



Automate &
Standardise
to produce consistent results



Our Story

Genea Biomedx is part of the Genea family (previously known as Sydney IVF) - fertility and IVF clinics that have been operating since 1986. We specialise in manufacturing IVF devices that reduce the variables that impact clinical outcomes, and we aim to standardise and automate processes involved in fertility treatment. Our vision is to simplify ART procedures by reducing the effects of difficult-to-control factors, such as human error or a change in temperature, while creating products that aim to significantly improve patient outcomes around the world.

Why us?

Being part of the Genea IVF family has given us direct access to doctors and embryologists whose insight and knowledge greatly contributes to the evolution of our product range. The **Genea Biomedx** R&D laboratories convert clinical challenges into practical solutions and they enable our team of scientists and engineers to conduct a multitude of research and experiments in-house during product development. Therefore, we ensure our products first pass the high standards of our own fertility clinics before launching them globally.

Products

Our product range covers different aspects of ART, from embryo culture and development, to vitrification and electronic witnessing.

Geri®

Embryo Culture and Development

Geri Connect® & Geri Assess®

Embryo Review and Assessment

Gems®

Culture Media for IVF

Gavi®

Automated Vitrification

Gidget®

Electronic Witnessing for ART laboratories

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Genea BIOMEDX Geri

History

Long before Geri® was even a concept, we developed a bench-top incubator that simulated the natural environment of human fallopian tubes. The MINC® incubators utilised low oxygen levels, maintained optimal temperature and introduced just the right amount of carbon dioxide to help embryos grow. Continuing to build on the MINC®, we went on to develop the Geri® incubator with an integrated embryo monitoring system. The Geri® incubators are now used across Australian Genea clinics and the the rest of the world.



An innovative incubator with integrated embryo monitoring system

What makes Geri® unique?

There is a difference between the technologies used in IVF labs. Unlike the large conventional incubators, Geri® is equipped with individually controlled incubation chambers for each patient and a time-lapse system that enables scientists to monitor each step of embryo development, eliminating the need to open patient chambers during culture.



Uninterrupted culture

- Six independent incubators/ chambers
- Minimum disturbance to embryos
- LCD screen control panel



Time-lapse with humidity

- Dry and/or humid time-lapse environment
- Independent CO₂ sensor in each chamber
- Fast recovery of gas and temperature for a stable culture condition
 - Recovery of CO₂ within 3 min.
 - Recovery of temperature within 1 min.



Continuous monitoring

- Dedicated camera in each chamber
- Real-time monitoring of embryo development
- Continues recording images of the embryo, every 5 minutes and up to 11 focal planes

Key Benefits

- A compact bench-top incubator that is designed to save space, easily integrate into your existing lab and ultimately improve your lab workflow¹.
- Modular design that enables each of the 6 chambers to work independently and focus on one patient at a time¹.
- Integrated time-lapse function that provides significantly more information about the development of embryos and enables observation of development of embryos without the need to remove the culture dish from the incubator.
- Significantly higher number of total blastocysts, number of high quality blastocysts and number of utilisable embryos in Geri^{®2}.
- Stable and controlled culture environment is achieved by controlling temperature and CO₂. Accurately and continuously monitored¹.
- Abnormal values are immediately detected in each chamber with audible and visual alarms, enabling lab staff to be alerted to any alarms during and outside of working hours.



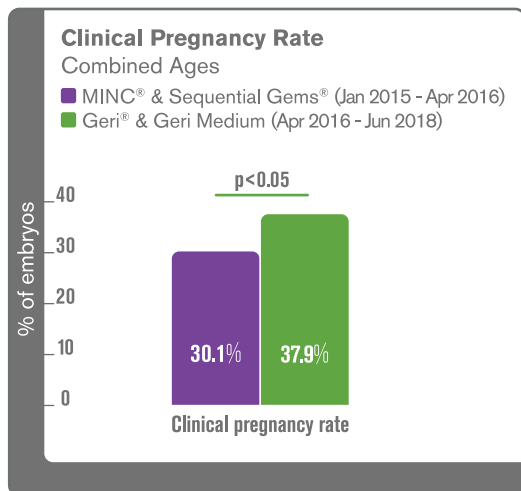


Figure 1: Clinical Pregnancy Rate - Combined Ages

Geri® in the lab

The use of Geri® with one patient per chamber resulted in statistically significant increase in clinical pregnancy rate when combined with Geri Medium, compared to a MINC® benchtop incubator as shown in Figure 1³.



