OC-FCa Quantitative Faecal Calprotectin

Building upon the world renowned OC-Sensor™ platform

- The OC-Sensor™ PLEDIA tests calprotectin directly from the primary sample collection device. No stool sample handling or laboratory extraction necessary.
- The OC F-Ca assay has a wide measurement range of 20-2,720µg/g and the PLEDIA has hook effect detection and automated dilution capability.

FIT + Calprotectin: Same sample, Same analyser, Same time!

- The ability to process both FIT and Calprotectin from the same sample improves compliance, increases diagnostic efficiency and enables a streamlined reflex testing algorithm.
- A throughput of 160 tests/hr for simultaneous or reflex testing both FIT and Calprotectin means the PLEDIA is able to handle very large workloads with ease.

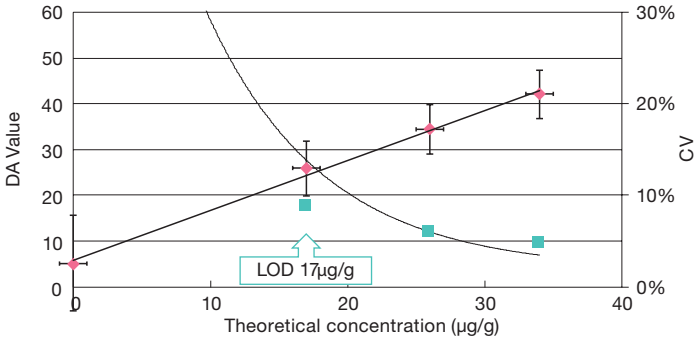
Purposefully designed to enhance usability and turnaround time

- As a fully automated random access platform, OC-Sensor™ PLEDIA enables the laboratories to process FIT & Calprotectin in real-time. No more batching samples to put on the routine chemistry analyser or to fill an ELISA plate.
- A bi-directional interface means samples can be analysed for the correct assay without any user intervention. Simply load up the sample racks and 'press start'.

INTRA-DAY REPRODUCIBILITY *Calprotectin solution

	Sample 1	Sample 2	Sample 3
N	20	20	20
Mean	169	532	1.377
S.D.	4.7	7.7	18.2
CV (%)	2.8	1.4	1.3
MAX.	182	544	1.405
MIN.	161	516	1.342

LIMIT OF DETECTION (LOD) *Calprotectin solution



OC-Sensor™ stands out from the crowd by offering a unique quantitative faecal calprotectin assay from the convenience of the FIT sample collection device.

FIT and Calprotectin multimode gives a sample throughput of 160 tests/ hour

Straightforward user software and touch screen operation

True two in one analysis available supported by a bi-directional interface

Load capacity of 200 samples with continuous feed ensuring maximum throughput

OC-Sensor™ PLEDIA Analyser Specifications

Principle	Latex agglutination immunoturbidity
Operation speed	Up to 320 tests/hour
Sample run capacity	20 × 10 sample rack
Sample loading	Random Access
Barcode reading	Rack barcode, sample barcode, reagent barcode (optional 2D barcode)
Analyte	Faecal Haemoglobin Faecal Calprotectin

Data input	Colour LCD touch panel (10.5 inches)
Data output	Thermal Printer, RS-232C, USB, LAN
Memory capacity	100,000 test results
Dimensions	W630mm × D630mm × H560mm
Weight	58Kg

OC-Sensor F-Ca

Order Code	Product	Unit	Storage
V-PH11	OC-FCA REAGENT	Latex 8 mL × 2 Buffer 15 mL × 2	2 – 10°C
V-PH12	OC-FCa Calibrator	6 mL × 2	2 – 8°C
V-PH13	OC-FCa Liquid Control - LV1	5 mL × 2	2 – 8°C
V-PH14	OC-FCa Liquid Control - LV2	5 mL × 2	2 – 8°C
V-PH15	OC-FCa Liquid Control - LV3	5 mL × 2	2 – 8°C

OC-Sensor FIT

Order Code	Product	Unit	Storage
V-PZ01	OC-Sensor™ PLEDIA Latex Reagent	5 × 15 mL	2 – 10°C
V-PZ03	OC-Sensor™ PLEDIA Buffer	500 mL	2 – 10°C
V-PH52	OC-Sensor™ Calibrator 2 Kit	1 × 3 mL STD	2 – 8°C
V-PH53	Liquid Control - LV1	2 × 5 mL	2 – 8°C
V-PH54	Liquid Control - LV2	2 × 5 mL	2 – 8°C
V-PH59	Liquid Control - LV3	2 × 5 mL	2 – 8°C

General Consumables

Order Code	Product	Unit	Storage
V-PH19	OC-SENSOR Sample Diluent	45 mL × 3	2 – 8°C
V-PZ26	OC-Auto Sampling Bottle 3 (without barcode)	100	1 – 30°C
MV5F07	OC-Sensor™ PLEDIA reaction cells (semi-disposable)	5 × 11	–
EU074	2ml QC Cups	1000	–
ST020	Thermal Printer rolls	20	–

Mast Group

IVD solutions through partnership

OC-Sensor™ is a trademark of EIKEN CHEMICAL Co., LTD.

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IVD solutions through partnership

Mast Group

OC-Sensor

Quantitative FIT and Calprotectin

- Fully automated analysis on the OC-Sensor™ PLEDIA
- Two assays available from the same sample bottle
- Ready to use liquid controls and calibrators
- NICE recommended technology for quantitative FIT

Introduction

Eiken Chemical Company released the first generation of OC-Sensor™ in 1989. OC-Sensor™ has since evolved as the standard for the detection of occult blood in faeces and is the only quantitative Faecal Immunochemical Test (FIT) product with FDA approval. With over 120 million samples distributed annually to more than 45 countries, you can be confident that OC-Sensor™ is the solution for your symptomatic and screening needs.

