

Full automation solution for stool analysis

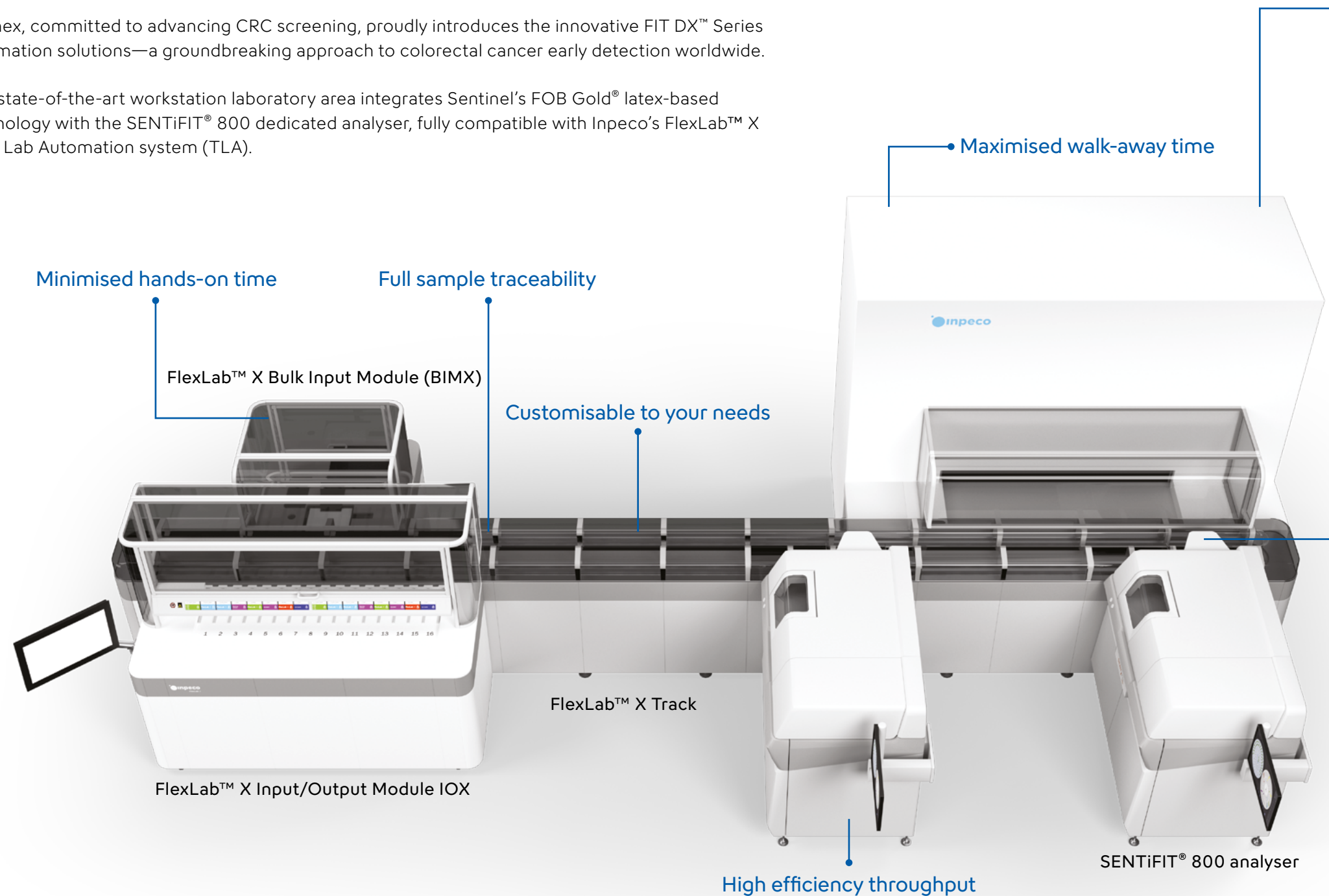
FIT DX™ Series



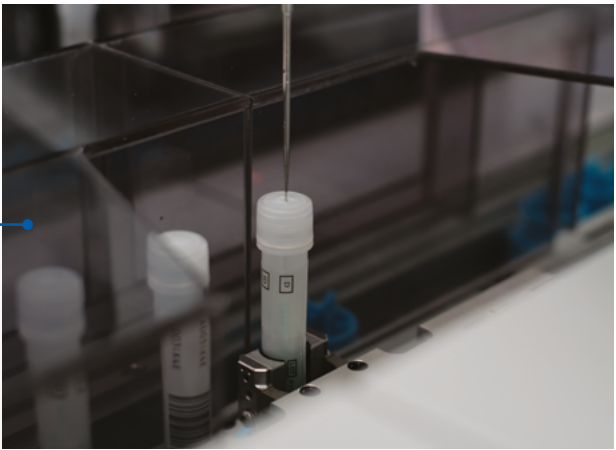
FIT DX™ Series – The future of CRC screening automation

Sysmex, committed to advancing CRC screening, proudly introduces the innovative FIT DX™ Series automation solutions—a groundbreaking approach to colorectal cancer early detection worldwide.

