

Serazym[®] Norovirus

Enzyme immunoassay for the qualitative detection of capsid protein (VP1) of human pathogenic noroviruses of genogroups GI and GII in stool samples of human origin

REF	E-061		96
IVD	In-vitro-diagnostic medical device		CE

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In-vitro diagnostic medical device	Unique device identifier	Manufacturer
Country of manufacture and date of manufacture	Article number	Serial number
Keep away from sunlight	Humidity limitation	Batch code
Consult instructions for use	Temperature limit	Do not reuse
Sufficient for <i>n</i> tests	Biohazard	Use-by date
		Attention

Intended Use

Serazym® Norovirus is an IVD test for the qualitative determination of capsid protein (VP1) of human-pathogenic noroviruses of genogroups GI and GII in stool samples of human origin through manual or semi-automatic processing by a laboratory professional user.

It is intended to aid in the diagnosis of norovirus-associated gastroenteritis in samples from patients with symptoms of gastroenteritis.

Principle of the Test

Serazym® Norovirus is an enzyme immunoassay based on polyclonal antibodies against norovirus capsid protein VP1 of genotypes GI and GII. Diluted, untreated stool samples as well as negative and positive controls are added into wells of the microtiter plate coated with polyclonal anti-norovirus antibodies. After incubation, the unbound components are removed by a washing step and peroxidase (HRP)-labeled polyclonal anti-Norovirus antibodies are dispensed into the wells. After incubation and a washing step, HRP converts the colorless substrate solution to a blue reaction product in the following enzymatic reaction step. The reaction is stopped by addition of the stop solution, resulting in a color change from blue to yellow. The optical density (OD) of the reaction product, measured at 450 nm measuring and ≥ 620 nm reference filter, respectively, is directly proportional to the concentration of the specifically bound norovirus antigen.

Test Components (Delivery Scope)

		For 96 wells	
1	WELLS	Microtiter plate coated with < 15 µg/mL polyclonal anti-norovirus antibodies (sheep)	12 single breakable 8-well strips, silver color marking, vacuum-sealed with desiccant
2	WASHBUF (10x)	Wash buffer (10x) Seramun® Wash buffer A TRIS-based buffer	100 mL concentrate for 1000 mL solution, colorless white cap
3	DIL	Sample diluent Seramun® Sample diluent A Phosphate-based buffer	100 mL, ready to use, colored yellow, black cap
4	CONTROL +	Positive control < 1 µg/mL recombinant norovirus antigen	2.0 mL, ready to use, colored blue, red cap
5	CONTROL -	Negative control TRIS-based buffer	2.0 mL, ready to use, colored blue, green cap
6	CONJ HRP	HRP conjugate < 5 µg/mL HRP-labeled polyclonal anti-norovirus antibodies (sheep)	15 mL, ready to use, colored green, green cap
7	SUBSTR	Substrate SeramunBlau® automat fast < 0.1 % 3,3',5,5'-tetramethylbenzidine; < 0.05 % hydrogen peroxide	15 mL, ready to use, colorless, blue cap
8	STOP	Stop solution SeramunBlau® stop 0.25 M sulphuric acid	15 mL, ready to use, colorless, yellow cap
9		Certificate of Analysis	1 piece
10		Instructions for Use	1 piece

Additional Materials and Aids Required for the Test Procedure

Adjustable single-channel micropipette • 8-channel micropipette or multi-channel micropipette with pipette tips • reagent container for multi-channel micropipettes • 8-channel wash comb with vacuum pump and waste bottle or microtiter plate washer • microtiter plate reader with 450 nm measuring filter and ≥ 620 nm reference filter • deionized water • measuring cylinder • tubes for sample preparation

Important Information



This device is for *in-vitro* diagnostic use only. Follow the instructions carefully. The kit may be used by health professionals only.

Do not use reagents from damaged packages or bottles. The shelf life specified must be observed. Do not mix components with reagents from other manufacturers.

Mixing of test kit components of different lots is permitted only for wash buffer (10x), sample diluent, negative control, substrate and stop solution.

Wash buffer (10x), Sample diluent, negative control, substrate and stop solution are universally applicable for Serazym® stool ELISA Adenovirus (E-017), Astrovirus (E-045), Norovirus (E-061), Rotavirus (E-020), Campylobacter (E-093), Clostridium difficile GDH (E-107), Clostridium difficile Toxin A+B (E-040), Cryptosporidium parvum (E-039), Entamoeba histolytica (E-018), Giardia (E-106) and H. pylori 2nd Gen. (E-114).

