

# CLIA Integral Solution

Diagnostic of infectious diseases



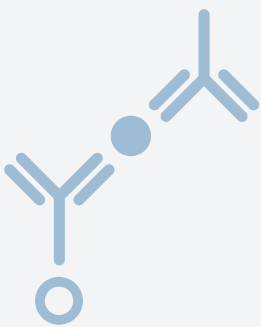
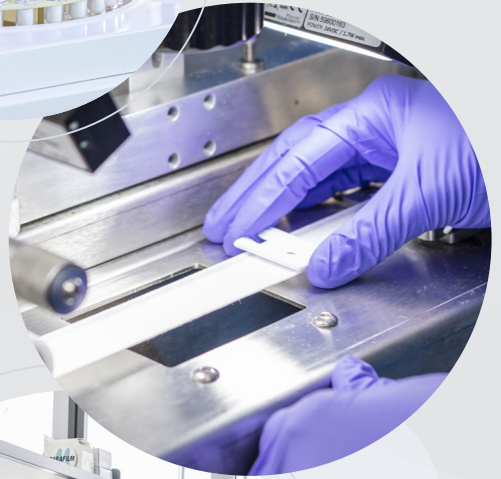
Certest Immunodiagnostic is committed to providing a comprehensive portfolio of diagnostic reagents for detecting infectious diseases and different markers, covering different needs of formats, types of use, throughput, precision, and time from sample to result.

### IMMUNOCHROMATOGRAPHY

provides rapid test solutions for aiding the professional of diagnostic with an immediate solution, needing no equipment, and having results usually in less than 15 minutes.

**TURBIDIMETRY** provides diagnostics solutions for automated and quantitative results and higher throughputs.

**CLIA** provides a high sensitivity, automated diagnostic solution based on the chemiluminescent amplification of an immunocapture.



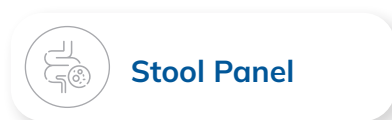
## CLIA

### Chemiluminescence Magnetic Particles Integral Solution

CLIA is the most sensitive and accurate immunodiagnostic technique, capable of performing readings with very low concentrations of analyte.

Designed for the **diagnostics of infectious diseases** in human samples. Specialists in gastrointestinal infections.

## Our panels



### Stool Panel

Helicobacter Pylori antigen

Campylobacter antigen

Clostridium difficile GDH antigen

Adenovirus antigen

Calprotectin antigen

## Stool specimen collection and preparation



- 1.** Take the sample dilution vial. Remove the stick by turning the thread of the white cap in the opposite direction.
- 2.** Introduce the stick in up to 4 different points of the sample.
- 3.** Shake the sample dilution vial, which contains diluent and sample, in order to obtain a good dispersion. Use a vortex until a maximum of 120 seconds. Once the sample is dissolved, centrifuge the tube between 1,000-3,000 rpm for 1 minute to deposit the particulate matter at the bottom.
- 4.** Remove the white cap and the green spacer, turning in the opposite direction.
- 5.** Introduce the sample vials into the analysis equipment.

\*(Images corresponding to the instruction for use of reference VFE-002)

# CLIA Integral Solution



Magnetic particles technology was applied in chemiluminescence assays during the last decade. In vitro diagnostic asks for more sensitivity, specificity, and reliability. Precise and reproducible washes using paramagnetic capacity of our particles, provides valuable results.

CLIA particles gather the advantages of this technology, and our expertise in the diagnostics of infectious diseases.



## Stool Panel

### Helicobacter Pylori antigen

Reference	Product name	Reference method
PYL001	H. pylori Ag 001; 200 determinations	Sensitivity: 95.0%; Specificity: 98.3% Reference technique: CLIA
PYLCal	H. pylori Ag Calibration set; one point	
VFE-002	H. pylori Faecal Sample Vials kit; 100 vials	

### Campylobacter antigen

Reference	Product name	Reference method
CAM001	Campylobacter Ag 001; 200 determinations	Sensitivity: 100.0%; specificity 93.0% Reference technique: CLIA
CAMCal	Campylobacter Ag Calibration set; one point	
VFE-001	Universal Faecal Sample Vials kit; 100 vials	

