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# SERATEC® AmylaseTest

**REF:** AMY, AMY8, AMY/40

## Application

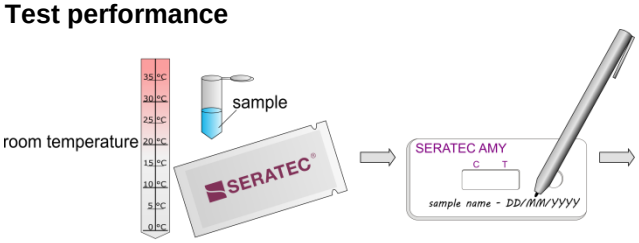
The SERATEC® AmylaseTest is a chromatographic immunoassay for rapid detection of human α-amylase to identify saliva in forensic samples. The product contains two monoclonal anti-human α-amylase antibodies as active components.

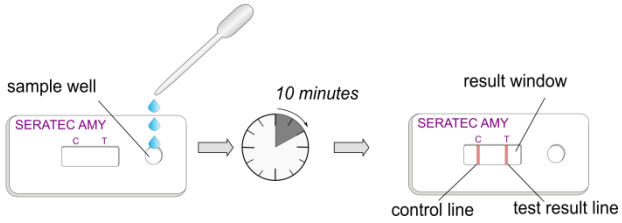
## Materials

- 8 (AMY/8) or 40 (AMY/40) individually packaged AmylaseTest in cassette format with one plastic pipette each
- 15 or 50 ml (AMY/8, AMY/40) extraction buffer
- Instructions for use

Additionally required: stopwatch or timer

## Test performance




1. Bring all test components to room temperature before performing the test. Low temperatures can lead to a decrease in sensitivity.
2. Remove the test cassette from the pouch and label it for identification.
3. Add 3 drops of the sample (approx. 120 µl) to the sample well with the enclosed plastic pipette and start the time measurement.
4. Read the test result after 10 minutes at room temperature. The liquid in the sample well should have been completely absorbed.
5. Keep the remaining sample material to perform further testing if necessary.

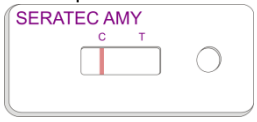
## Interpretation of results

After 10 minutes, up to two lines may be visible in the result window:

**Test result line (T):** only visible when the sample is α-amylase-positive; the colour intensity of the line may vary and depends on the α-amylase concentration of the sample.

**Control line (C):** Control for potential application errors and for the integrity of the test components. This line is always visible after successful performance of the test.

**Negative result** (human α-amylase is not detectable; no α-amylase in the sample or concentration below the limit of detection):

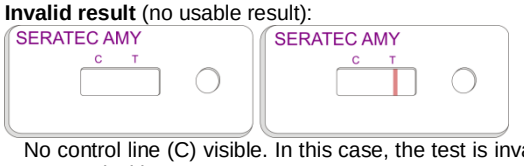



One line visible in the result window. The test result line (T) is not visible. The appearing control line (C) confirms that the test has been performed correctly.

**Positive result** (human α-amylase detectable):


Two lines visible in the result window: the test result line (T) and the control line (C). Any visible T-line (with strong or weak intensity) is to be considered a positive result.

**Invalid result** (no usable result):




No control line (C) visible. In this case, the test is invalid and should be repeated with a new test cassette.

## Sample preparation

In order to obtain optimal test results, follow these instructions:

- It is not recommended to use unknown samples undiluted. Liquid samples should be diluted at least 1:100 prior to testing.
- Viscous samples should be diluted until the sample flows smoothly on the test membrane.
- Use the buffer solution included in the scope of supply, as it has been developed specifically for the AmylaseTest. Other buffer solutions or the use of water may result in reduced sensitivity or fluctuating line intensities.
- Do not use liquids with a pH below 3 or above 12, as this may cause incorrect or invalid results.
- Tissue particles do not affect the test result.
- Cotton swabs, cloth or condom pieces should be extracted in a sufficient amount of buffer. The cut piece should be between 0.25 and 1 $cm^2$ in size and should be extracted in approx. 0.5 – 1 ml buffer.
- An extraction time of approx. 10 minutes is recommended. You should however follow the rule that the older or smaller the stain, the longer the recommended extraction time.
- Extracted samples are stable at room temperature for about 2 days. Samples kept for longer periods should be stored dry and cold (2 – 8 °C). Liquid samples may be frozen.

## Extraction buffer

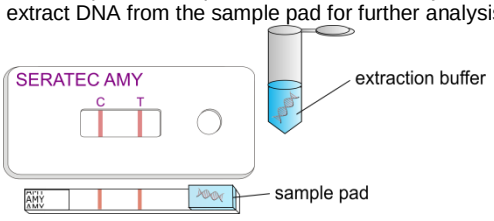
The supplied extraction buffer contains the following constituents (in 1 l distilled $H_2O$):
8,0 g NaCl; 0,2 g KCl; 1,44 g $Na_2HPO_4 \cdot 2H_2O$; 0,24 g $KH_2PO_4$; 0,1 ml 10 wt% $NaN_3$; pH 7,4.

## Further analysis

Prior to use of the SERATEC® AmylaseTest, we recommend using **SERATEC® AmylasePaper** as a mapping tool for the quick preliminary detection and the localisation of saliva on forensically relevant objects.