50,000+ fertilised oocytes have been cultured in Geri® incubators²



26,000+ embryos cultured in Geri® incubators have been utilised, resulting in approximately 5,000 pregnancies and over 20,000 cryopreserved embryos for future cycles²



Each chamber has its own dedicated camera, capturing up to 11 focal planes every 5 minutes in 2,560 x 1,928 pixels¹



Geri® Dish

The Geri® dish is a polystyrene, non-pyrogenic device used as an embryo culture dish with the Geri® Embryo Incubator. Its central well contains 16 high-precision and high-clarity micro-wells for the storage of oocytes or embryos during incubation¹.



Geri® Water Bottle

The Geri® Water Bottle is a single use consumable to be used in a single Geri® chamber. The use of Geri® water bottle provides a humidified environment inside a Geri® chamber¹.

Geri® Filter

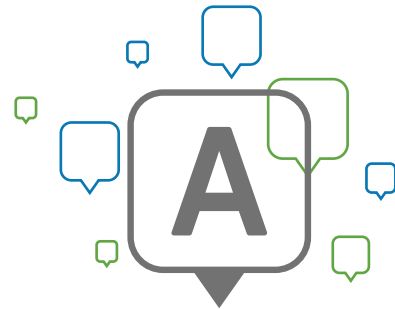
The Geri® Filter is used to improve the purity of the gas as it enters each chamber. The filter has a polypropylene housing and is placed on the gas flow line inside each chamber at the rear¹.



Geri Geri Connect Assess

What is Geri Connect® & Geri Assess®?

Geri Connect® & Geri Assess® provide remote access to information from the Geri® incubators, with added functionality to manually or automatically annotate embryo development and assist with embryo grading.



Remote access with
different embryo
assessment solutions

What makes Geri Connect® & Geri Assess® unique?

The Geri Connect® platform synchronises your data and enables you to access and review time-lapse sessions via LAN, while the Geri Assess® assessment solutions enable you to choose between user-defined or automated annotations.



Remote access

- Connects up to five Geri® instruments via LAN
- Multiple users can access and review patient data
- Ability to monitor the status of your Geri® incubators



Embryo monitoring

- Enhanced video playback using the sharpest image from the available z-stack
- Different embryo assessment tools
- Automated annotations and custom scoring algorithms



Data Synchronisation

- Patient information
- Time-lapse sessions
- Embryo fate decisions



User-defined annotation and scoring system

Geri Assess® 1.0 is a user-defined scoring system performed by embryologists to assess embryos. This tool displays relevant events and observations during embryo development divided into six Development Chapters, each chapter with at least one key embryo development event.



Automated annotations & Custom scoring algorithms

Developed using an artificial intelligence deep learning technique, **Geri Assess® 2.0** is a premium embryo development assessment tool that automatically detects and annotates key morphokinetic events and observations as they occur.

Geri Assess® 2.0 can automatically detect the following key events in embryo development, as well as fragmentation:



Genea BIOMEDX Gavi

History

Launched at ESHRE 2015 as the World's first automated vitrification instrument, Gavi® was designed to automate the equilibration steps in the manual vitrification process to minimise the variability that occurs during cryopreservation⁴. This closed system provides rapid, efficient and reproducible vitrification and reduces embryo handling therefore minimising embryo stress⁵.



The world's first
automated vitrification
instrument

What makes Gavi® unique?

Intended for use in a laboratory or clinic environment, Gavi® enables you to select between three vitrification protocols for preparation and vitrification of oocytes, zygotes, cleavage and blastocyst stage embryos.



