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.

CSQ MED ISO 13485

CE

We understand that clinicians need information before assessing the best reproductive process of each couple. Semen analysis is vital and using halotech DNA's patented SCD system, the all-important genome 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 specialized 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.

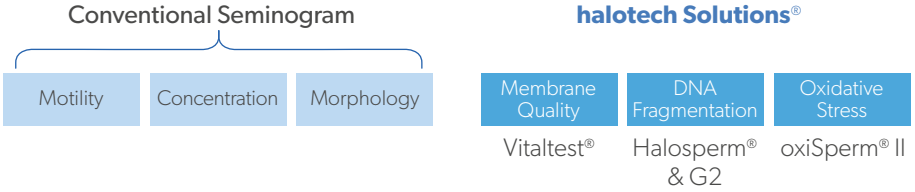
Our unique process is the patented Sperm Chromatin Dispersion (SCD) test. It simply and easily measures sperm DNA Fragmentation without the need for complex laboratory equipment.

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

References
Fortunato A et al. (2013) Zygote. 21:330-6 ; Zini A et al. (2001) Fertil Steril. 75:674-7.

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.
(Zini 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

IVD

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."

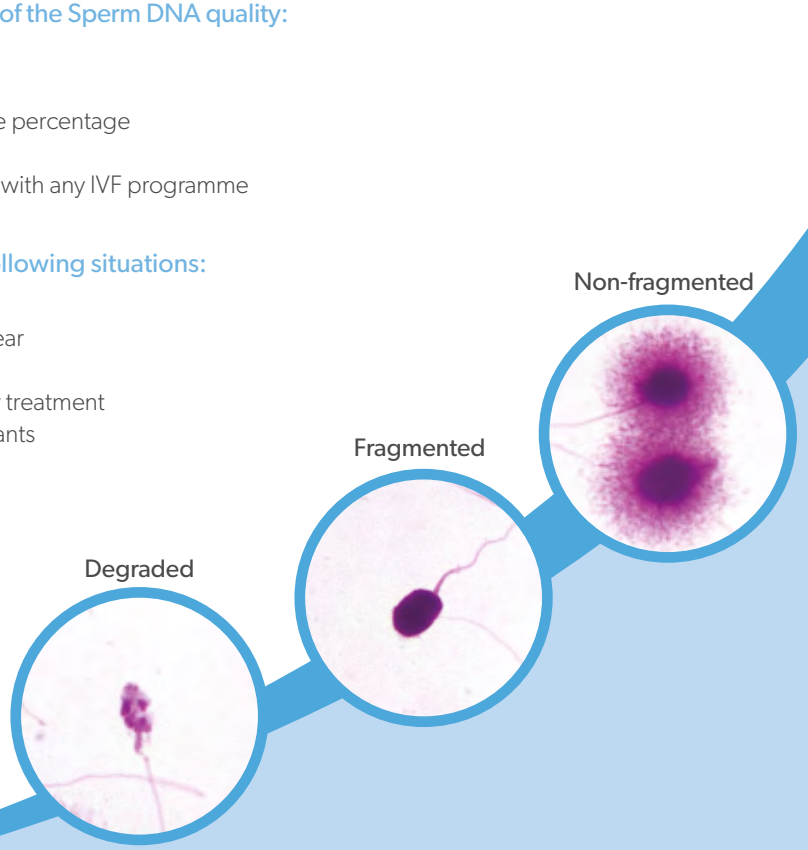
A recent survey has confirmed that clinicians use the information of the Sperm DNA quality:

- 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***®



IVD

halosperm® G2

Quick, user-friendly, reduced-odour proc ess

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.

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 for a reliable visualization under bright field and so avoid inter-laboratories staining differences.

halosperm® G2 *belongs to the* ***halosperm Kits Family®*** *and* ***halotech Solutions®***

IVD

dyn-halosperm®

Enhanced DNA fragmentation analysis

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

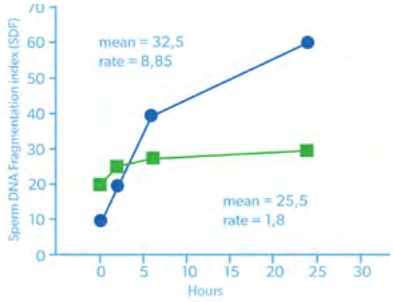
Sperm DNA fragmentation is present from the first moment of ejaculation but its value increases over time while the sample is handled in the laboratory.

dyn-halosperm® operates just like the halosperm® test and allows the study of sperm DNA fragmentation over time to calculate sperm DNA longevity. Assessment of DNA longevity inform the clinician about using long or shor periods of *in vitro* sperm manipulation tc assure the best fertilization of the oocyte

dyn-halosperm® is extremely useful fo. identifying the optimal time to carry out fertilization, for assessing the quality of semen samples and for providing answers to cases of unexplained infertility and repeated abortions.

Discriminating between two different sperm DNA longevities

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

dyn-halosperm® *belongs to the* ***halosperm Kits Family®*** *and* ***halotech Solutions®***

IVD

oxiSperm® II

Assessment of pro-oxidant activity

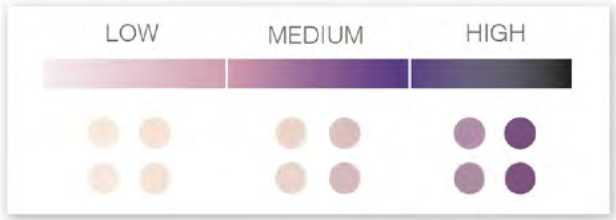
oxiSperm® II based on a colorimetric reaction, allows a qualitative determination of NBT-reactivity associated to the neat ejaculate, in seminal plasma or at the level of the individual sperm cell.

Between 25 to 50% of patients attending infertility clinics have high concentration of ROS that may be associated with abnormal sperm motility, membrane integrity and poor DNA quality. Some of these patients are treated with antioxidant cocktails to correct this problem but without any previous assessment of the level of ROS present in the ejaculate.

oxiSperm® II has been designed to provide clinicians with easy to apply and reliable technology for assessment of NBT-reactivity in the ejaculate.
After the reaction, three levels of NBT-reactivity can be established: NBT-LOW, NBT-MEDIUM and NBT-HIGH.

Applications of oxiSperm® II

- Easy detection of pro-oxidant activity in a single ejaculate: Neat sample, Seminal Plasma and Spermatozoa.
- Determination of pro-oxidant activity level in an ejaculate and re-analysis after treatment with antioxidants
- Assessment of pro-oxidant activity variation within each patient to select the best sperm sample



Colour pallet according to NBT-reactivity (according to oxiSperm® II)

oxisperm® *belongs to* ***halotech Solutions®***

References
de la Casa et al. (2015) JFIV Reprod Med Genet. 3:1-5.
Iommiello VM et al. (2015) International Journal of Endocrinology. ID 321901.

RUO

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 versus 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. Analysis can also be measured by a 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-Pérez et al. 2004)*, and a high percentage of viable, 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 sperm samples
- Determination of necrozoospermia

vitalTest®** belongs to **halotech Solutions®

References:
Chemes EH, Rawe YV (2003) Hum Reprod Update. 9:405-28.
Correa-Pérez JR et al. (2004) Fertil Steril. 81:1148-50.
Wilton LJ et al. (1988) Fertil Steril. 49:1052-58.

Innovative Specialist **Visionary**

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

DNA Fragmentation
Pro-oxidant activity
Membrane Integrity

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 2.0 - Oct 26 2015

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