This state-of-the-art workstation laboratory area integrates Sentinel’s FOB Gold® latex-based technology with the SENTiFIT® 800 dedicated analyser, fully compatible with Inpeco’s FlexLab™ X Total Lab Automation system (TLA).



FlexLab™ X Storage and Retrieval Module (SRMX)



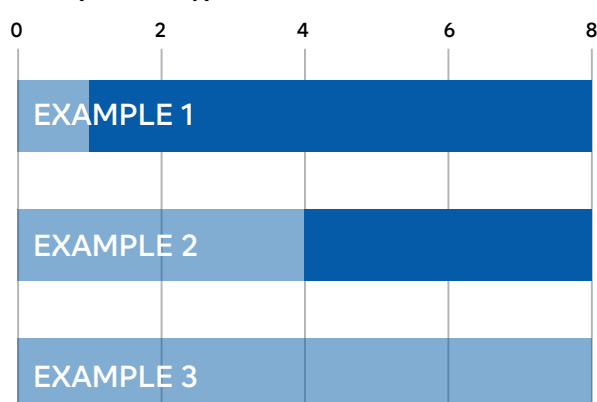
SENTiFIT® pierceTube 2-in-1 tube for collection and extraction

Modularity – enabling customisation

The FIT DX™ Series full automation solution is modular, allowing you to adapt it to your needs in terms of space, throughput, and budget. This flexibility ensures that the system can be tailored to fit various laboratory configurations and operational requirements, providing an efficient and cost-effective solution for colorectal cancer screening programmes.

The figure highlights the workflow efficiency of the FIT DX™ Series during a routine lab workday, comparing three configurations. It emphasises reduced “Hands-on time” (light blue) and optimised “Walk-away time” (dark blue), allowing technicians to focus on other tasks. This balance enhances productivity, making the FIT DX™ Series ideal for streamlined, high-performance lab operations.

Working day
time (hours/day)



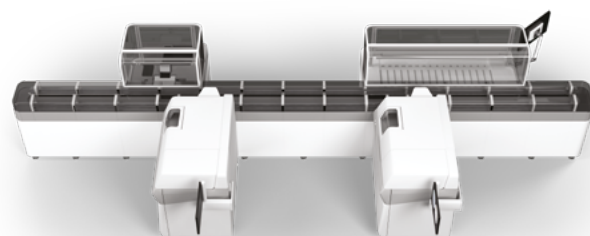
Hands-on time Walk-away time



Example 1: configuration with FlexLab™ X Track, BIMX, IOX, and SRMX.



Example 2: configuration with FlexLab™ X Track, BIMX, and 2 IOX.



Example 3: configuration with FlexLab™ X Track, BIMX, and IOX.

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FlexLab™ X is a trademark of Inpeco SA.

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The perfect FIT no matter your workload

SENTiFIT[®] 800 Analyser



SENTiFIT[®] 800 Analyser - dedicated high-throughput platform for faecal immunochemical testing