All serious incidents occurring in relation with Serazym® Norovirus must be reported to the manufacturer and the competent authority of the EU member state in which user and/or patient are located.

Information on Assay Procedure

All reagents should be stored at 2...8 °C. Bring all test components to room temperature before use. Reagents that appear contaminated should not be used.

Each well of a microtiter plate can be used once only. Each sample and control have to be pipetted with a new pipette tip. Positive and negative control are ready to use.


For larger sample series, pipetting reagents from liquid reservoirs using a multichannel micropipette is recommended to avoid time delays and contaminations. Follow the pipetting scheme and time schedules of the protocol.

The aspiration and washing steps can be performed manually or with the help of a microplate washer or waterjet pump. Allow the wash buffer to remain in the wells for at least 5 seconds per wash cycle. Remove wash buffer residues by thoroughly aspirating or tapping out the wells!
Protect the substrate from light!

Safety Instructions

Reagents must not be swallowed. Contact with skin or mucous membranes should be avoided. Handle all components and patient samples as potentially hazardous and infectious. Additional information may be taken from the Material Safety Data Sheet.

Product contains the following hazardous component/-s:

Test component	Hazard labeling and supplementary information on ingredients
WELLS	Contains material of animal origin.
WASHBUF (10x)	EUH208: Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction. EUH210: Safety data sheet available on request. Preservatives: < 0.0015 % reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1); < 0.1 % 5-bromo-5-nitro-1,3-dioxane
DIL	Contains material of animal origin. Preservatives: < 0.1 % sodium azide
CONTROL +	Contains material of microbial and animal origin. Preservatives: < 0.1 % sodium azide
CONTROL -	Contains material of animal origin. Preservatives: < 0.01 % sodium azide
CONJ HRP	EUH210: Safety data sheet available on request. Contains material of animal origin. Preservative: < 0.01 % 5-bromo-5-nitro-1,3-dioxane
SUBSTR	Hazard component: 2-Pyrrolidone Signal word: Danger  H360: May damage fertility or the unborn child. P201: Obtain special instructions before use. P280: Wear protective gloves/protective clothing/eye protection/face protection. P308+P313: IF exposed or concerned: Get medical advice/attention. Restricted to professional users. Preservatives: < 0.00015 % reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
STOP	-

Limitations of the Procedure

The qualitative enzyme immunological detection of norovirus antigens in stool samples does not allow correlation between the measured OD and the severity of infection. Also, it is not allowed to correlate absorbances of samples with the absorbance of the positive control.

Cross contamination of reagents and samples may result in false positive results. Incorrect dilutions, insufficiently homogenized samples, and particles not sedimented by centrifugation may cause false positive as well as false negative test results. A negative test result obtained with Serazym® Norovirus does not exclude an infection. False negative tests may result from improper timing of sample collection or inhomogeneous antigen distribution in the sample. The overall interpretation of the ELISA test result should consider the full clinical picture. Individual cases may require retesting at intervals of several weeks.

Sample Treatment

Sample Collection

Collect stool sample in suitable sampling container.

Example: Feces tube, with spoon, screw cap, (LxØ): 107 x 25 mm, transparent

Sample Shelf Life and Storage

Stool samples should be stored at 2...8 °C immediately after collection and examined within 72 h or stored frozen at -20 °C. Repeated (> 3x) freezing and thawing of samples should be avoided due to the risk of incorrect results. Stool samples that have already been diluted in Seramun® Sample diluent A according to the instructions for use can be stored at 2...8 °C for up to 72 h and subsequently analyzed by ELISA.

Sample Preparation

Mix untreated stool samples well and dilute 1 : 6 with sample buffer.

Example: Pipette 500 µL sample buffer into a reaction tube. For solid or semi-solid stool samples transfer 100 mg (approx. 2 – 3 mm diameter) with a disposable stick, for liquid stool samples transfer 100 µL into the sample buffer and mix thoroughly. If necessary, sediment suspended particles by centrifugation in a microcentrifuge for 1 min at maximum speed.

Reagent Treatment

Reagent Shelf Life and Storage

The complete test kit with sealed reagent bottles and microtitration strips can be stored at 2...8 °C until the printed expiration date. All opened test kit components are stable for up to 2 months when stored properly at 2...8 °C. The diluted wash buffer can be stored at 2...8 °C for up to 1 month.