Oocyte protocol

1 or 2 oocytes per Gavi® Pod



Zygote/cleavage protocol

1 or 2 embryos per Gavi® Pod



Blastocyst protocol

1 embryo per Gavi® Pod

Features and Benefits

- Closed system that reduces the risk of cross-contaminants
- Gavi® Pod design acts as a container for embryos throughout equilibration and cryo storage
- Precise temperature control
- Automated fluid aspiration and dispense, with controlled flow rates
- Controlled timing and exposure to cryoprotectants

Gavi® in the lab

Gavi® reduces variability through standardisation by reducing the time taken to achieve vitrification competency when compared to Cryotop®⁶.

Clinical outcomes of blastocysts vitrified using the Gavi® system are comparable to, or better than, the manual system⁶.

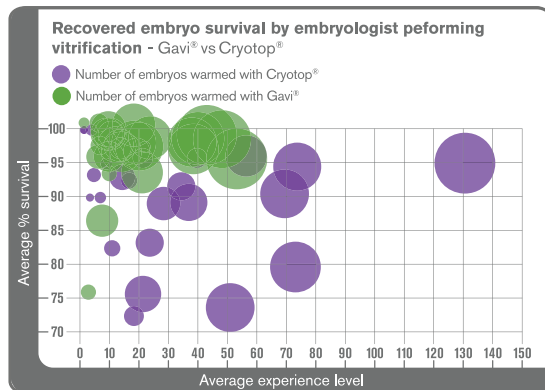


Figure 1: Gavi® vs Cryotop®

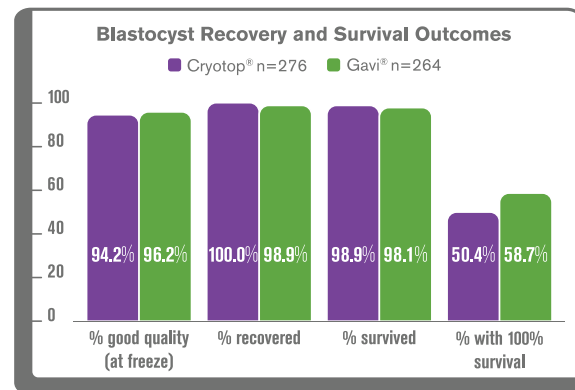


Figure 2: Gavi® vs Cryotop®

 **7,000+** blastocysts vitrified using Gavi®⁷

 **5 out of 6** blastocysts warmed had $\geq 95\%$ survival⁷

 **1,500+** blastocysts warmed and transferred⁷



Gavi® Consumables

Gavi® Pod

Gavi® Pod is a container with the capacity to hold two oocyte or zygote/cleavage stage embryos or one blastocyst during vitrification, storage and warming.



Gavi® Cassette

The Gavi® Cassette holds up to four individual Gavi® Pods for vitrification and long-term cryogenic storage.



Gavi® Medium Cartridge

The Gavi® Medium Cartridge comes preloaded with two vials containing ready-to-use vitrification solutions for the Gavi® Instrument.



Gavi® Tip & Seal

The Gavi® Tip & Seal Cartridge contains the disposable Pipette Tip for dispensing vitrification solutions and foil lid to seal the Gavi® Pods.



Gavi® Operating Tray

Intended for use within the Gavi® instrument to hold the Gavi® Medium Cartridge, Gavi® Cassette (plus Gavi® Pods) and Gavi® Tip & Seal.



Gavi® LN₂ Bucket

Intended to hold liquid nitrogen for the Gavi® Cassette to be dunked in for completing the vitrification process.

Gavi® Tweezers

The Gavi® Tweezers are used to grasp and hold the Gavi® Cassette as it is dunked into the LN₂ Bucket.



Gavi® Storage Dividers

Cryogenic storage canisters that provide orderly organisation of Gavi® Cassettes and Gavi® Pods (Round and square configurations to fit current storage systems).



Gems

History

Genea's devoted embryologists and andrologists worked passionately in ART for decades, while our company continues to evolve from its early days as Sydney IVF.