## DNA Profiling

The extracted samples can be stored for further analyses (e.g. DNA profiling; see Sample preparation).
The extracted sample is compatible with DNA analyses. It is also possible to extract DNA from the sample pad for further analysis.[1,2]




## Safety information

Forensic samples are potentially infectious material which should be examined with the appropriate care and only when suitable protective measures (e.g. gloves, laboratory clothing) are applied. Materials used to perform the test should be autoclaved before disposal, as they contain potentially infectious material. Observe the following instructions:

- Do not use the product if damaged.
- Only remove the test cassette from the pouch immediately before use.
- Do not use the product after the expiration date.
- The materials used in the test (e.g. antibodies) are potentially infectious materials. When used and disposed of properly, however, there is no danger to the user or others.
- Do not freeze the test cassette.

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## Background

The enzyme α-amylase is used in the body to break down polysaccharides and occurs in various organs and body fluids. Its concentration in saliva and pancreatic fluid is particularly high. The α-amylase found in saliva (also called ptyalin) initially breaks down insoluble starch into soluble forms (amylodextrin, erythrodextrin and achrodextrin), then breaking those down further into maltose.
There are several methods for the detection of saliva in forensic sample material by means of detecting α-amylase. Saliva tests that do not directly detect human α-amylase, but its activity (e.g. Phadebas), may indicate positive results regardless of the origin of the amylase (human, animal, plant). The SERATEC® AmylaseTest features **high sensitivity and specificity** and the **detection of human α-amylase as a marker of saliva** offers the following benefits in forensic applications:

- Easy handling without additional equipment – directly at the crime scene or in the laboratory.
- A quick and reliable result after 10 minutes.
- High specificity through direct detection of human α-amylase (see Specificity).

**Note:** Since α-amylase can also occur in other body fluids and secretions/ excretions, e.g. blood, urine, stool, seminal fluid, vaginal fluid, these samples may show a positive test result. The recommended sample dilution (see Sample preparation) reduces the probability that samples not containing any saliva show a positive test result. Please note that stool contains saliva amylases because of natural swallowing of saliva. For this reason, stool samples may show a positive test result. Breast milk likewise contains α-amylase and can cause a low positive test result in large concentrations. Overall, breast milk reacts about 20 times weaker than saliva. Pure urine samples may also cause a positive result. In this case, however, a dilution by 1:10 already leads to negative results. More information and recommendations on the use of the SERATEC® AmylaseTest in forensic biology have been gathered by the manufacturer in a freely available document.[3]

## Sensitivity

The SERATEC® AmylaseTest can be used to detect quantities of min. 50 mIU/ml human α-amylase. The **high dose hook effect** will not impact a positive test result. Human saliva diluted in the range between 1:1 and $1:10^3$ is successfully detected in the recommended extraction buffer.

## Specificity

The SERATEC® AmylaseTest does not show any cross-reactivity with other proteins in saliva. No cross-reactivity has been observed with the saliva of various animal species (dog, cat, rabbit, horse, cow, pig, mouse, goat, sheep, hamster and others). A probable exception is saliva from higher primates, but no data on cross-reactivity are available. *

## Storage and shelf life

- Store test cassettes and buffer solution at +2 to +30 °C (38 to 86 °F).
- Keep test cassettes in the pouch until use.
- Do not use after the specified expiration date.

## Quality features

Our products are manufactured according to the quality standards of European standard ISO 9001. The performance characteristics are confirmed during final quality control in application of the following standard: *α-Amylase from human saliva* (Lee Biosolutions, 120-10 *or* Sigma Aldrich, A1031).

Please contact us if you have any questions or require more information.

## Literature

[1] A. Barbaro, P. Cormaci, S. Votano, A.L. Marca, Evaluation study about the SERATEC® rapid tests, Forensic Sci. Int. Genet. Suppl. Ser. 5 (2015) e63–e64. doi:10.1016/j.fsigss.2015.09.025.
[2] H. Holtkötter, C.R. Dias Filho, K. Schwender, C. Stadler, M. Vennemann, A.C. Pacheco, G. Roca, Forensic differentiation between peripheral and menstrual blood in cases of alleged sexual assault—validating an immunochromatographic multiplex assay for simultaneous detection of human hemoglobin and D-dimer, Int. J. Legal Med. 132 (2018) 683–690. doi:10.1007/s00414-017-1719-y.
[3] SERATEC GmbH, Evaluation of the SERATEC AmylaseTest.

## Symbols


Expiry date


Storage temperature

Lot number

* As of June 2019

# Certificate

**mdc medical device certification GmbH**
certifies that

**SERATEC**
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for the scope

**design, development, manufacture and sales of**
**in-vitro diagnostic devices for determination of**
**fertility, hormones, drug abuse, oncology and disease prevention**
**as well as of laboratory assays for the forensic application**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

## EN ISO 9001

Quality management systems –
Requirements

(ISO 9001:2015)

| | |
|---|---|
| Valid from | 2021-10-11 |
| Valid until | 2024-10-10 |
| Registration no. | D1063500034 |
| Report no. | P21-01253-211764 |
| Stuttgart | 2021-09-16 |

Head of Certification Body

medical device certification mdc

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## EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

| | |
|---|---|
| Valid from | 2021-10-11 |
| Valid until | 2024-10-10 |
| Registration no. | D1063500035 |
| Report no. | P21-01253-211768 |
| Stuttgart | 2021-09-16 |

Head of Certification Body

medical device certification mdc

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