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Your Expert

Using the MagBench™ cfDNA Extraction Solution for Sage™ NIPT Workflow from Yourgene Health

Yourgene Health

YEX015

In this edition of Your Expert, Yourgene Health interviewed **Hanchiang Chin (HC)** & **You-Hsuan Lin (YHL)**, two superusers from within our Taipei laboratory on their thoughts and experiences using Yourgene Health's MagBench™ cfDNA Extraction Solution to understand the key benefits of the system when used in combination with Non Invasive Prenatal Testing (NIPT) workflows.

Hanchiang Chin

Senior Technical Manager

Yourgene Health

You-Hsuan Lin

Business and Product Support Manager

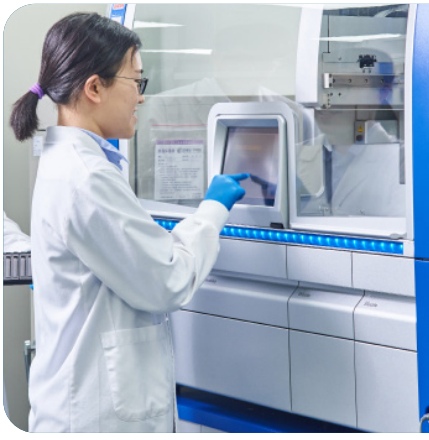
Yourgene Health

Yourgene Taipei's service laboratory focuses on providing reliable services in the field of reproductive health, including NIPT and Preimplantation Genetic Screening (PGS), tumour profiling, research services such as Taiwan Biobank, clinical research services, and customised bioinformatic solutions for customers in the Asia Pacific (APAC) region.

HanChiang Chin, Senior Technical Manager - Taipei, worked with NGS in the biomedical industry for more than 10 years and has acted as a technician, and technical manager in the lab. "I mainly oversee the Technical Support department in APAC and also the technical details in the service lab. We do many different tests from NIPT to metagenomics. I participate in the development of our NIPT workflow and also help many customers build our Sage™ Workflow into their laboratories".

You-Hsuan Lin, Business & Product Support Manager – Taipei , "I joined Yourgene in 2010, and my current position is Business and Product Support Manager. My main responsibility is to listen to customers' needs and find the most suitable solutions to meet their requirements. Before taking on my current role of Business and Product Support Manager in 2022, I served as a Laboratory Manager at Yourgene, accumulating over 10 years of experience in NGS."

Question 1: What sorts of investigations does the Taipei laboratory do?



Our Taipei service laboratory has ISO/IEC 17025:2017 accreditation and is listed as a qualified Laboratory Developed Tests (LDTs) provider for its NIPT (Non Invasive Prenatal Testing). Assessments under Taiwan Accreditation Foundation (TAF) for the ISO/IEC 17025 accreditation and Taiwan FDA for the LDTs listing ensure that our laboratory meets the relevant requirements, including the operation of a quality management system and the ability to demonstrate that specific activities are performed within the criteria set out in the relevant standard.

The accreditations provide confidence that the Yourgene Taipei Service Laboratory delivers quality levels of performance and competence and confirms that the Company is operating a genomic service that is safe, reliable and consistent, conveying trust to stakeholders and decision-makers and allowing for a more rigorous system in operation.

Question 2: What prompted the Taipei lab to source and install MagBench™ into their existing NIPT Workflow?

YHL: During the initial setup of the NIPT testing process, the Yourgene Taipei Service Laboratory utilised a column-based DNA extraction method that heavily relied on manual labour for various tasks, including blood handling, sample transfers, centrifugation, and DNA elution. Processing DNA extraction for ten samples at that time would take a full half-day of manpower, making the process extremely time-consuming. Additionally, manual handling required cautious and slow manipulation of tubes to avoid sample cross-contamination, which could potentially impact the test results. Moreover, the process of transferring samples between tubes required lots of re-confirmation to prevent any errors that could lead to inaccurate results.

As Yourgene's sample volume continued to rise, Yourgene Taipei began exploring the feasibility of introducing automated extraction methods. Once we exceeded 192 extractions per month (12 batches x 16 sample runs per month) we realised that the impact of increasing hands-on time justified automation.