In the early 1990's we recognised that ART culture media should be tailored for use with human embryos, and that is why we have developed, produced and used our own media formulations. Our 1st and 2nd generation formulations were licensed to Cook Medical, and Gems[®] – our 3rd generation formulation – continues the success story, in use clinically since 2013 and entering the market with human clinical data. To date an estimated 6,500 babies have been born using Gems^{®2}.



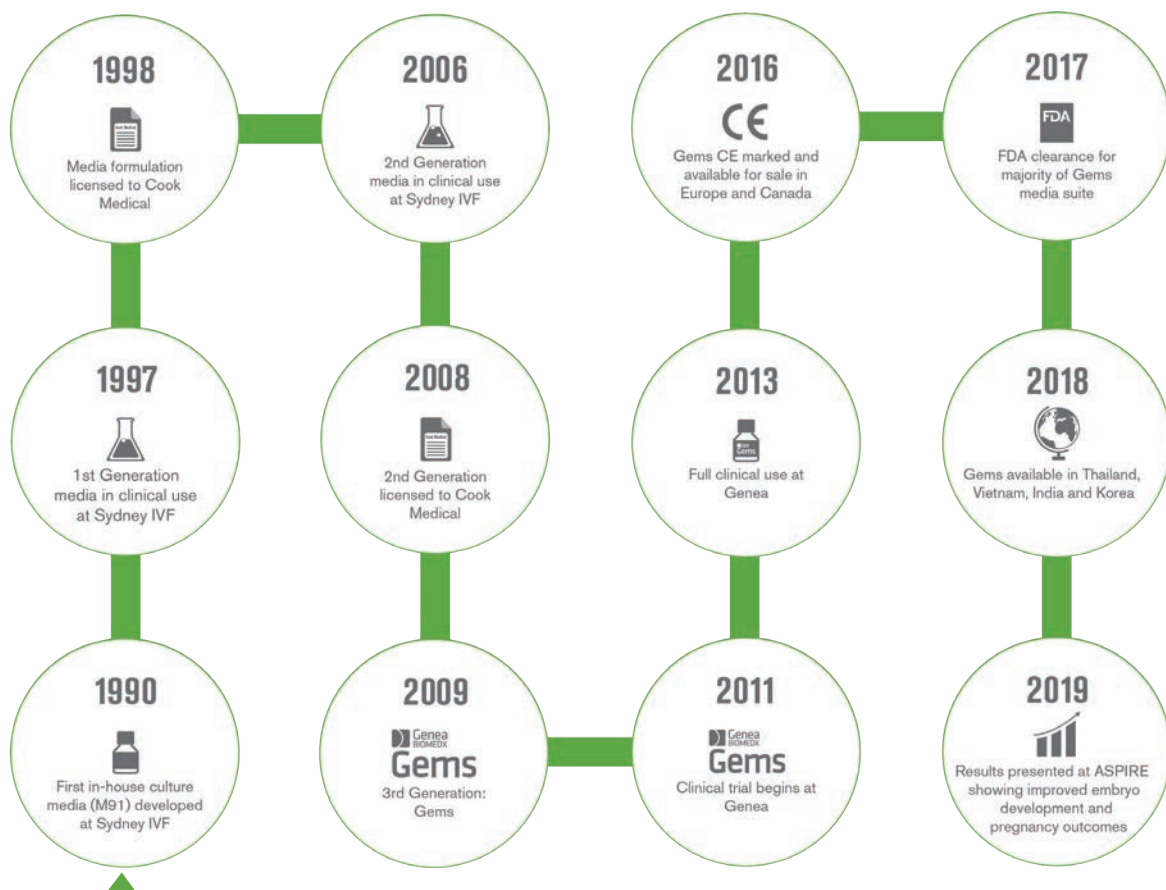
60,000+ bottles of Gems[®] media produced in our ISO 13485 manufacturing facility²



100,000+ fertilised oocytes cultured in Gems[®], resulting in over 6,500 live births²



40,000+ fertilised oocytes have been cultured in Gems[®] Geri medium, resulting in over 2,000 live births²





