



FI-620

Fluorescent Immunoassay Analyzer

P

Point-of-Care
Testing (POCT)



High performance
and reliability

LIS

LIS compatible

HD

7-inch HD LCD
touchscreen

Intended Use

The fluorescent immunochromatographic analysis technology is used in combination with fluorescent immunochromatographic reagents labeled with fluorescent microspheres produced by KEYU, for the *in vitro* quantitative detection of target analytes in human samples.

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Detection Principle

Fluorescence immunochromatographic analysis uses fluorescent microspheres as tracers to label antigens or antibodies. After reacting with the sample, the fluorescence intensity of the final conjugate reflects the analyte concentration. When the reagent card is inserted into the analyzer, the sensor converts the fluorescence signal into a photoelectric signal, which is then analyzed through a calibration curve to obtain the quantitative result.

Product Specifications and Performance

Test Item	Model	Specification	Working Range	Limit of Detection	Test Time
Fecal Occult Blood	FOB-F-I	25 tests/kit	20-2000 ng/mL	7 ng/mL	15 min
Fecal Calprotectin	FC-F-I	25 tests/kit	35-2100 µg/g	15 µg/g	15 min
H.Pylori	HP-F-I	25 tests/kit	0.5-500 ng/mL	0.4 ng/mL	15 min
Pancreatic Elastase 1	FE-F-I	25 tests/kit	In progress	In progress	15 min

Linearity

- 1 Fecal Occult Blood: The correlation coefficient ($|r|$) should be ≥ 0.9900 within the range of 20-2000 ng/mL.
- 2 Fecal Calprotectin: The correlation coefficient ($|r|$) should be ≥ 0.9900 within the range of 35-2100 µg/g.
- 3 H.Pylori: The correlation coefficient ($|r|$) should be ≥ 0.9900 within the range of 0.5-500 ng/mL.

Storage and Shelf Life

- 1 Valid for 12 months if sealed and stored in a cool and dry place at 2-30°C. Keep away from direct sunlight.
- 2 After the test cassette is taken out of the pouch, it should be used within 1 hour. If not, reseal it tightly in the pouch and use it within 3 days.

Quality Control Specifications

Test Item	Model	Specification	Remarks	Storage and Shelf Life
Hemoglobin Quality Control (Quantitative)	FOB-QC-4	60 bottles/box	For 60 times	Store at 2-8°C, with a shelf life of 12 months.
Calprotectin Quality Control (Quantitative)	FC-QC-4	20 bottles/box	For 60 times	

KEYU

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