Reagent Preparation

Microtiter plate with breakable 8-well strips vacuum sealed with desiccant. Allow packaging to reach room temperature before opening. Protect unused wells from moisture and store refrigerated with desiccant in the original bag carefully resealed. Dilute wash buffer (10x) 1 : 10 with deionized water.

Example: 10 mL wash buffer (10x) + 90 mL deionized water.

Assay Procedure

1. Allow test reagents and required number of wells to reach room temperature (RT). Shake reagents gently before use. Avoid foaming.
2. Pipette 100 μL **CONTROL +** Positive control
100 μL **CONTROL -** Negative control
100 μL **diluted stool specimen** each.
3. Cover the plate and incubate for 60 min at RT.
4. Decant, then wash each well 5x with 300 μL diluted wash buffer. Tap dry onto absorbent paper if necessary.
5. Add 100 μL **CONJ HRP** HRP conjugate per well.
6. Cover plate and incubate for 30 min at RT.
7. Decant, then wash each well 5x with 300 μL diluted wash buffer. Tap the plate dry on absorbent paper if necessary.
8. Add 100 μL **SUBSTR** substrate per well.
9. Incubate for 10 min at RT **protected from light**.
10. Add 100 μL **STOP** stop solution per well, mix gently.
11. Read OD at 450 nm and ≥ 620 nm with a microplate reader within 30 min following reaction stop.

Evaluation of Results

Qualitative Evaluation

Cut-off determination: OD negative control + 0.10

Samples showing OD values equal to or higher than the cut-off are considered positive, samples with OD values below cut-off are considered negative for norovirus antigens.

The test run is valid, if:

- the mean OD value of the negative control is ≤ 0.20 (manual processing)
 ≤ 0.30 (automatic processing)
- the mean OD value of the positive control is ≥ 1.20

If one of the above-mentioned quality criteria is not met, test should be repeated strictly following the test procedure (incubation times and temperatures, sample and wash buffer dilution, wash steps, etc.). In case of repeated failure of the quality criteria contact the manufacturer.

Interpretation of Results

Positive	\geq cut-off
Negative	$<$ cut-off

It is recommended that each laboratory establishes its own normal and pathological reference ranges.

Performance Characteristics

Precision

To determine precision, 4 samples were measured multiple times. For the determination of the intra-assay coefficient of variation (CV), the samples were measured in an 8-fold determination in one test run. The determination of the inter-assay coefficient of variation was done by an 8-fold determination on 2 days in six different test runs.

Sample	Intra-assay coefficient of variation		Inter-assay coefficient of variation	
	\bar{x} OD	CV (%)	\bar{x} OD	CV (%)
1	2.132	2.0	1.924	7.6
2	0.902	3.9	0.813	3.2
3	0.534	3.3	0.562	3.7
4	0.217	5.9	0.247	2.8

Detection Limit

The lower detection limit of the Serazym® Norovirus has been determined at < 10 ng/mL capsid protein for genogroups I and II.

Sensitivity and Specificity

Sensitivity and specificity of Serazym® Norovirus have been determined in a retrospective study with 159 stool specimens in comparison to a commercially available ELISA.

	ELISA positive	ELISA negative
Serazym® ELISA positive	111	3
Serazym® ELISA negative	6	39

Sensitivity: 94.9 %

Specificity: 92.9 %

Cross reactivity

Stool samples positive for one of the following pathogens did not show any cross reaction with Serazym® Norovirus:

Adenovirus, astrovirus, rotavirus, *Clostridium difficile*, *Campylobacter jejuni*, *Helicobacter pylori*, *Giardia lamblia*, *Cryptosporidium parvum*, *Entamoeba histolytica* / *dispar*.

Negative stool suspensions were spiked with the following microorganisms with a bacterial count of $\geq 10^6$ colony-forming units per mL in sample buffer and tested negative in the Serazym® Norovirus (450 nm measurement and ≥ 620 nm reference filter < cut-off):

Adenovirus	Typ 41
<i>Aeromonas hydrophila</i>	ATCC 7966
Astrovirus	serotype 4
<i>Bacillus cereus</i>	ATCC 117788
<i>Bacillus subtilis</i>	ATCC 6633
<i>Bacteroides fragilis</i>	ATCC 25285
<i>Campylobacter jejuni</i>	ATCC 33291
<i>Candida albicans</i>	clinical isolate
<i>Citrobacter freundii</i>	ATCC 8090
<i>Clostridium sordelli</i>	ATCC 9714
<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Enterobacter cloacae</i>	ATCC 13047
<i>Enterococcus faecalis</i>	ATCC 29212
<i>Escherichia coli</i>	ATCC 25922
<i>Klebsiella pneumonia</i>	ATCC 13883