Features and Benefits

- Designed by users for users
- Available in 20 mL and 50 mL bottles to suit your laboratory needs
- Media for every step of the ART process from oocyte collection, sperm preparation, embryo culture (continuous or sequential), vitrification and warming
- Manufactured in ISO 13485 accredited manufacturing facility in Sydney, Australia
- Each lot of media produced is QC tested for sterility, endotoxin, biocompatibility by mouse embryo assay, osmolality and pH
- Validated global distribution network, to ensure that the same, high-quality Gems® product arrives at your laboratory every single time
- Colour coded labels maximise ease-of-use and minimised errors in the laboratory
- We stand by our products, with Genea Fertility using the same lots of media that are distributed globally.



Gems® Clinical Data

Our results speak for themselves; in a clinical study of over 60,000 embryos, statistically significant improvements in embryo development and utilisation were revealed when using Geri Medium with the Geri® Incubator in comparison to bench-top incubator with sequential media².

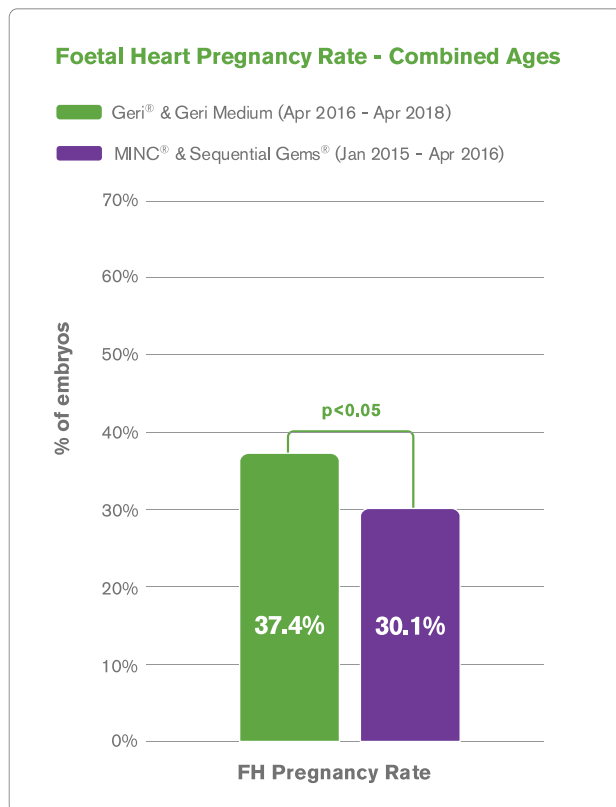


Figure 1 - Foetal heart rate after culture

Gems® Geri Medium enables uninterrupted culture of embryos in an optimised micro-environment and results in an increase in blastocyst quality and embryo utilisation⁸.



Gems® Geri Medium components³:

L-Carnitine: shown to have multiple advantages for developing embryos such as increasing energy metabolism through facilitating the movement of fatty acids across the mitochondrial membrane; acting as a scavenger for damaging free radicals and protecting against DNA damage by preventing mitochondrial dysfunction.

Glycine: allows embryos to maintain cell homeostasis and increases their ability to react to osmolality changes via importation using the GLYT1 transporter.

Antioxidants: protect against oxidative stress by scavenging free radicals. Geri Medium also contains all of the required constituents for glutathione production, not only important due to its function as an antioxidant, but also shown to have a critical role in the regulation of developmental signalling.



