Kinetix™ Assay

An Advanced Sperm Test That Detects Unexplained Male Infertility Issues

Fertility problems affect about one out of every six couples trying to have a baby. Sometimes, doctors can't find a clear reason for the infertility, so the couple is given a diagnosis of "unexplained" infertility. Recent research shows that the male partner is responsible for up to half of these cases. However, until now, current tests don't give a full picture of how healthy or functional the sperm in a semen sample really is.

Don't Confuse Motion with Action

For over 75 years, semen analysis has been an important tool for checking male fertility. These tests give information about how much semen is produced and details about the sperm, like how it looks, moves, and its quantity. However, they don't tell us much about how well the sperm actually works when it comes to fertilizing an egg.

When sperm is first released, it can't fertilize an egg right away. It has to go through a maturation process called **capacitation**, which helps it become able to fertilize. This process doesn't happen all at once—groups of sperm become fertile and then lose that ability over time. These short periods are called **fertility windows**, and they're when sperm has the best chance to fertilize an egg. If a sperm sample doesn't have these fertility windows, it may not be able to cause pregnancy—even if the semen analysis looks normal. If it has windows, when they occur is important to know. This helps sperm banks and clinics use the sperm at its best time, just as is done with eggs during ovulation.

There are many semen tests that give a general idea of sperm quality. But only the **Kinetix™ Sperm Assay** can measure two things: if these fertility windows are present and how they change over time. The Kinetix test gives helpful information to your doctor about how likely a sperm sample is to cause pregnancy and how it might affect assisted reproductive treatments.

Semen Analysis Testing

	Kinetix Assay Score	Standard Semen Tests	CAP Score™ Test	DNA Fragmentation
Measures # of sperm, size, shape & ability to move	✗	✓	✗	✗
Measures the amount of damaged DNA in a sperm sample	✗	✗	✗	✓
Predicts odds of sperm being able to fertilize an egg	✓	✗	✓	✗
Provides ART clinics with highly probable fertility timing windows for a sperm sample used in IUI and IVF procedures	✓	✗	✗	✗

Studies show that the Kinetix Assay may help increase pregnancy success rates by measuring how sperm works over time. The test results can help doctors understand whether a sperm sample can lead to pregnancy and can guide them to the best timing to use the sample for treatments like **IUI, IVF**, and **ICSI**.

Kinetix™ Assay - Determining Sperm Quality and Optimum Fertility Windows

The Kinetix Assay is a new and advanced way to test a cryopreserved semen sample. It looks at how sperm function changes over time as they mature and become ready to fertilize an egg. Each sperm sample is given a rating: fertile, subfertile, or infertile. These results help doctors and fertility clinics better understand how likely the sperm sample is to cause a pregnancy. Importantly, the test also shows the best timing window for fertility, which can help improve success rates of the sperm from the sample with treatments like IUI or ICSI.

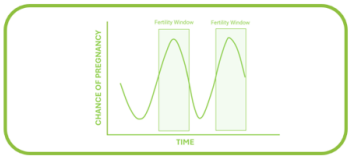
What Will The Kinetix™ Sperm Assay Tell Me?

The Kinetix Assay

- Determines the capability of a sperm sample to produce pregnancy
- Provides optimum timing window for insemination to increase the potential for success

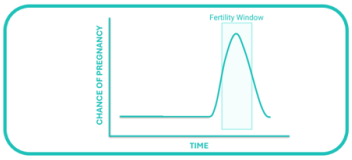
Fertile

ROBUST FERTILITY WINDOWS
- Multiple fertility windows
- Suitable for all forms of ART including IUI

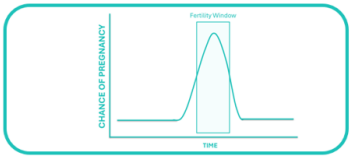


Subfertile

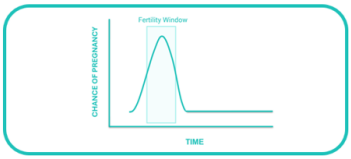
LATE FERTILITY WINDOW
- Fertility window only at late time points
- Insemination timing is critical for all forms of ART including IUI



MIDDLE FERTILITY WINDOW
- Fertility window appears at middle time points
- Insemination timing is critical for all forms of ART including IUI

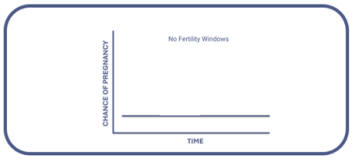


EARLY FERTILITY WINDOW
- Fertility window only at early time points
- Insemination timing is critical for all forms of ART including IUI



Infertile

NO FERTILITY WINDOWS
- Ferility windows do not exist
- Infertility and cycle failures for ART and IUI expected



Significant Increase In IUI Pregnancy Rate

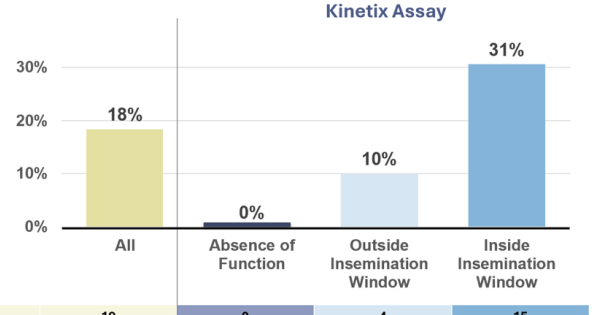
Results of a clinical study conducted at two clinical sites show that IUI pregnancy rate significantly increased when insemination occurred within the Kinetix Assay fertility windows.

In the study, among the 103 IUI cycles completed, overall there were 19 total pregnancies (18%). Pregnancy was achieved in 31% (15/49) of cycles when IUI was performed during the Kinetix fertility window while 10% (4/40) achieved pregnancy when IUI was performed outside the Kinetix fertility window. There were no pregnancies from samples (0/14) where there were no Kinetix fertility windows found.

Clinical Data: IUI Patient Evaluation - 2 Clinical Sites

Kinetix™ Fertility Windows Improved IUI Pregnancy Rates

- *N=103 IUI cycles*
- *Overall Pregnancy Rate: **18%***
- *Pregnancy Rate using Kinetix Assay Fertility Windows: **31%***



	All	Absence of Function	Outside Insemination Window	Inside Insemination Window
# Pregnancies	19	0	4	15
# Cycles	103	14	40	49

(p = 0.037, one-sided Chi-square test for equality of binomial proportions with Yates' continuity correction)

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