Digitally signed by Ceaicovschi Tudor
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Certificate

We hereby certify the company

SERATEC Gesellschaft für Biotechnologie mbH
Ernst-Ruhstrat-Straße 5
37079 Göttingen
Germany

the introduction and application of a

Quality management system according to EN ISO 9001

in 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

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 9001:2015 - ISO 9001:2015
Quality management systems – Requirements

Valid from	2024-10-16	Registration No.	D1063500040
Valid until	2027-10-10	Report No.	P24-01075-307344

Stuttgart, 2024-10-16

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

Certificate

We hereby certify the company

SERATEC Gesellschaft für Biotechnologie mbH
Ernst-Ruhstrat-Straße 5
37079 Göttingen
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

design, development, manufacture and sales of in-vitro diagnostic devices for determination of fertility, hormones, drug abuse, oncology and disease prevention

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2024-10-16	Registration No.	D1063500039
Valid until	2027-10-10	Report No.	P24-01075-307346

Stuttgart, 2024-10-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16002-06-00

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SERATEC® HemDirect

REF: HBF07, HBF07/8, HBF07/30

Application

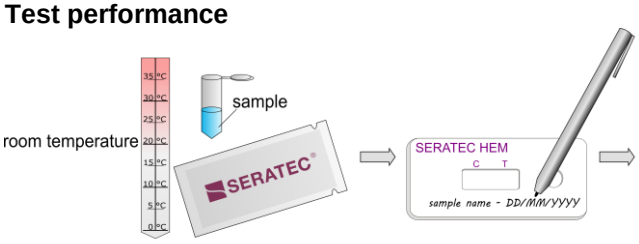
SERATEC® HemDirect is a chromatographic immunoassay for rapid detection of human hemoglobin (Hb) to identify blood in forensic samples. The product contains two monoclonal anti-human Hb antibodies as active components.

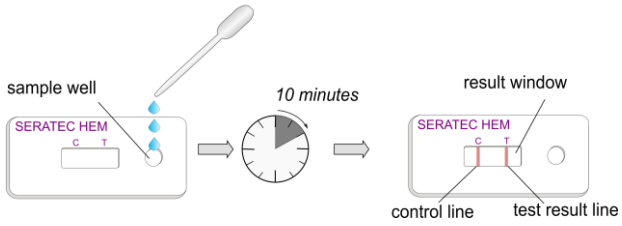
Materials

- 8 or 30 (HBF07/8, HBF07/30) individually packaged HemDirect in cassette format with one plastic pipette each
- 8 or 30 (HBF07/8, HBF07/30) vials with 1.5 ml 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.

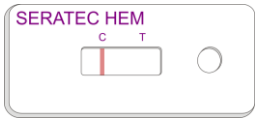
Interpretation of results

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

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

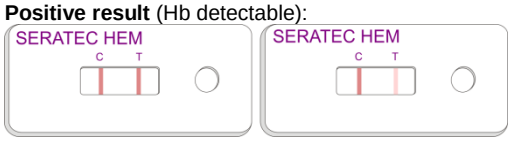
Control line (C): Control for potential application errors and for the integrity of the test components. This line is always visible after successful performance of the test.

Negative result (Hb is not detectable; no Hb in the sample or concentration below the limit of detection):



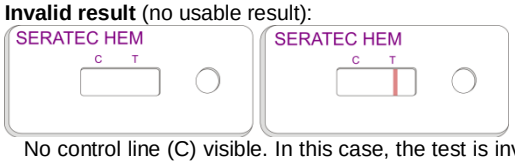
One line visible in the result window. The test result line (T) is not visible. The appearing control line (C) confirms that the test has been performed correctly.

Positive result (Hb 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 1:500 prior to testing. The colouration of the sample can be a visual indicator of a suitable dilution factor: the visible colouration of blood samples will disappear at a dilution between approx. $1:10^3$ and $1:10^4$.
- 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 HemDirect. 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.
- Adding detergents such as SDS, sarcosyl or bleach to the sample material may cause incorrect or invalid results. This is probably caused by the denaturation of Hb.
- 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 can be given directly into the buffer vial. Alternatively the samples can be collected with the applicator attached to the lid of the buffer tube.
- 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.[1,2]
- 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

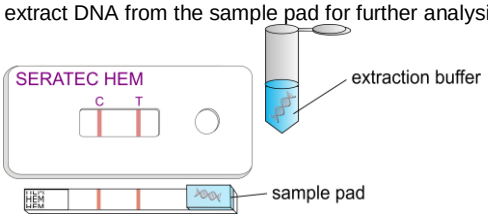
The supplied extraction buffer contains the following constituents (in 1 l distilled H_2O):
12,1 g Tris; 8,8 g Na_3Citrat; 0,2 g NaN_3; 0,5 g Tween 20; 5 g BSA; pH 6,8.

Further analyses

For the further differentiation of blood traces, we recommend using the **SERATEC® PMB Test** for detection of Hb and D-dimer to identify and differentiate peripheral blood and menstrual blood.

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.[3,4]



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.

Background

The red blood pigment hemoglobin (Hb) is a protein complex which occurs in red blood cells and primarily serves to transport gas in the body. It has a molecular weight of 64.5 kDa and consists of 4 subunits (amino acid chains), two of which are identical. Each subunit is associated with a haem group, an iron complex responsible for oxygen binding. At concentrations of 120-160 mg/ml (women) and 140-180 mg/ml (men), Hb is one of the most common proteins in blood.
There are several methods for the detection of blood in forensic sample material by means of detecting Hb. However, many detection methods are unspecific regarding the origin (human or animal) of the sample. This means that further examinations are necessary, which usually cannot be performed directly at the crime scene. SERATEC® HemDirect features **high sensitivity and specificity** and the **detection of human hemoglobin as a marker of blood** 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.
- Very high specificity through direct detection of human Hb (see Specificity).
- High stability of Hb; positive detection could be obtained with 31-year-old samples.[1]

Sensitivity

SERATEC® HemDirect can be used to detect quantities of min. 20 ng/ml human Hb. In very high Hb concentrations, the **high dose hook effect** can cause reduced line intensity; therefore, it is recommended to always dilute fresh liquid samples (see Sample preparation). Human blood diluted in the range between 1:50 and $1:10^7$ is positively detected in the recommended extraction buffer.

Specificity

SERATEC® HemDirect does not show any cross-reactivity with other proteins in blood. No cross-reactivity has been observed with the blood of various animal species (dog, rabbit, cat, cattle, pig, wild boar, horse, chicken, sheep, mule, goat, red deer and others).[1] