

CLIA Immunodiagnostic





**Maximum sensitivity
and specificity**
for highly accurate
results



Advanced technology
with **high-throughput
automated
detection**



Excellent precision
even at **very low
analyte
concentrations**



Optimized for
laboratories requiring
**reliability in
advanced
diagnostics**

CLIA



Chemiluminescence Magnetic Particles Integral Solution

In vitro diagnostic asks for more
sensitivity, specificity and reliability.

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

Designed for assays requiring **high
sensitivity**, such as the diagnosis
of infectious diseases in faecal
samples.

CLIA Integral Solution offers:

- ✓ Detection of antigens in faecal and urine samples.
- ✓ Ready to use reagents, minimum handling needed.
- ✓ Batch and random sample access available.



Detection of antigens



Helicobacter pylori

Campylobacter

Adenovirus

Rotavirus IVDR

Clostridium difficile GDH

Clostridium difficile Toxin A/B IVDR

Calprotectin

Entamoeba RUO

Crypto RUO

Giardia RUO

Norovirus GI RUO

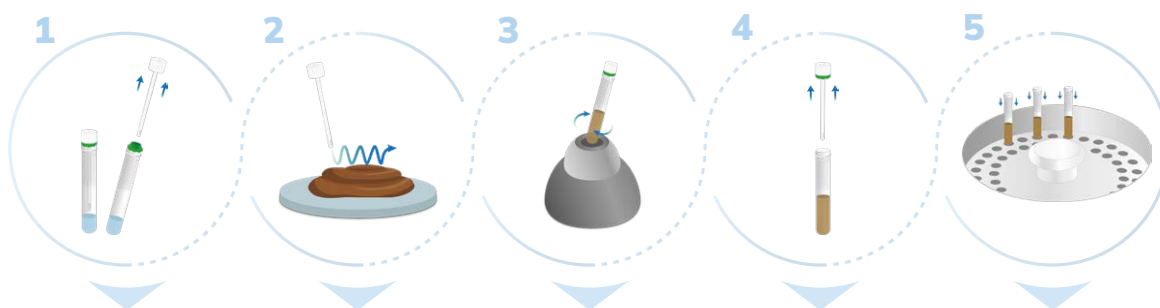
Norovirus GII RUO



S. pneumoniae RUO

Legionella RUO

Faecal specimen collection and preparation



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

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**. Fully insert the stick with faecal material into the vial through the separator.
3. Shake the sample dilution vial in order to obtain a good dispersion. **Use a vortex until a maximum of 120 seconds**. Centrifuge the tube at **1,000-3,000 x g** for **10 minutes** 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**.



Antigens in faecal samples

HELICOBACTER PYLORI

Reference	Product name	Technical information
PYL000	<i>Helicobacter pylori</i> Ag (100 determinations)	Sensitivity: 93.7% (89.5 - 96.6%) Specificity: 96.5% (94.6 - 97.9%)
PYL001	<i>Helicobacter pylori</i> Ag (200 determinations)	
PYLCal	<i>Helicobacter pylori</i> Ag Calibration set (one point)	
VFE-002	<i>Helicobacter pylori</i> Faecal Sample Vials kit (100 vials)	

CAMPYLOBACTER

Reference	Product name	Technical information
CAM000	<i>Campylobacter</i> Ag (100 determinations)	Sensitivity: 97.7% (92.0 - 99.7%) Specificity 99.1% (94.9 - 100.0%)
CAM001	<i>Campylobacter</i> Ag (200 determinations)	
CAMCal	<i>Campylobacter</i> Ag Calibration set (one point)	

ADENOVIRUS

Reference	Product name	Technical information
ADV000	Adenovirus Ag (100 determinations)	Sensitivity: 100.0% (97.2 - 100.0%) Specificity: 100.0% (92.9 - 99.0%)
ADV001	Adenovirus Ag (200 determinations)	
ADVCal	Adenovirus Ag Calibration set (one point)	

ROTAVIRUS

Reference	Product name	Technical information
CL-RTV000	Rotavirus Ag (100 determinations)	Sensitivity: 98.9% (93.8 - 100.0%) Specificity: 95.2% (89.2 - 98.4%)
CL-RTV001	Rotavirus Ag (200 determinations)	

CLOSTRIDIUM DIFFICILE

Reference	Product name	Technical information
CDG000	<i>Clostridium difficile</i> GDH Ag (100 determinations)	Sensitivity: 97.4% (93.5 - 99.3%) Specificity: 96.4% (93.1 - 98.4%)
CDG001	<i>Clostridium difficile</i> GDH Ag (200 determinations)	
CDGCal	<i>Clostridium difficile</i> GDH Ag Calibration set (one point)	

