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Enzyme immunoassay for the qualitative detection of hexon protein of human-pathogenic adenoviruses in stool samples of human origin

<b>REF</b>	E-017		96
<b>IVD</b>	In-vitro-diagnostic medical device		



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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® Adenovirus is an IVD test for the qualitative determination of hexon protein of human-pathogenic adenoviruses 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 an adenovirus-associated gastroenteritis in samples of patients with symptoms of gastroenteritis.

## Principle of the Test

Serazym® Adenovirus is an enzyme immunoassay based on monoclonal antibodies against an epitope of the capsid protein hexon, common to all human-pathogenic adenovirus serotypes. Diluted, untreated stool samples as well as negative and positive controls are dispensed simultaneously with peroxidase (HRP)-labeled monoclonal anti-adenovirus antibodies into the wells of the microtiter plate coated with monoclonal anti-adenovirus antibodies. After incubation, unbound components are removed by a washing step, then HRP converts the colorless substrate solution to a blue reaction product in the following enzymatic reaction step. After incubation 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 filter and  $\geq 620$  nm reference filter is directly proportional to the concentration of specifically bound adenovirus antigens.

## Test Components (Delivery Scope)

		<b>For 96 wells</b>	
1	<b>WELLS</b>	<b>Microtiter plate</b> coated with $< 5 \mu\text{g/mL}$ monoclonal anti-adenovirus antibodies (mouse)	12 single breakable 8-well strips, violet color marking, vacuum-sealed with desiccant
2	<b>WASHBUF (10x)</b>	<b>Wash buffer (10x)</b> Seramun® Wash buffer A TRIS-based buffer	100 mL concentrate for 1000 mL solution, colorless, white cap
3	<b>DIL</b>	<b>Sample diluent</b> Seramun® Sample diluent A Phosphate-based buffer	100 mL, ready to use, colored yellow, black cap
4	<b>CONTROL +</b>	<b>Positive control</b> $< 1 \mu\text{g/mL}$ native Adenovirus- reactive sample, inactivated	2.0 mL, ready to use, colored blue, red cap
5	<b>CONTROL -</b>	<b>Negative control</b> TRIS-based buffer	2.0 mL, ready to use, colored blue, green cap
6	<b>CONJ HRP</b>	<b>HRP conjugate</b> $< 5 \mu\text{g/mL}$ HRP-labeled, monoclonal anti-adenovirus antibodies (mouse)	15 mL, ready to use, colored green, green cap
7	<b>SUBSTR</b>	<b>Substrate</b> SeramunBlau® automat fast $< 0.1 \%$ 3,3',5,5'- tetramethylbenzidine; $< 0.05 \%$ hydrogen peroxide	15 mL, ready to use, colorless, blue cap

8	<b>STOP</b>	<b>Stop solution</b> SeramunBlau® stop 0.25 M sulphuric acid	15 mL, ready to use, colorless, yellow cap
9		<b>Certificate of Analysis</b>	1 piece
10		<b>Instructions for Use</b>	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® Adenovirus 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 only be used once. Each sample and control should be pipetted with a new pipette tip. Positive and negative controls are ready to use.

For larger sample series, pipetting reagents from liquid reservoirs using a multi-channel 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 Safety Data Sheet.

Product contains the following hazardous component/-s:

Test component	Hazard labeling and supplementary information on ingredients
<b>WELLS</b>	Contains material of animal origin.
<b>WASHBUF (10x)</b>	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
<b>DIL</b>	Contains material of animal origin. Preservatives: < 0.1 % sodium azide
<b>CONTROL +</b>	Contains material of microbial and animal origin. Preservatives: < 0.1 % sodium azide
<b>CONTROL -</b>	Contains material of animal origin. Preservatives: < 0.01 % sodium azide
<b>CONJ HRP</b>	EUH210: Safety data sheet available on request. Contains material of animal origin. Preservative: < 0.01 % 5-bromo-5-nitro-1,3-dioxane
<b>SUBSTR</b>	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)
<b>STOP</b>	-

### **Limitations of the Procedure**

The qualitative enzyme immunological detection of adenovirus-specific antigens in stool samples does not allow a correlation between the measured OD and the severity of an 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 results. Incorrect dilutions, insufficiently homogenized samples, and particles not sedimented by centrifugation may cause false positive as well as false negative test results. Sample taking within the acute phase of an infection is recommended as the number of excreted particles in this phase is expected to reach its maximum. A negative test result obtained with Serazym<sup>®</sup> Adenovirus does not exclude an adenovirus 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.

## **Sample Treatment**

### **Sample Collection**

Collect stool sample in suitable sampling container.

Example: Stool collection 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<sup>®</sup> 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 is 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 75  $\mu$ L **CONJ HRP** HRP conjugate per well.
3. Add 75  $\mu$ L **CONTROL +** Positive control  
75  $\mu$ L **CONTROL -** Negative control  
50  $\mu$ L **diluted stool specimen** each and mix gently.
4. Cover the plate and incubate for 60 min at RT.
5. Decant, then wash each well 5x with 300  $\mu$ L diluted wash buffer.  
Tap the plate dry on absorbent paper if necessary.
6. Add 75  $\mu$ L **SUBSTR** substrate per well.
7. Incubate for 10 min at RT **protected from light**.
8. Add 75  $\mu$ L **STOP** stop solution per well, mix gently.
9. Read OD at 450 nm measuring filter and  $\geq$  620 nm reference filter with a microplate reader within 30 min following reaction stop.

