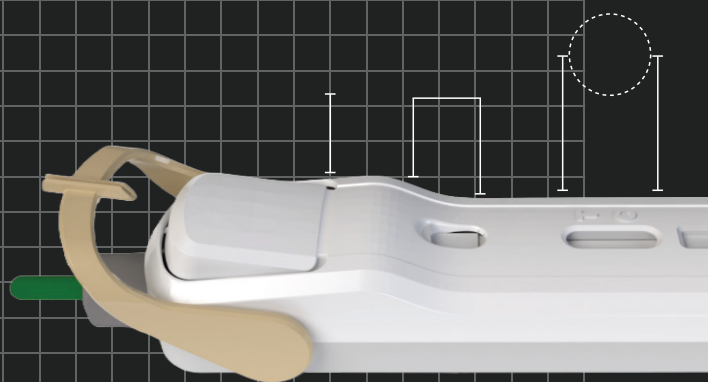




OEM CASE STUDY

NG Biotech: Pioneers in blood-based rapid hCG pregnancy testing

From its impressive and newly expanded manufacturing plant close to the beautiful village of Guipry in northwest France, NG Biotech is rapidly scaling-up production to meet growing demand for its innovative products. The village setting is in stark contrast to the cutting-edge nature of NG Biotech's technologies which include multiplex assays and mHealth interfaces used in biodefense diagnostics as well as human and animal health diagnostics.



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Milovan Stankov Pugès - CEO, NG Biotech

An ambitious company intent on being a global leader in its field, NG Biotech identified a game-changing growth opportunity for its blood-based pregnancy rapid diagnostic test (RDT): disruption of both the professional use market and the rapidly expanding over-the-counter (OTC) market. Having developed a lab-accurate lateral flow test strip, the company went in search of a design partner with innovative and proven products that would help them create a best-in-class medical device for use in both point-of-care (POC) and home-testing settings.

NG Biotech first approached Atomo Diagnostics to discuss its requirements at the Medica trade fair, held in Dusseldorf, Germany, in November 2015. Just 12 busy months later at the 2016 event, NG was able to unveil the world's first fully-integrated blood-based rapid diagnostic test for pregnancy: NG-Test® Blood Precision hCG.

“We value how Atomo is committed to designing products that work to eliminate user errors. We knew that this would be vital if this project was to attract professional users who need to improve patient outcomes, and to attract OTC home-test customers who currently have no choice but urine based pregnancy tests which have some limitations.”

Milovan Stankov Pugès
CEO, NG Biotech

The benefits of blood-based hCG testing

Testing of hCG (human chorionic gonadotropin) levels is routinely performed in emergency departments when a female patient is admitted with abdominal pain or bleeding: as many as 20 million hCG tests are carried out across the US and Europe each year. Current hCG test methods include laboratory analysis of venous blood samples, where results are typically obtained in 1-2 hours, and urine rapid tests that give less accurate results in 20- 40 minutes.

Traditionally considered quick and easy, urine tests have long proved problematic in busy primary care environments. Sample collection can be challenging and time intensive, and urine is a less sensitive sample medium

than blood. Insufficient or diluted urine samples can also affect test accuracy and cause false negative results. Similarly, use of blood-based hCG testing in critical POC settings has previously been far from ideal because of the time taken to get results back from the laboratory. As well as being an effective means of saving time and cost, prompt diagnosis is central to improving patient outcomes.

The NG-Test® Blood Precision hCG has been designed specifically to address the performance, usability and convenience issues associated with current forms of hCG testing, with particular regard to POC diagnosis in primary care and emergency settings.

Collaborating to create a best-in-class test



Giving a reliable result in just 5 minutes, NG-Test® Blood Precision hCG combines the highly accurate test strip developed by NG Biotech with an easy-to-use medical device designed by Atomo Diagnostics: the innovative AtomoRapid™ 'Pascal' platform. Incorporating multiple features to make testing easier and more convenient, including an integrated safety lancet and unique blood collection and delivery mechanism, the device platform is also the first in the world to have a built-in buffer delivery system.

These features overcome the problems commonly associated with standard, multi-component rapid diagnostic test kits, particularly those relating to collection and transfer of blood to the test, and improper use or inadequate delivery of buffer solution. The product's convenience and usability is further supported by compatibility with NG Biotech's pioneering immunoassay reader.

Requiring only a 10µL blood sample, collected easily and comfortably from the fingertip, the test delivers a highly accurate result at any time of day offering significantly greater convenience, particularly for at-home testers. Current urine tests should only be used with the first morning urine for utmost accuracy in early stage pregnancy.



Supporting self-testing with simplicity in design

Beyond professional use in emergency departments, doctors' offices, IVF clinics and first response situations, NG Biotech will also be launching a self-test version of the product for OTC markets. The user-centred design and lab-accurate performance of NG-Test® Blood Precision hCG makes it ideal for lay users wanting an accurate and unambiguous result in the early stages of pregnancy. Despite the home pregnancy testing market being firmly established, there has previously been only limited differentiation between the various urine tests available. Customers find it difficult to make meaningful comparisons and often resort to making choices based purely on price. As the world's first fully-integrated hCG blood test, NG-Test® Blood Precision hCG aims to disrupt the pregnancy testing market when the product is made available OTC during 2018.

"The user-centred design that we have achieved with this product – as a result of our collaboration with Atomo – also makes this product ideal for OTC markets and self-testing. We are confident that it will be well received by customers wanting a highly accurate home test."

Milovan Stankov Pugès
CEO, NG Biotech



For more information about NG-Test Blood Precision hCG, contact NG Biotech at info@ngbiotech.com

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Working in partnership to facilitate efficient product development

Explaining the success of NG Biotech's first collaborative project with Atomo Diagnostics, Milovan Stankov Pugès described how:

"As a young, dynamic and innovative company, we were looking to achieve a rapid route to market. Atomo Diagnostics and NG Biotech are similar in this respect. Atomo's track record in award-winning design and manufacturing meant that we were confident in its development capabilities right from the start. The supportive and collaborative partnership that has evolved has fed our desire to plan more projects together. We are already discussing new RDT projects for cardiology and infectious diseases."

Discover how partnering with Atomo Diagnostics can provide your business with an efficient and low-risk pathway from product development to commercialisation of your rapid diagnostic test.

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<https://www.atomodiagnostics.com/technology/>

