in a semen sample is especially important. This test acts as a check on motility evaluation, since the number of dead cells should not exceed the percentage of immotile sperm cells.

The presence of a large proportion of immotile and non-viable cells - necrozoospermia - may indicate epididymal pathology *(Wilton et al., 1988; Correa-Perez et al., 2004)*, and a high percentage of vital, but immotile, cells may be indicative of structural defects in the flagellum *(Chemes and Rawe, 2003)*.

Applications of Vitaltest®

- Instant determination of sperm viability in ejaculated sperm
- Determination of necrozoospermia

Vitaltest® *belongs to* ***Halotech Solutions®***

Innovative Specialist **Visionary**

You can rely on Halotech DNA To deliver fast, accurate and reliable genetic sperm quality results.

DNA Fragmentation
Oxidative Stress
Membrane Vitality

The Complete Halotech **Solutions**®

- Easy, Simple Application
- Reliable, Reproducible Results
- Quality Manufacturing
- Specialist DNA Expertise
- Extensive Network Knowledge
- Unique, Innovative Approach
- Cost-effective Methodology
- Established World Distribution
- Total Support Accountability
- 10% R&D Investment

Human Brochure Version 1.0 - May 26 2015

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halotech®

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