Reduced hands-on time thanks to high automation

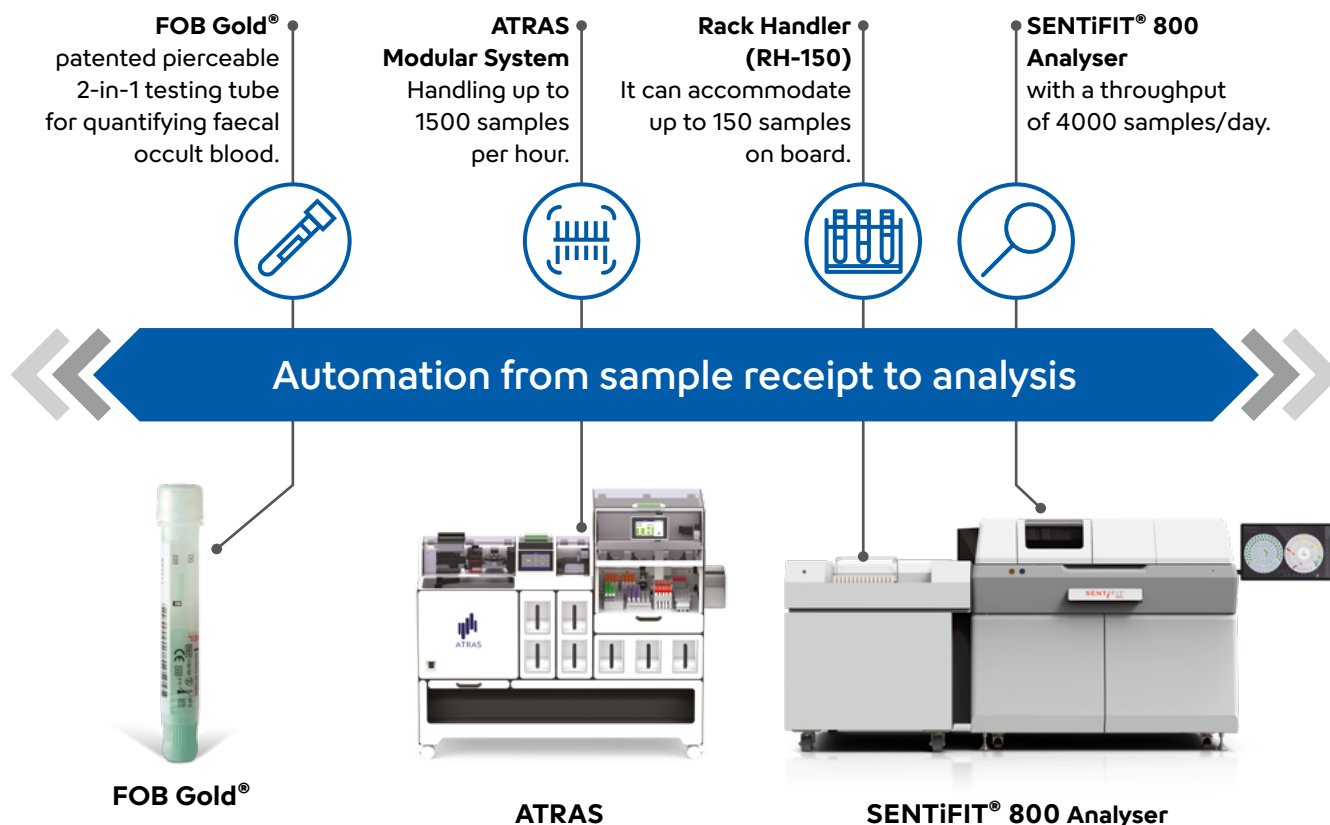
- Floor-standing analyser with a possible TLA connection
- No sample preparation needed
- Automatic cap-piercing function
- Automatic dilution for over-range samples
- Direct connection to water supply and drainage
- Automatic dilution of concentrated wash solutions
- High throughput: 550 test/h

Timesaving from easy handling

- Parallel, continuous loading of samples with random access
- Stable on-board refrigeration of reagents for long periods
- Barcode reading for full traceability of all samples and reagents
- Quality control can be performed multiple times a day without stopping routine operations
- New samples can be loaded into the inner carousel without interrupting the routine

Semi-automated solution for stool testing

Sysmex delivers a high-throughput, semi-automated platform designed for immunological stool testing. Featuring the SENTiFIT® 800 Rack Handler (RH-150) and ATRAS, this solution ensures fast, reliable, and efficient results, streamlining laboratory workflows.



Specifications

Technology	SENTiFIT® 800 Analyser, dedicated clinical-chemical analyser for quantitative immunoturbidimetric identification of various antigens in stool samples.
Throughput	up to 550 tests/hour
On-board capacity	>11,000 determinations (for FOB)
Result frequency	New result every 6.5 seconds
Dimensions/weight	1300 x 1150 x 850/300 (W x H x D [mm/kg])
Automatic sample rack loader	Rack Handler RH-150
Dimensions/weight	890 x 924 x 850/110 (W x H x D [mm/kg])
Compatibility	TLA system connection