Recent advancements in the prominent OC-Sensor™ range mean that haemoglobin and calprotectin can be tested from the same sample. This exciting development will pave the way for streamlining clinical pathways and better inform referral decisions. These important faecal markers are useful in identifying patients at the highest risk of bowel disease requiring further investigation.

OC-Sensor™ is a complete solution:

OC-Sensor™ PLEDIA analyser	-	Fully automated high throughput analysis with a large on board reagent and sample capacity. Long reagent stabilities on board mean that the PLEDIA is suitable for medium to large workloads.
Proven Sample Collection Device	-	Sample collection is simple, hygienic and convenient for the patient. The device is engineered to achieve unparalleled haemoglobin stability and exemption from UN3373 regulations.
Ready-to-use liquid reagents	-	Unique stabilising technology means that all controls and calibrators are provided in a liquid format. No more rehydration and aliquoting issues!

OC-Sensor™ Reagents:

OC-Sensor™ FIT and Calprotectin reagents are expertly designed to enable simple and reliable operation in the laboratory.

- Packaging is kept to a minimum to reduce storage requirements.
- Specifically designed to be resilient to the hook effect (Prozone).
- The latex reagent is stable once opened for up to 4 weeks.
- Automatically create calibration curves and perform QCs using ready-to-use kits requiring less than 1 minute of hands on time. Simply add drops to cups as directed and press start. Simple as that!
- Three levels of controls ensures confidence at clinical decision points.
- FIT and Calprotectin reagents are handled in the same way for ease of use in the laboratory.

Expertise, efficiency and excellence with... OC-Sensor™

Ready-to-use liquid quality control

Unique LV3 QC for confidence at low concentrations

High volume reagents with long on board stability

Pack sizes prevent wastage and reduce storage needs

OC-SENSOR™ PLEDIA

High Throughput Sampling

Capable of analysing up to 320 tests/hr on a fully random access basis. Up to 200 samples can be loaded on the machine with automatic rack detection. The PLEDIA has multiple reagent slots for uninterrupted processing for high throughput population screening.

Advanced Usability

10.5 inch colour LCD touch screen panel with a straightforward and user friendly interface. The display screen is angle adjustable to improve user visibility. Data output via built in printer, USB, RS-232C or LAN connection.

Benchtop analyser

W630mm × D630mm × H560mm.

Light blue - Patient sample rack.

Green - Retest rack. Enable automatic sample retesting by switching off the foil punch mechanism.

Orange - Dilution rack enables automatic ×15 and/or ×250 dilutions.

Dark Blue - QC and Calibration rack.

Information Generation

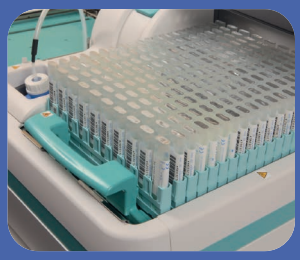
Real-time information generated, including details on reagents and sample processing time. Extensive QC functions are available including X-R control screen and CV auto calculation.

Multimode capability

The OC-Sensor™ PLEDIA is now able to test for haemoglobin and calprotectin from the same sample bottle supported by a bi-directional interface.

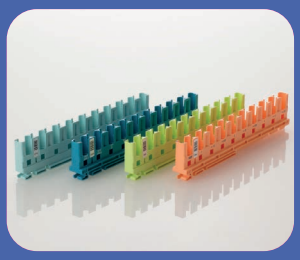
Complete Automation

Capable of automatic startup, maintenance and shutdown. Automatic identification of measurement modes based on barcoded racks. Racks are differentiated both visibly and automatically through barcodes.

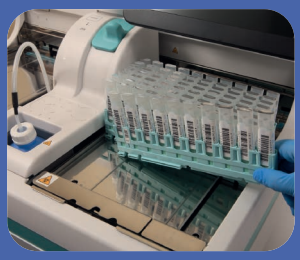


Used in national screening programmes and local symptomatic FIT testing

High reagent load capacity



Coloured function racks for hands free operation

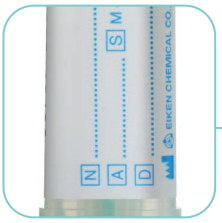


Random access allows the PLEDIA to handle up to 320 tests/hour

OC-SENSOR™

Sample Collection Device

The only FIT device to feature an intergrated filter. This filtered solution prevents the inflow of particulate matter into the analyser, minimising machine maintenance. Sedimentation is not needed so on receipt to the lab the device is ready to test.



Flat surface for easy patient labelling and application of laboratory barcodes.

A hollow lid, along with an integrated scraper and internal hollow chamber captures excess stool while delivering precise quantities of stool into the buffer solution.

Analyser pierces foils and squeezes buffered sample into the collection portion of the device, where an aliquot is taken for testing. Any remaining solution flows back through the filter leaving a dry device that is spill proof once analysed and ready for retesting.

Twist and push to close device with an audible click, proven to be simple and easy to use.

Screw thread wand to scrape along the stool surface for collection where blood is most likely to be found as the stool passes through the bowel.

Double walled clear plastic design for robust transportation and easy sample viewing.

Narrow device collar to discourage overloading of devices when sampling.

The little green bottle that makes a big difference

With over 120 million used globally each year, OC-Sensor™ sample collection bottles are a proven solution for simple, hygienic stool collection.

Patients collect the stool directly into the OC-Auto 3 Sample collection bottle in the comfort of their own home, immediately stabilising the stool ready for analysis in the laboratory.

This single bowel testing kit for FIT and/or Calprotectin supports patient pathway development and benefits laboratories through primary tube sampling, ensuring no unpleasant extraction.