## Adenovirus antigen

Reference	Product name	Reference method
ADV001	Adenovirus Ag 001; 200 determinations	Sensitivity: 100.0%; Specificity: 100.0% Reference technique: Immunoassay
ADVCal	Adenovirus Ag Calibration set; one point	
VFE-001	Universal Faecal Sample Vials kit; 100 vials	

## Clostridium antigen

Reference	Product name	Reference method
CDG001	Clostridium difficile GDH Ag 001; 200 determinations	Sensitivity: 100.0%; Specificity: 94.3% Reference technique: CLIA
CDGCal	Clostridium difficile GDH Ag Calibration set; one point	
VFE-001	Universal Faecal Sample Vials kit; 100 vials	

## Calprotectin antigen

Reference	Product name	Reference method
CLP001	Calprotectin Ag Quantitative 001; 200 determinations	Sensitivity: 95.0%; Specificity: 98.3% Reference technique: CLIA
CLPCal	Calprotectin Ag Calibration set; six points	
VFE-001	Universal Faecal Sample Vials kit; 100 vials	



### CLIA Integral Solution offers:

- **Stool panel for infectious diseases diagnostics**
- **Ready to use reagents, minimum handling needed**
- **Batch and random sample access available**

## CLIA Integral Solution. Magnetic particles analysers.

Stool panel for infectious diseases.



CL-007



CL-008

### Technical Specification

Overview	CL-007	CL-008
Principle	Direct CLIA	Direct CLIA
Throughput	60 test/hour	200 test/hour
Time to First Result	≤ 30 min	≤ 30 min
LIS connection	Bidirectional	Bidirectional
Assay Cup Loading	200 cups, continuous loading and offloading	500 cups, continuous loading and offloading
Substrate Loading	2 bottles	2 bottles
Solid Waste	Up to 350 assay cups	Up to 500 assay cups
Liquid Waste	20 L container	20 L container
Physical information	CL-007	CL-008
Construction	Desktop	Desktop
Weight	< 60 kg	< 150 kg
Dimension	433 (L) x 679 (W) x 638 (H)	1000 (L) x 670 (W) x 640 (H)

Sample Assembly	CL-007	CL-008
Sample feeder	Inner reagent disk	By sample racks
Sample capacity	30	60
Sample type	Serum, stool, respiratory	Serum, stool, respiratory
Sample probe	Single steel probe for both sample & reagents	Single steel probe for both sample & reagents
Probe detection	Clot, bubble & liquid detection	Clot, bubble & liquid detection
Sample tube	Optional	Optional
Barcode reading	External	Internal or external (accessory needed)
Random access	No	Yes

Reagent Assembly	CL-007	CL-008
Reagent feeder	Inner reagent disk	Inner reagent disk
Reagent capacity	10	25
Cooling system	2-8°C	2-8°C
Reagent mixing	Non-touch rotary mixing for magnetic particles	Non-touch rotary mixing for magnetic particles
Reagent type	100% ready-to-use liquid reagents	100% ready-to-use liquid reagents
Calibration mode	Optional	Optional

## Ordering information

Reference	Product name
S-CUPS	Assay cup (1000UD)
S1-WTANK	Waste tank (1UD), for Shine i1910 (i1910)
S2-WTANK	Waste tank (1UD), for Shine i2910 (i2910)
FA001-100mL	Pretrigger A (100mL)
FB001-100mL	Trigger B (100 mL)
WASH-003-500mL	Wash buffer 20x (500mL)
S1-COVER	Cover for Shine i1910
S-ADAPTORS	Vial adaptor for Shines

## High Quality reagents for human infectious diseases.

CLIA Integral Solution is the new line of Certest Immunodiagnostic division. Adaptable to small spaces with big needs, our Integral Solution brings the access of infectious diseases diagnostic everywhere.

**certest**  
IMMUNODIAGNOSTIC

**Certest Biotec, S.L.**

Pol. Industrial Río Gállego II · Calle J, N°1  
50840, San Mateo de Gállego, Zaragoza (Spain)  
Tel. (+34) 976 520 354  
salesidx@certest.es · www.certest.es



Certest CLIA/GEN-1224EN

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