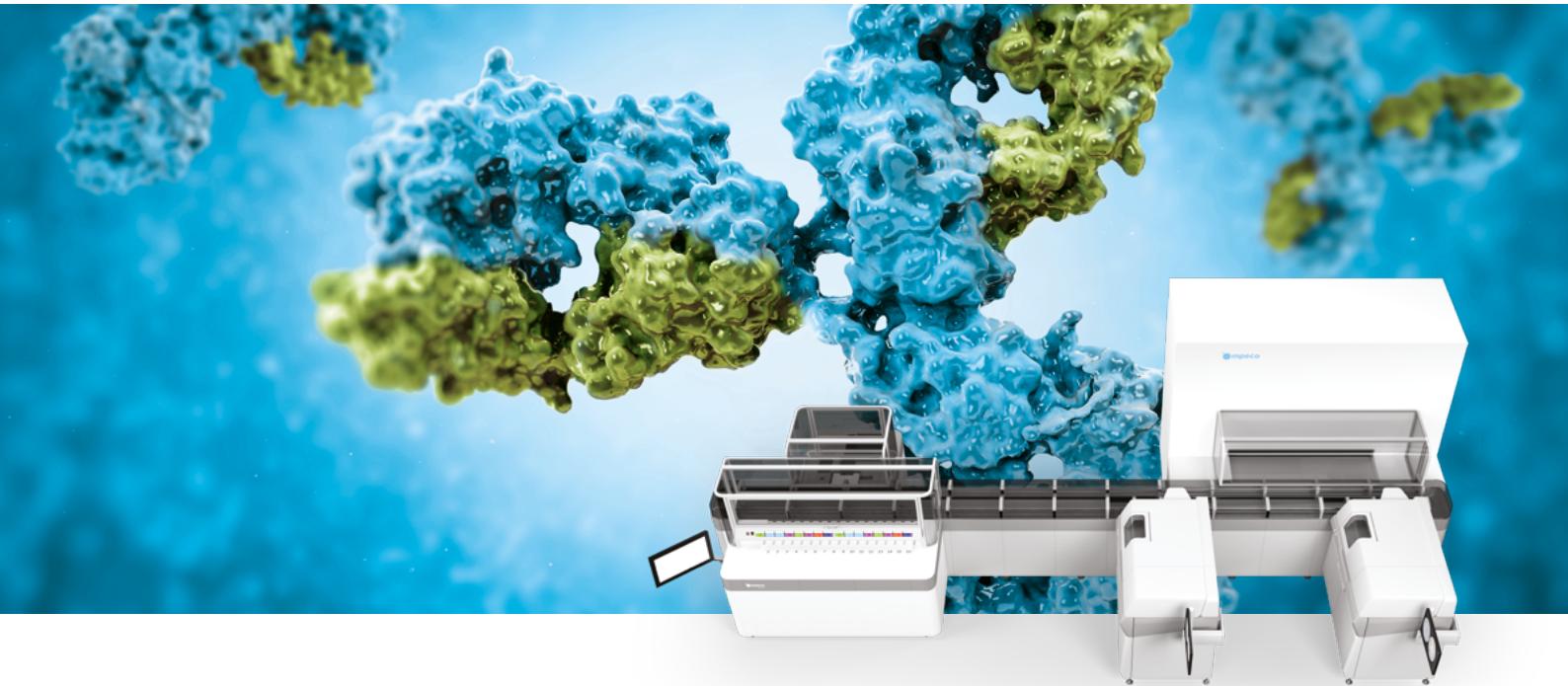
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 Manufacturer Atras R4 SL: T&O LabSystems GmbH & Co. KG · www.to-labsystems.com
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Inpeco Total Laboratory Automation system

FlexLab™ X



FlexLab™ X Total Laboratory Automation modules

Key features

Inpeco's FlexLab™ X Total Lab Automation solutions streamline laboratory workflow, increase efficiency of the lab and provide full sample traceability. FlexLab™ X Total Laboratory Automation modules are specifically designed to be easy to use, quiet and reliable, as well as compact in size. By integrating advanced technologies and modular designs, Inpeco's automation system can fulfil the requirements of any clinical lab.

1. Track Module

The Track Module is a modular system designed to transport sample tubes along the automation system.

- Flexibility: U-turns and L-turns.
- High throughput: **up to 15,525 tubes per hour.**
- Robust design: double motors and improved carrier design, ensuring continuous operation.
- Ease of installation: standardised track components.

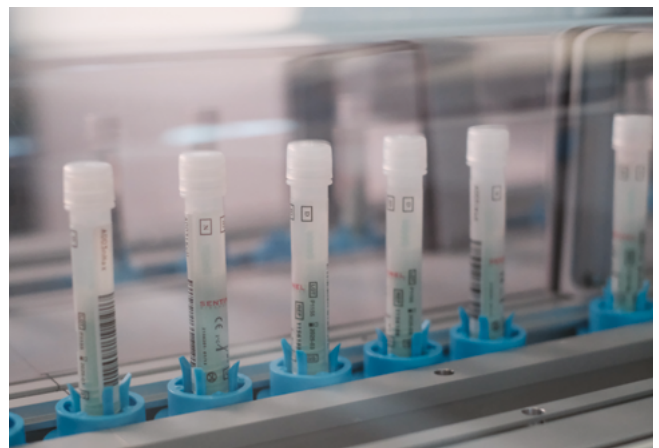


Figure 1. FlexLab™ X track and sample carriers

2. Bulk Input Module (BIMX)

The Bulk Input Module (BIMX) allows for easy and fast loading of samples in bulk.

- High throughput: **up to 1,200 tubes/hour.**
- Wide compatibility: tubes supported from 11 x 65 mm up to 16 x 100 mm.
- Vision system: checks label, tube type and cap colour, and identifies non-compliant labels.
- Priority handling: dedicated loading area for STAT samples enables high-priority processing.