"Many systems are designed for high-throughput and large-scale sample requirements, resulting in high costs per batch of DNA extraction and a lack of flexibility in handling smaller sample quantities. For certain tests, such as NIPT, with a short turnaround time (TAT) requirement, it was not practical to wait for a large accumulation of samples before performing the extraction".

Thus, the demand was for a medium-to low-throughput system capable of rapid and high-quality DNA extraction, with the flexibility to process around 1 to 20 samples per batch, and the ability to complete the DNA extraction on the same day, for library construction the following morning. Additionally, while some automated machines could perform DNA extraction automatically, the instrument setup and reagent preparation before extraction remained complex, requiring considerable time and effort from technologists. Although this kind of instrument can avoid issues related to sample contamination and handling errors, it still can not reduce the manpower required for instrument and reagent setup.

"Finally, we found the MagBench™ extraction system. With MagBench™, each extraction can handle 1 to 16 samples individually, using separate cartridges for each sample instead of a shared reagent pool. This feature allowed efficient processing even with a single sample, without the need to consume the reagents required for a full batch of 16 samples.

Moreover, for the extraction of cell-free DNA from maternal blood, MagBench™ required only 10 minutes of hands-on time, and the automated extraction process could complete one batch of DNA extraction in just 75 minutes.

During the waiting time, laboratory personnel could focus on other quality assurance tasks, such as reviewing consent forms, resulting in significant time savings. MagBench™'s automation eliminated a substantial amount of manual labor, thus avoiding the occurrence of sample cross-contamination and transfer errors".

HC: *"A manual extraction workflow is not realistic when working with high sample throughputs. Especially if we want to keep the quality, it is very important to have a stable and stringent workflow.*

Question 3: How does the MagBench™ extraction instrument fit into an NIPT Workflow?

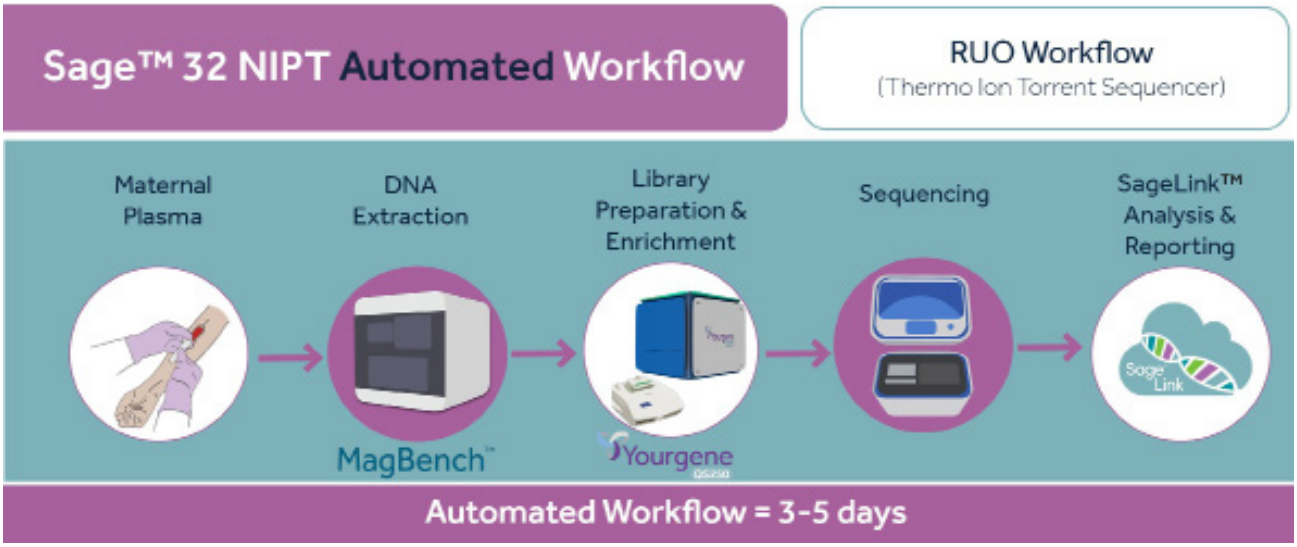
YHL: The number of NIPT samples received by the laboratory may vary each day, ranging from as low as one sample to over 30 samples. However, with the MagBench™ extraction system, DNA extraction can be performed even with just one sample, which conveys far greater flexibility and efficiencies in the ability to reuse reagents. For NIPT testing with a short TAT requirement, the laboratory can process the samples immediately upon receipt, without the need to wait for a larger batch.