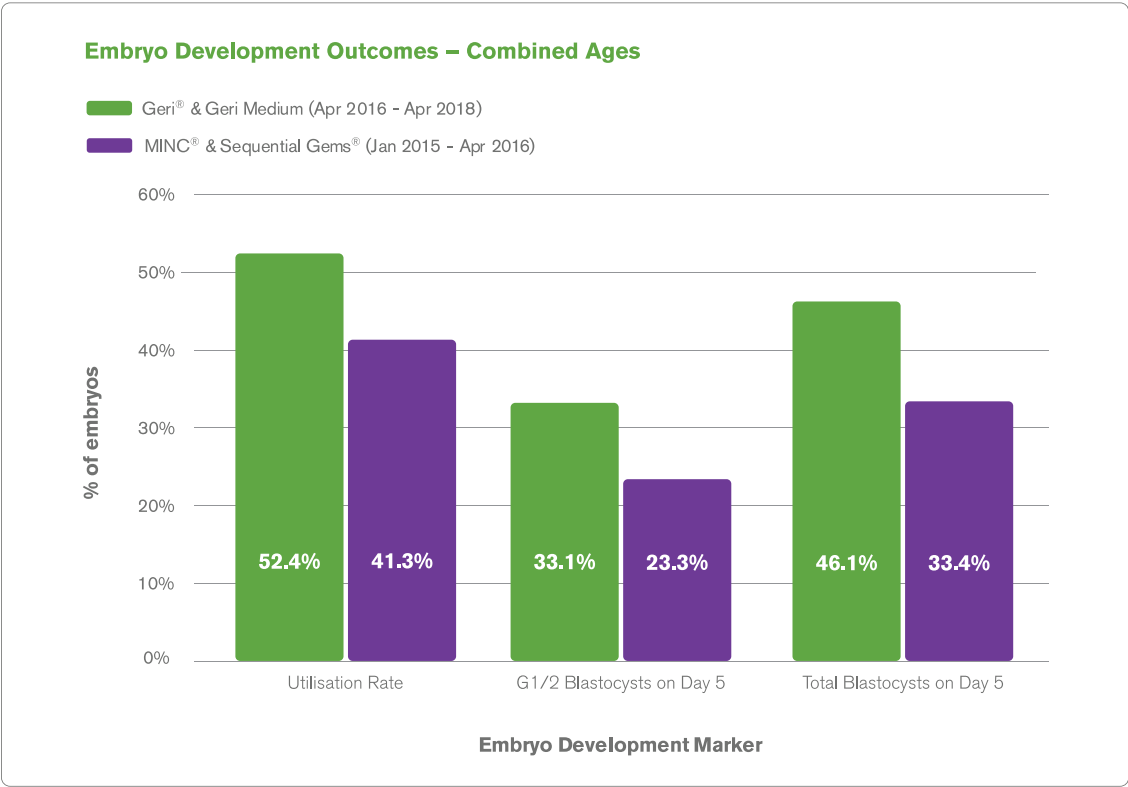


Figure 2 - Blastocyst number & quality and utilisation rate following culture using each system



Gidget

What is Gidget®?

Gidget is a handheld electronic device that aids in the identification of patient samples during movements in the ART procedures. It consists of handheld scanners and a server computer, which communicates with the clinic's server to retrieve patient records and manage laboratory processes. Gidget includes additional tools such as process scheduling, task workflow and consumables tracking.



What makes Gidget® unique?

Thanks to the intuitive design and the easy-to-use handheld devices, Gidget is customisable and configurable to your lab processes. The system provides electronic witnessing through every step of the patient cycle and aids error prevention by identifying gametes and embryos down to sample level while facilitating high visibility of daily activities in the lab.



Modular

- Easy integration with future functionalities and with scalable number of handheld devices based on your clinic's need.
- EMR connectivity with bi-directional communication



