



THE abioSCOPE® PLATFORM

TIME WAITS FOR NO ONE
ACT NOW!

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THE abioSCOPE®

FAST RELIABLE ACCURATE

The **abioSCOPE®** is a compact and ultra-fast diagnostic solution, providing quantitative, semi-quantitative or qualitative results at the PoC from only a single drop of patient sample.



RESULTS WITHIN 7 MINUTES

abioSCOPE® provides highly accurate, actionable results at the PoC. 7 minutes for quantitative results and 2 minutes for qualitative ones.



MAINTENANCE-FREE DEVICE

abioSCOPE® does not require regular maintenance. Its corresponding IVD CAPSULEs are factory-calibrated.



DISPOSABLE CAPSULE

Single-use capsules eliminate the risk of contamination and ensure maximum quality between runs.



ONE DROP OF SAMPLE

50 µl of patients's sample to perform a test.



INTUITIVE & EASY TO USE

abioSCOPE® requires minimal training and its step-by-step on-screen process is designed for anyone to use.

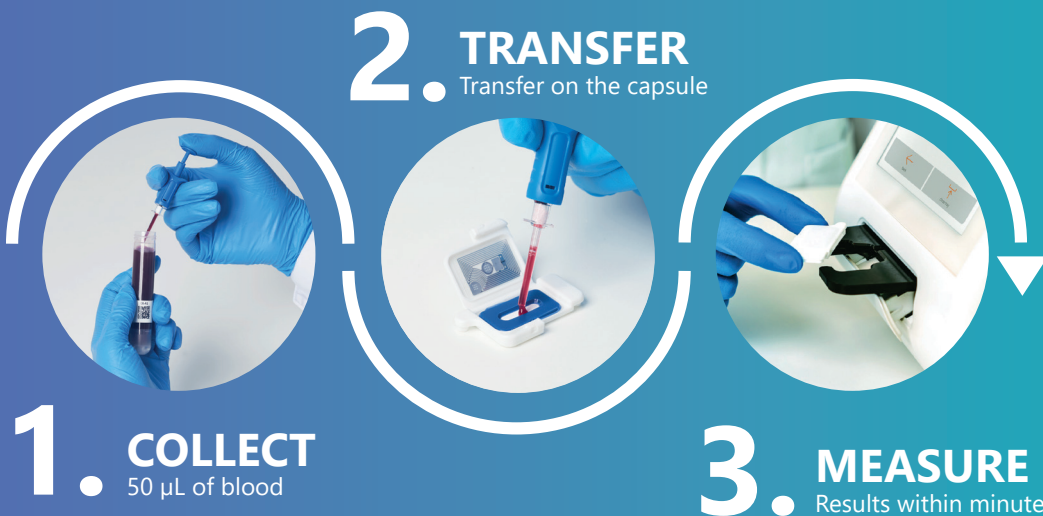


IT SYSTEM

The **abioSCOPE®** connects into Hospital/Laboratory Information Systems and integrates results into Electronic Health Records.

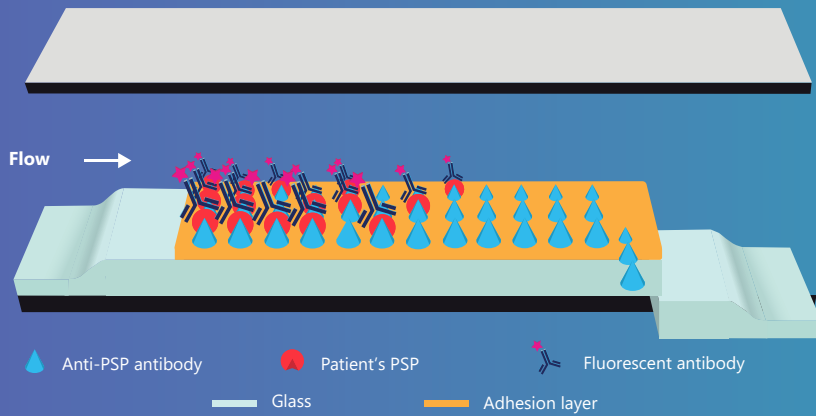
IVD CAPSULE

EASY-TO-USE & VERSATILE



abioSCOPE® - BENCHTOP RAPID DIAGNOSTIC PLATFORM

Innovation: Nanofluidic Immunoassay, Delivering Fast, Reliable, and Accurate Results



Using a single cartridge and a drop of blood, Abionc's patented technology delivers lab-quality results within minutes.

Molecules are forced into a nanochannel, limiting their travel distance to a few hundred nanometers, reducing incubation time to 2 minutes.

As the surface-to-volume ratio is extremely high, and non-specific background noise is negligible, the process is greatly simplified by removing unnecessary washing steps.

PANCREATIC STONE PROTEIN (PSP)

The **IVD CAPSULE PSP** is a rapid, single-use *in vitro* diagnostic test for the quantitative measurement of Pancreatic Stone Protein (PSP). The test is intended to be used in conjunction with other clinical assessments and laboratory findings to aid in the early detection of sepsis in adults.



1 DROP OF BLOOD

50µl of capillary whole blood or K₂-EDTA or K₃-EDTA anticoagulated venous or arterial whole blood.



WIDE MEASURING RANGE

20 - 600 ng/ml.



7 MINUTES

3 simple handling steps and only 7-minute measuring time to get accurate results.