Sage™ 32 NIPT Workflow

In cases where the laboratory performs the Sage™ 32 NIPT Workflow, which requires extracting DNA from more than 16 samples in a day, MagBench™'s batch extraction of 16 samples only takes 75 minutes of reaction time. This allows the laboratory to start preparing the second batch of plasma centrifugation and sample-receiving QC processes while the first batch of 16 samples is undergoing DNA extraction. Once the first batch of DNA extraction is completed, the second batch's plasma separation and sample receiving QC processes are also finished, enabling the continuation of DNA extraction for the second batch.

"With MagBench™, DNA extraction for 32 samples can be completed within three hours or less, compared to manual extraction, which would take half a day for only 10 samples. Thus, MagBench™ significantly saves time in the process".

HC: By using only ~1.2 ml plasma, you can get reliable cfDNA products in 2 hours. The procedure is simple with everything included in the kit. It is also flexible to run only one sample or a maximum of 16 samples in a run.



Question 4: What can customers expect from point of receipt, through installation, validation and implementation?

YHL: Commercial DNA extraction machines typically require a larger space for installation in the laboratory. In contrast, the MagBench™ machine has a compact size of only 52 x 60 x 60 cm, allowing it to be placed on a laboratory bench, thus saving a significant amount of space. Additionally, MagBench™ does not require the purchase of additional accessories or the installation of pipelines. The laboratory only needs to clear out space for its installation.

Regarding its mechanical setup, MagBench™ employs a co-axial movement for the X, Y, and Z axes, where they move together as one unit, instead of having individual samples moving separately along each axis. This setup simplifies the installation process of MagBench™, requiring calibration only for the X, Y, and Z axes positions and subsequent volume confirmation for each corresponding pipette. This equipment installation or periodic calibration process typically takes only 1 to 2 hours.

Figure 1: The cartridge rack and T-rack loaded and ready for extraction

MagBench™ provides explicit three-axis position calibration data and a pipette volume confirmation procedure. Compared to the manual extraction process, where different operators may have slightly different handling methods, leading to potentially unstable quality of extracted samples, standardising the operational workflow in the laboratory becomes challenging. In contrast, MagBench™'s co-axial movement and the characteristic of one sample corresponding to one pipette makes equipment adjustment and calibration much simpler and quicker compared to other automated extraction systems.

"While other extraction machines may take an entire day for equipment installation or calibration, MagBench™ only requires 1 to 2 hours, making the process much more straightforward".

Yourgene Health provides first line technical support, including Installation, Qualification, Operational Qualification and Performance Qualification. We also offer two Support Plans to cover preventative maintenance over 12 or 24 month terms.

A Solution for Automated Extraction of cfDNA for Sage™ 32 NIPT Workflow

MagBench™ Sage™ 32 NIPT Workflow

Question 5: How does the MagBench™ instrument and MagBench™ Extraction Kit work together for best results?

YHL: Compared to other commercially available DNA extraction instruments, where all samples in the same batch require reagents mixed in a single cartridge, the MagBench™ Extraction Kit is designed with each sample using a separate cartridge (Figure 2). The preparation before extraction only involves placing the cartridge into the machine, eliminating the need for additional configurations of other solutions (e.g., alcohol) by the laboratory personnel. There's also no manual tearing of cartridge film, significantly reducing the risk of external DNA contamination and avoiding cross-contamination between different samples within the same batch.

MagBench™ arranges samples along the X-axis sequentially, and during the instrument operation, samples move only along the Y and Z axes. This ensures that samples do not cross each other during the extraction process, further minimising the potential for sample contamination. The simplicity of MagBench™'s design, with co-axial movement along the Y and Z axes compared to more complex DNA extraction instruments with separate movements along all three axes, greatly reduces the likelihood of mechanical failures during the machine's operation. This, in turn, prevents losses of plasma samples due to mechanical issues and **avoids the need for patients to undergo repeated blood draws.** The unique cross-notch design of the tips allows pipetting of precise volumes, and minimises liquid retention (Figure 3).

Based on the experience of Yourgene Taipei Service Laboratory, we have encountered almost no incidents of mechanical failures or operational stoppages with MagBench™. It has proven to be a highly reliable DNA extraction instrument that we can trust.