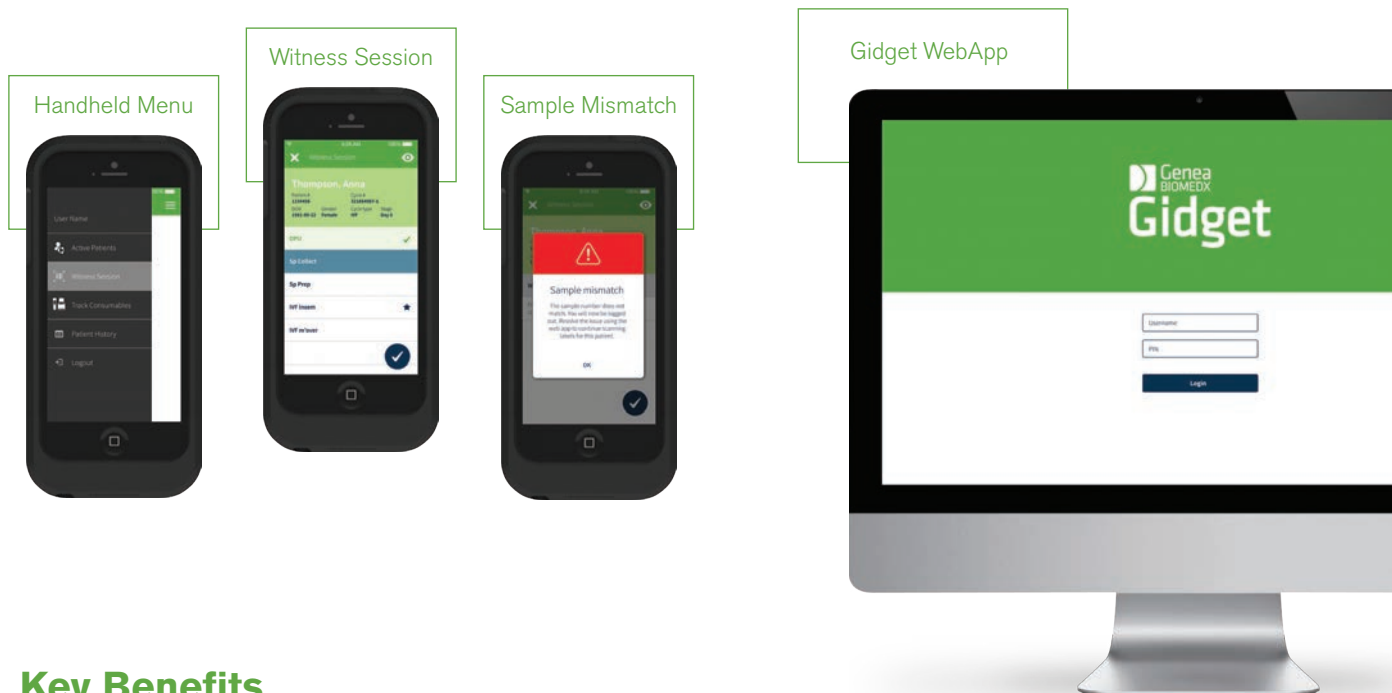
Non-disruptive

- Designed to adapt to your existing lab infrastructure and procedures
- Communicates via the Clinic's Wi-Fi



Flexible

- Label options compatible with the most commonly used consumables in ART.



Key Benefits

- Significant time savings and increased efficiency in lab operations
- High workflow visibility with the Gidget WebApp that can be accessed via browser or viewed on a wall mounted display
- Error prevention through sample-level tracking of gametes and embryos
- Full traceability via comprehensive reports for user activities and lab consumables





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References:

1. Genea Biomedx, 2019. OFRM422 Geri/Geri+ User Manual. 2. Genea Biomedx, 2019. QRTV318. Unpublished internal document. 3. Genea Biomedx, 2018. QRTM209 Statistically significant increases in clinical pregnancy rates and embryo development outcomes are observed when using Geri® and Gems® Geri Medium, in comparison to a conventional culture environment. Unpublished internal document. 4. Genea Biomedx, 2019. OFRM168 Gavi User Manual. 5. Genea Biomedx, 2019. OFRM649 Gavi Clinical Evaluation Report. Unpublished internal document. 6. Genea Biomedx, 2018. QRTM210 The use of a semi-automated vitrification system (Gavi®) delivers comparable clinical outcomes, minimises variability between embryologists and reduces the training time required to achieve competency when compared with a manual system (Cryotop®). Unpublished internal document. 7. Genea Biomedx, 2019. QRTV224. Unpublished internal document. 8. Beckett T., Murray A., McArthur S., Bowman M., Does an uninterrupted culture system result in improved embryo development and pregnancy outcomes? Poster presented at the 9th Congress of the Asia Pacific Initiative on Reproduction, 2 – 5 May 2019, Hong Kong.