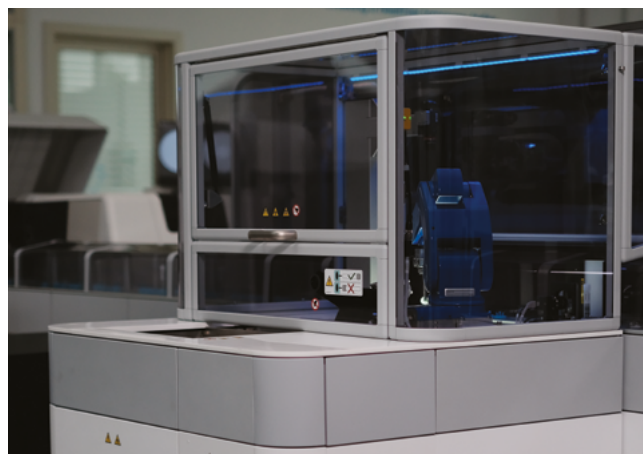


Figure 2. FlexLab™ X Bulk Input Module

3. Input/Output Module (IOX)

The Input/Output Module (IOX) provides various functions such as input, output, sorting, parking, and error management for tubes in racks.zy

- High throughput: **up to 1,000 tubes/hour.**
- Vision system: captures sample IDs and detects tube specifications (label, tube type and cap colour) and efficiently detects non-compliant tubes.
- Versatility: Multi-vendor Rack Management.
- Space-saving design with back-to-back installation options.



Figure 3. FlexLab™ X Input/Output Module

4. Storage Module (SRMX)

The Storage Module (SRMX) allows for a fully traceable sample storage in a temperature-controlled environment.

- Dual temperature zones: 12,672 tubes at a controlled temperature and 576 tubes at room temperature.
- High throughput: **up to 1,500 tubes/hour**, with double gripper and dual lane systems.
- Quick retrieval: less than 30 seconds/sample.
- Emergency access: Walk-in area for easy and safe access in contingency situations.