CLOSTRIDIUM DIFFICILE TOXIN A/B

Reference	Product name	Technical information
CL-CDX000	<i>Clostridium difficile</i> Toxin A/B Ag (100 determinations)	Sensitivity: 95.6% (90.1 - 98.6%) Specificity: 95.4% (91.4 - 97.9%)
CL-CDX001	<i>Clostridium difficile</i> Toxin A/B Ag (200 determinations)	

CALPROTECTIN

Reference	Product name	Technical information
CL-CLP000	Calprotectin Ag Quantitative (100 determinations)	Sensitivity: 96.0% (86.3 - 99.5%) Specificity: 93.3% (83.8 - 98.2%)
CL-CLP001	Calprotectin Ag Quantitative (200 determinations)	
CLPCal	Calprotectin Ag Calibration set (six points)	

ENTAMOEBA NEW RUO

Reference	Product name
CL-ENT000RUO	Entamoeba Ag (100 determinations)
CL-ENT001RUO	Entamoeba Ag (200 determinations)

CRYPTOSPORIDIUM NEW RUO

Reference	Product name
CL-CRY000RUO	Crypto Ag (100 determinations)
CL-CRY001RUO	Crypto Ag (200 determinations)

GIARDIA NEW RUO

Reference	Product name
CL-GIA000RUO	Giardia Ag (100 determinations)
CL-GIA001RUO	Giardia Ag (200 determinations)

NOROVIRUS GI NEW RUO

Reference	Product name
CL-NGV000RUO	Norovirus GI Ag (100 determinations)
CL-NGV001RUO	Norovirus GI Ag (200 determinations)

NOROVIRUS GII NEW RUO

Reference	Product name
CL-NPV000RUO	Norovirus GII Ag (100 determinations)
CL-NPV001RUO	Norovirus GII Ag (200 determinations)



Antigens in urine samples

S. PNEUMONIAE NEW RUO

Reference	Product name
CL-SPN000RUO	<i>S. pneumoniae</i> Ag (100 determinations)
CL-SPN001RUO	<i>S. pneumoniae</i> Ag (200 determinations)

LEGIONELLA NEW RUO

Reference	Product name
CL-LPN000RUO	<i>Legionella</i> Ag (100 determinations)
CL-LPN001RUO	<i>Legionella</i> Ag (200 determinations)



Universal vials kits

Reference	Product name
VFE-001	Universal Faecal Sample Vials kit (100 vials)
VUR-001.RUO	Universal Urine Sample Vials kit (100 vials)

CLIA Integral Solution. Magnetic particles analysers.



CL-007



CL-008

Technical Specification

Overview	CL-007	CL-008
Model	Shine i1910 (i1910)	Shine i2910 (i2910)
Principle	CLIA Flash	CLIA Flash
Throughput	80 test/hour	160 test/hour
Time to First Result	≤ 30 min	≤ 30 min
LIS connection	Bidirectional	Bidirectional
Urgent samples	✓	✓
Assay Cup Loading	200 cups, continuous loading	500 cups, continuous loading
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
Touch screen	LED	LED
Weight	< 60 kg	< 150 kg
Dimension	433 (L) x 679 (W) x 638 (H)	1000 (L) x 670 (W) x 640 (H)

Sample specifications	CL-007	CL-008
Feeder	Inner reagent disk	By sample racks
Capacity	30	60
Continuous loading	✓	✓
Random access	✗	✓
Type	Serum, stool, respiratory	Serum, stool, respiratory
Probe	Exclusively for samples and reagents	Exclusively for samples and reagents
Probe detection	Clot, bubble & liquid detection	Clot, bubble & liquid detection
Sample tube	Optional	Optional
Barcode reading	External	Internal and external

Reagent specifications	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
Calibration mode	Optional	Optional

Ordering Information: Reagents, Consumables and Accessories

Type	Reference	Product
Reagent	START002	Starting Kit
	FA001-100mL	Pre-trigger A (100mL)
	FB001-100mL	Trigger B (100 mL)
	WASH-003-500mL	Wash buffer 20x (500mL)
	CLEAN001	Daily probe cleaning solution
Consumable	S-CUPS	Assay cup (1000 pcs)
	S1-WTANK	Waste tank (1 pc), for Shine i1910 (i1910)
	S2-WTANK	Waste tank (1 pc), for Shine i2910 (i2910)
	S-ADAPTORS	Vial adaptor for Shine Equipments
Accessory	S1-COVER	Cover for Shine i1910

Powering precision immuno- diagnostics

Maximum sensitivity
& specificity

High-throughput
automation

Excellent low-level
precision

Reliable advanced
diagnostics

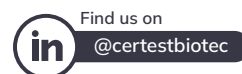
From Discovery
to Delivery,
Biotech you
can trust.



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CLIA/GEN-0726EN

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