## Evaluation of Results

### Qualitative Evaluation:

Cut-off determination: OD negative control + 0.20

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 hexon protein of human-pathogenic adenoviruses.

The test run is valid if:

- the mean OD value of the negative control is  $\leq$  0.20 (manual processing)  
 $\leq$  0.30 (automatic processing)
- the mean OD value of the positive control is  $\geq$  1.20

If the above-mentioned quality criteria are 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 stool samples were measured multiple times. For the determination of the intra-assay coefficient of variation (CV) 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 in 6 different test runs.

Sample	Intra-assay coefficient of variation		Inter-assay coefficient of variation	
	$\bar{x}$ OD	CV (%)	$\bar{x}$ OD	CV (%)
1	2.792	5.7	1.850	5.8
2	2.059	8.1	1.057	6.5
3	1.368	6.9	0.574	7.3
4	0.718	9.4	0.312	9.6

### Detection Limit

The lower detection limit of Serazym® Adenovirus has been determined by titration of purified adenovirus antigen (hexon protein) at 6 ng/mL.

### Sensitivity and Specificity

Sensitivity and specificity of Serazym® Adenovirus have been determined in a retrospective study with 330 stool specimens in comparison to a commercially available ELISA.

n = 330	ELISA positive	ELISA negative
<b>Serazym® ELISA positive</b>	55	1
<b>Serazym® ELISA negative</b>	2	272

Sensitivity: 96.5 %

Specificity: 99.6 %

## Cross Reactivity

Stool samples positive for one of the following pathogens have been tested with Serazym® Adenovirus and showed no cross reactivity:

Astrovirus, *Campylobacter coli*, *Campylobacter jejuni*, *Clostridioides difficile*, *Giardia lamblia*, norovirus, *Salmonella enteritidis* and rotavirus.

Negative stool suspensions were spiked with the following microorganisms with a bacterial count of  $\geq 10^8$  colony-forming units per mL in sample buffer and tested negative in the Serazym® Adenovirus (450 nm measuring filter and  $\geq 620$  nm reference filter < cut-off):

<i>Aeromonas hydrophila</i>	(ATCC 7966)
<i>Bacillus cereus</i>	(ATCC 11778)
<i>Bacillus subtilis</i>	(ATCC 6633)
<i>Bacteroides fragilis</i>	(ATCC 25285)
<i>Candida albicans</i>	(ATCC 10231)
<i>Campylobacter coli</i>	(ATCC 33559)
<i>Campylobacter jejuni</i>	(ATCC 33291)
<i>Citrobacter freundii</i>	(ATCC 8090)
<i>Clostridium sordellii</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 pneumoniae</i>	(ATCC 13883)
<i>Peptostreptococcus anaerobius</i>	(ATCC 27337)
<i>Proteus vulgaris</i>	(ATCC 8427)
<i>Pseudomonas aeruginosa</i>	(ATCC 10145)
<i>Salmonella enterica serovar enteritidis</i>	(ATCC 13076)
<i>Salmonella enterica serovar typhimurium</i>	(ATCC 14028)
<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 parahaemolyticus</i>	(ATCC 17802)
<i>Vibrio cholerae</i>	Clinical isolate
<i>Yersinia enterocolitica serotypes O3 and O9</i>	Clinical isolates

## Interference

None of the following substances in the indicated concentrations added to adenovirus positive and negative stool samples showed 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 (1.25 %), 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

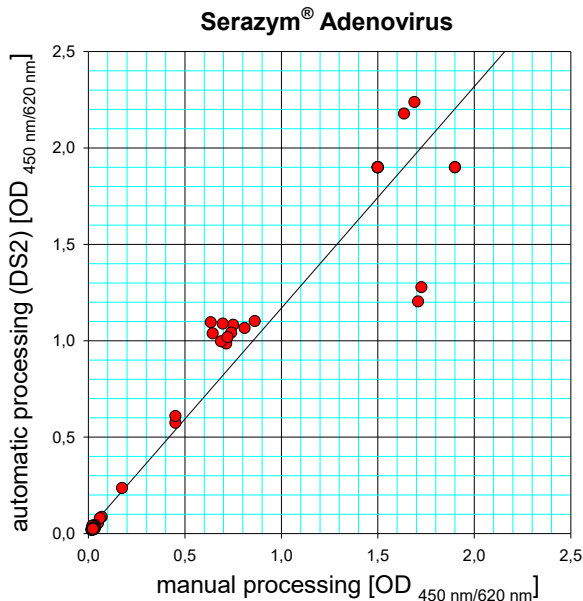
### Automatic Processing

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® Adenovirus 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 wash steps may be increased to 7x or 8x.

### Correlation: manual – automatic processing

A panel of 111 stool specimens was processed manually and automatically in parallel (DS2®, Dynex Technologies). The correlation coefficient was calculated at  $r = 0.974$ .



## Change History

<b>Version</b>	<b>Section</b>	<b>Modifications</b>
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