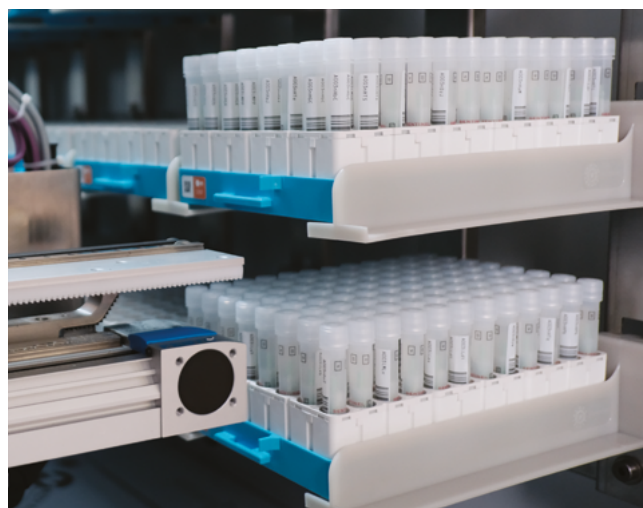


Figure 4. FlexLab™ X Storage and Retrieval Module

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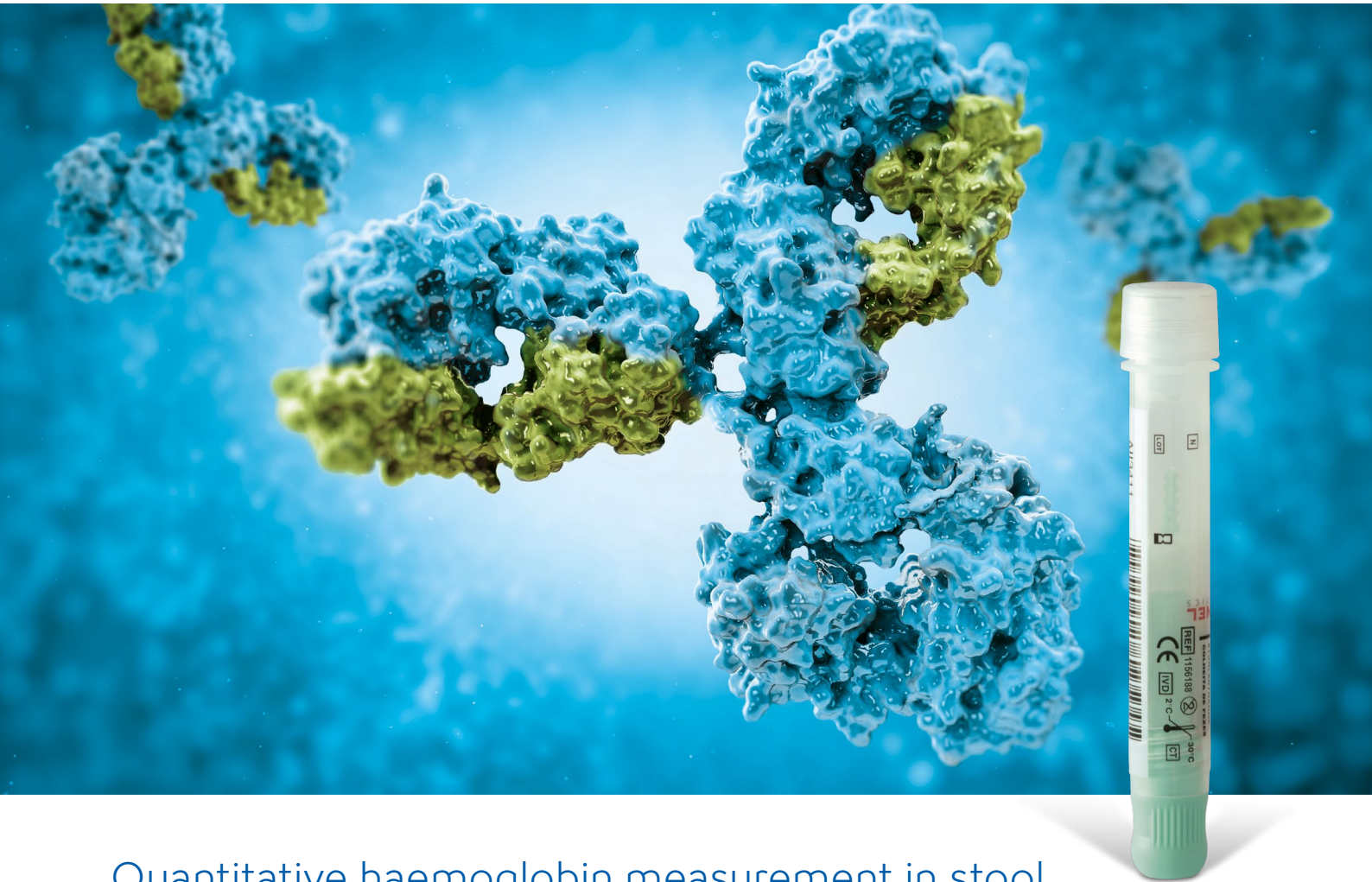
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Standardised stool sampling and direct analysis

FOB Gold[®]



Quantitative haemoglobin measurement in stool

The FOB Gold[®] technology combines a "2-in-1" pierceable tube for sample collection with a next-generation immunological latex reagent for determining faecal occult blood.

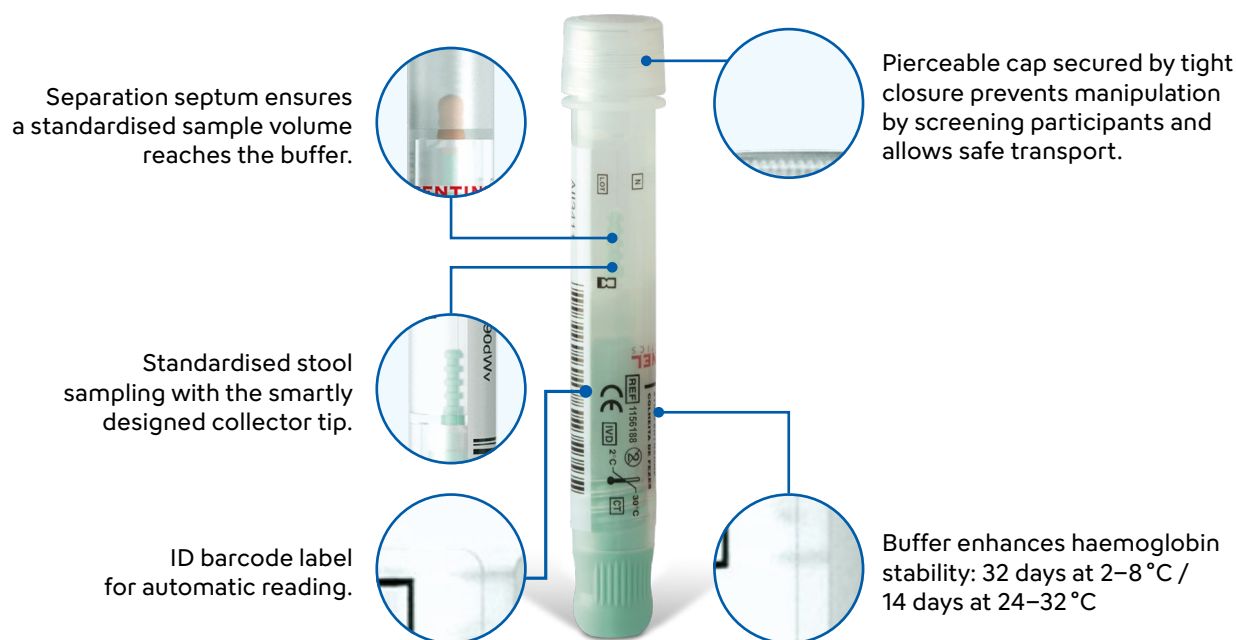
FOB Gold[®] test

Its high-quality diagnostic performance has been demonstrated by multiple studies and has been proven in national and international screening programmes. The FOB Gold[®] test fulfils the requirements set by the WEO CRC Screening Committee recommendations and several other country-based guidelines:

- Illustrated instructions that are easy to understand so the patient can correctly sample his/her stool
- Standardised test implementation in the laboratory by using automated processes
- High diagnostic accuracy: sensitivity 34.3%, specificity 95.9%, PPV 51.4%.