<i>Peptostreptococcus anaerobius</i>	ATCC 27337
<i>Proteus vulgaris</i>	ATCC 8427
<i>Pseudomonas aeruginosa</i>	ATCC 10145
Rotavirus	strain SA11
<i>Salmonella enterica</i> Serovar typhimurium	ATCC 14028
<i>Salmonella enterica</i> Serovar enteritidis	ATCC 13076
<i>Shigella flexneri</i>	ATCC 12022
<i>Shigella sonnei</i>	ATCC 25931
<i>Staphylococcus aureus</i>	ATCC 25923
<i>Staphylococcus epidermidis</i>	ATCC 12228
<i>Vibrio cholerae</i>	RV 2011/ST5
<i>Vibrio parahaemolyticus</i>	ATCC 17802
<i>Yersinia enterocolitica</i> O:9	clinical isolate
<i>Yersinia enterocolitica</i> O:3	clinical isolate

Interference

None of the following substances in the indicated concentrations added to norovirus positive and negative stool samples did show a significant impact on the test result:

Barium sulfate (5 %), Buscopan® (2 mg/mL), Cyclamate (5 %), Diclofenac (2 mg / mL), human hemoglobin (5 mg/mL), human blood (5 %), Hylak® N (5 %), Iberogast® (5 %), Imodium® akut duo (0.2/12.5 mg/mL), Loperamide (0.2 mg/mL), Metronidazole (2 mg/mL), Mucin (5 mg/mL), Nexium® (2 mg/mL), palmitic acid (20 %), Pentofuryl® (2 mg/mL), Pepto-Bismol (1 mg/mL), Perenterol (2.5 mg/mL), Rennie® (8 mg/mL), Simage® (2 mg/mL), stearic acid (20 %), Vancomycin (2 mg/mL).

Application

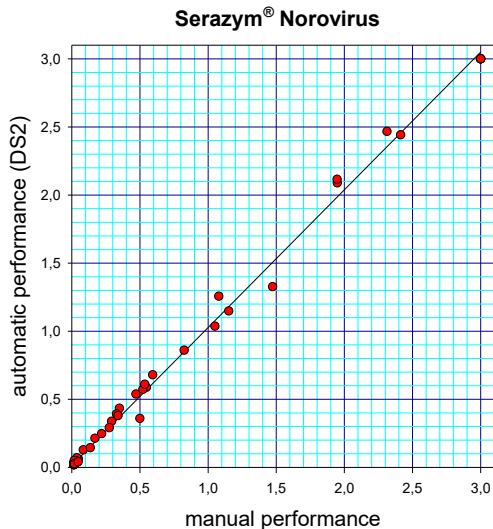
Automatic processing

The operator is responsible for the validation of the microtiter plate processors and associated application files before using this product. Application files for the use of the automated microtiter plate processors listed below may be requested from your local distributor.

Performing Serazym® Norovirus on fully automated microplate processors (e.g. DS2®, DSX®, Dynex Technologies) may cause elevated absorbance values in comparison to the manual procedure caused by differences in the wash procedures and technical specifications of the equipment. In these cases, a maximum value of OD = 0.3 is permissible for the negative control. It is recommended to program a wash protocol with at least 10 s soak time per strip and wash step. A final wash step with deionized water and a soak time of 10 s is recommended after each wash cycle. If necessary, the number of washing steps may be increased to 7x or 8x.

Correlation: manual – automatic processing

A panel of 90 stool specimens was processed manually and automatically in parallel (DS2®, Dynex Technologies). The correlation coefficient was calculated at $r = 0.999$.



Change History

Version	Section	Modifications
2026-04	Cover sheet	Adjustment of REF number to packaging concept
	Test Components (Delivery Scope)	Adjustment of volumes to packaging concept, addition of quantity or concentration of the active ingredient
	Additional Materials and Aids Required for the Test Procedure	Addition of "reagent container for multi-channel micropipettes"
	Important information	Addition of negative control as a component across lots and products; Table under "Safety instructions": Adjustment to the labeling on the label
	Sample Treatment	Addition of sample vessel example
	Assay Procedure	Adaptation to packaging concept
2026-05	Application: Automatic Processing	Addition of user responsibility for the validation of microtiter plate processors