LAB QUALITY RESULTS

Performances in line with laboratory requirements.




QC PRODUCTS


ABIOSCOPE CONTROL

The **abioSCOPE Control** is a ready-to-use kit for the **abioSCOPE®** device and intended for professional use in clinical laboratories or point-of-care (PoC), including near-patient testing. The **abioSCOPE Control** kit contains a capsule with a reference signal for quality control that must be performed to confirm that the system is functioning properly and providing reliable results. A QC Program can be configured to set up lockout parameters for the abioSCOPE control. It can be based on either the number of capsule tests performed or a predefined time interval to ensure long-term quality and reliability.


QUALITY RESULTS

 Use regularly to ensure that all electronic and laser components are working properly.


3 MINUTES


 No handling steps required and only 3-minute measuring time to get QC results.

QC FREQUENCY

 On a monthly basis, during new trainings, when unexpected test results are obtained, or following local regulatory requirements.

SHELF LIFE

 6 months shelf life when kept refrigerated at 2-8°C. It can be used a maximum of 100 times for QC.



IVD CAPSULE CONTROL PSP

The **IVD CAPSULE Control PSP** is a single use kit, intended to ensure the accurate quantification of PSP at the PoC by the user in the professional healthcare setting. It contains a verification dose of a known concentration of PSP that is used to perform a quality control (QC) of the **IVD CAPSULE PSP** on the **abioSCOPE®**.



LOW VOLUME

 Only 50 µl of PSP Control solution to be taken with the same abioPIPETTE as for an **IVD CAPSULE PSP**.

7 MINUTES

 3 simple handling steps & only 7-minute measuring time to get accurate QC results.

QC FREQUENCY

 On a monthly basis, during new trainings, when unexpected test results are obtained, or following local regulatory requirements.

SHELF LIFE

 15 months shelf life when kept refrigerated at 2-8°C.

OUR **MANUFACTURING** CAPABILITIES

A TAILOR-MADE PRODUCTION LINE FOR HIGH-TECH CUSTOMIZABLE CAPSULES

Our fully automated manufacturing line has been designed to meet the highest international medical standards with a current capacity of 2 million tests produced annually. We are currently looking to strongly increase this capacity in strategic locations.

2 000 000 TESTS PER YEAR

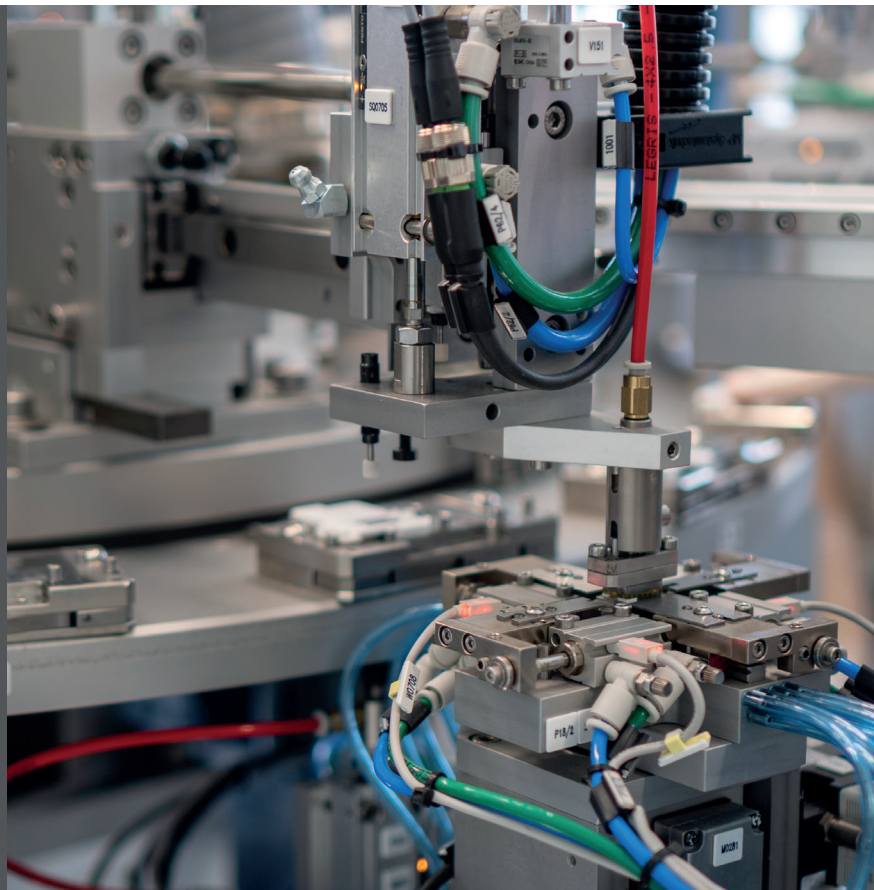
The current manufacturing capacity in Switzerland is up to 2M kits per year.

ISO 13485:2016 CERTIFIED

Since 2012, we are maintaining a quality management system meeting the requirements of ISO 13485 standard for the R&D, production and commercialization of IVD products.

CUSTOMIZABLE MANUFACTURING

High tech and fully automated manufacturing process that allows customization of IVD CAPSULE in house.





The abioSCOPE® and the IVD CAPSULE are CE marked.

The IVD CAPSULE PSP and the abioSCOPE® devices are compliant with the EU IVD Regulation 2017/746 and have received FDA clearance.



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