SENTiFIT® pierceTube

- Notches on the sampling stick and the integrated wipe-off septum result in standardised amount of sample collection and the correct amount of stool (10 mg).
- No sample preparation whatsoever after sample collection and before measuring.
- Pierceable lid is secured by a tight seal.
- The preferred tube for CRC screening according to a questionnaire of ~21,000 participants in a Dutch screening programme (De Klerk *et al.* 2019) – the FOB Gold® tube was reported as significantly easier to use.
- The SENTiFIT® pierceTube meets packaging regulation P650 of ADR*.



Specifications

Test tube	SENTiFIT® pierceTube
Reagents	SENTiFIT® FOB Gold® latex Wide (R1 and R2) FOB Gold® Screen Diluent
QC and calibrator	FOB Gold® Control Set Wide (levels 1 and 2) FOB Gold® Calibrator Wide
Analysis system	SENTiFIT® 800, SENTiFIT® 270 and SENTiFOB® analysers

* Accord européen sur le transport des marchandises dangereuses par route, European Agreement concerning the International Carriage of Dangerous Goods by Road and IATA (International Air Transport Association)

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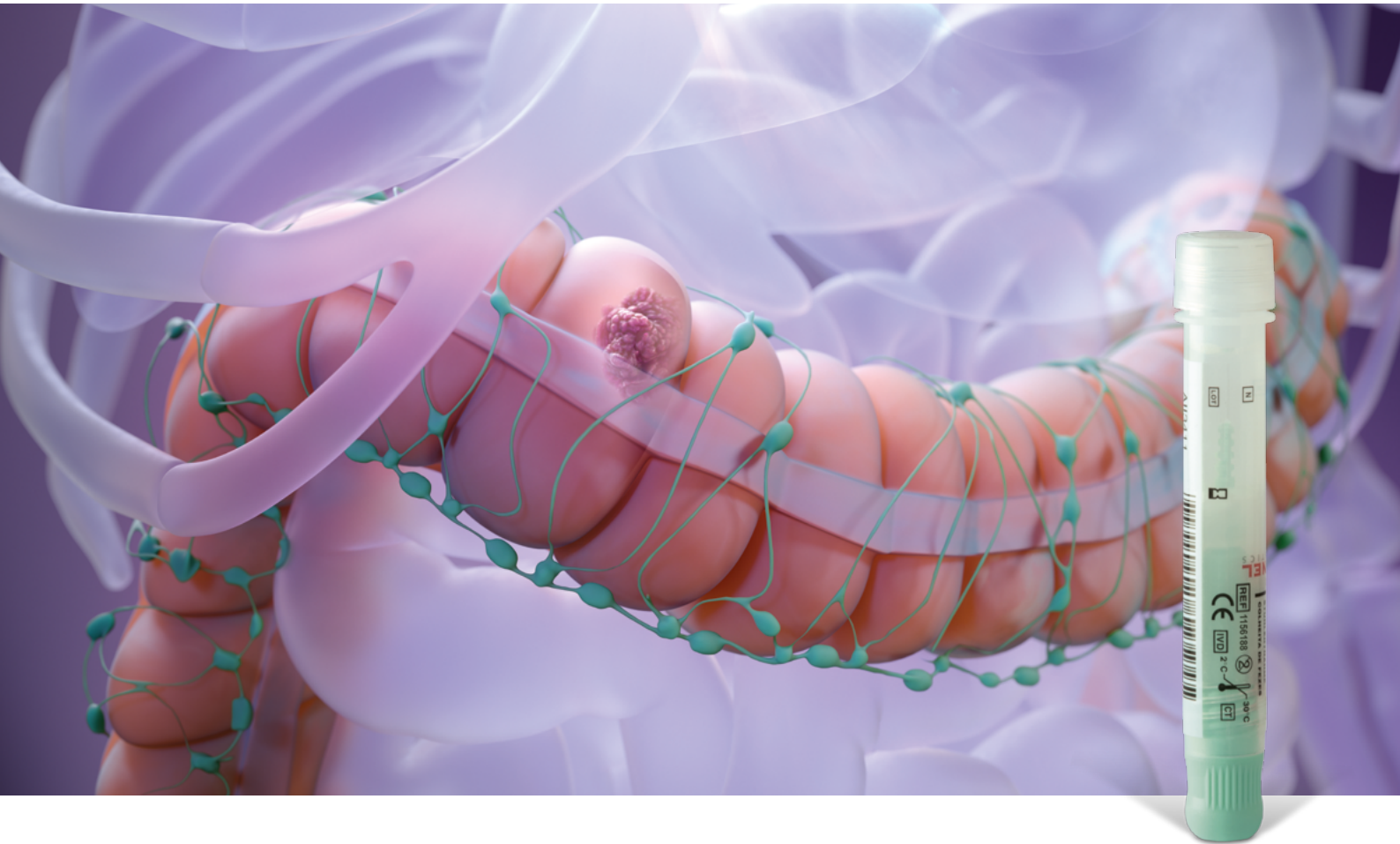
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Transforming colorectal cancer screening