Figure 2: cfDNA extraction cartridge (105), optimised for use with MagBench™ extraction instrument.

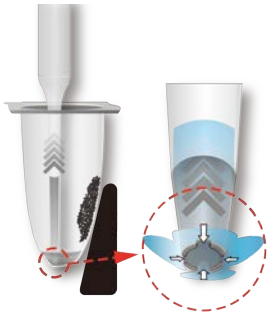


Figure 3: Demonstrating the cross-notch design of the pipette tips.

HC: The extraction kit is designed in a linear direction for each sample (Figure 4). Each lane is used for one sample, with a strip of pre-aliquotted with reagents and buffers. As the robot only moves in a linear direction and uses a new strip for each sample, it significantly reduces any risk of contamination.

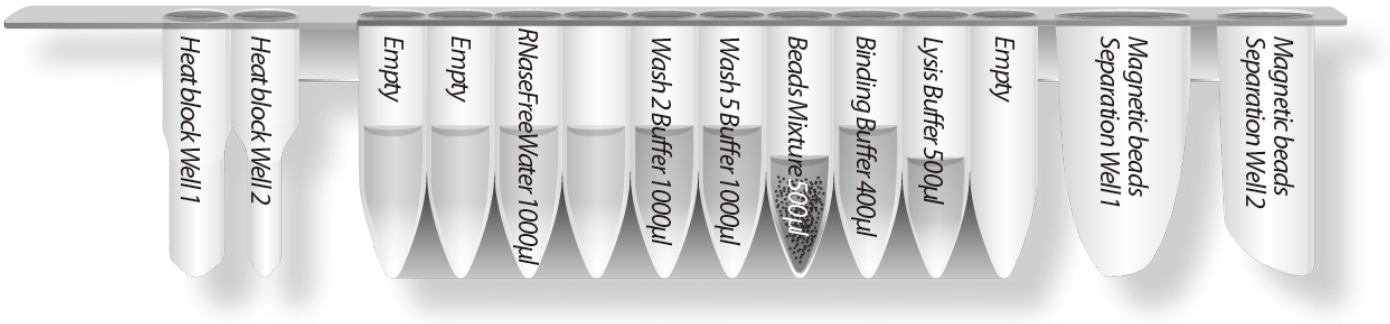


Figure 4: Cross sectional view of individiual cartridge strip with pre-aliquotted regents and buffers.

Question 6: How does the MagBench™ impact a laboratory's day to day activities?

YHL: In addition to sample handling, the laboratory also invests significant effort in maintaining quality management systems. MagBench™ automates DNA extraction, relieving laboratory personnel from performing manual extraction, which requires high concentration and saves them from spending a considerable amount of time on sample handling. As a result, the time saved allows laboratory personnel to focus more on quality assurance during each sample testing process or allocate time for other testing tasks. Furthermore, MagBench™'s high stability prevents the need for laboratory personnel to troubleshoot the instability issues that may arise during manual DNA extraction.

"If we calculate the time saved by MagBench™ daily as 2 hours, it amounts to 40 hours per month and 480 hours per year. This is a significant time saving which contributes to a substantial improvement in the laboratory's operational efficiency".

HC: The hands-on time is greatly reduced. Technicians only needs to do the plasma separation followed by the addition of Proteinase K.

The running time is around 70~80 minutes and the instrument permits true walkaway time whilst other daily activities are completed by the technicians.

Ordering Information

Product Name	Part Number
Yourgene® MagBench™ Extraction Instrument	40161000
Yourgene® MagBench™ cfDNA Extraction Kit Sage™ Workflow	40162000

Learn more about how MagBench™ can enhance your Sage™ 32 NIPT Workflow

Scan the QR code to learn about Yourgene's Sage™ 32 NIPT Workflow.

Click the 'Workflow' tab to learn specifically about MagBench™ to enhance the DNA extraction stage in the workflow.

Contact Us

If you are interested in introducing or enhancing your Sage™ 32 NIPT Workflow with MagBench™, please contact sage@yourgenhealth.com to speak to our team.

About YOURGENE HEALTH

Yourgene Health is an international molecular diagnostics group which develops integrated genomic technologies and services *enabling genomic medicine*

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