FIT DX™ Series



Superior performance and flexibility in faecal occult blood testing – large-scale screening

The faecal immunochemical test (FIT) for occult blood in stool, which is recommended alongside colonoscopy in early colorectal cancer (CRC) detection guidelines, detects human haemoglobin with high specificity using antibodies.

FOB Gold® is designed to meet the specific needs of your CRC screening programme, featuring the SENTiFIT® pierceTube and scalable analyser platforms to accommodate your throughput requirements. FOB Gold® offers superior performance compared to conventional qualitative tests, providing several key advantages. It requires no dietary restrictions prior to testing, eliminates concerns about drug interference, and ensures seamless automation and traceability. These features make it ideally suited to meet the demands of large-scale screening programmes.

The strength of the FIT DX™ Series lies in its flexibility, offering an ideal solution for efficiency, reliability, and high throughput in processing samples.

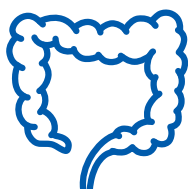
Early detection is the key – advancing global health

CRC is the world's third most common cancer and one of the leading causes of cancer-related deaths [1]. One of the biggest things that sets CRC apart from other cancers is the ease and convenience of early detection, which presents an opportunity to reduce mortality across the globe. Sysmex's goal is to decrease mortality and focus on the early detection of CRC, as this can result in a 90% survival rate.

What you need to know about colorectal cancer



More than **1,880,725** men and women worldwide are diagnosed every year



915,550 people are killed by CRC worldwide every year



90% of new cases occur in people **aged 50** or older

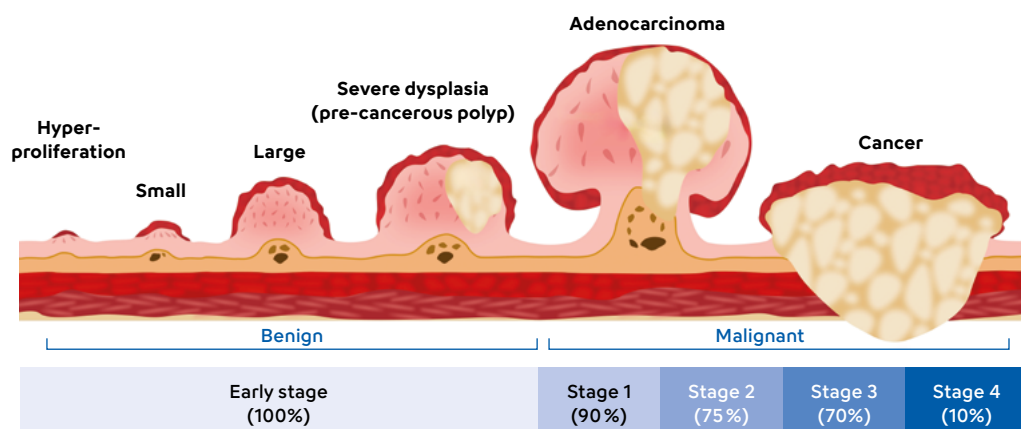
Risk factors:

- Personal and/or family history of polyps or cancer
- Over the age of 45
- Genetic conditions

From polyp to cancer – enhancing survival rates and health outcomes

Over 30% of individuals aged 50 and above have polyps, with approximately 10% of these polyps progressing to CRC. As the polyp advances to cancer, the patient's chances of survival decrease. Early detection of colorectal lesions is associated with higher survival rates. Population-wide screening initiatives can significantly contribute to the early identification of CRC, leading to improved health outcomes.

CRC progression and 5-year survival rate by stage



Early identification of colorectal cancer, leading to improved health outcomes [2]

[1] Source: World Health Organization. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries (Sung, 2021).
[2] Source: Digestive Cancers Europe <https://digestivecancers.eu/colorectal-what/>
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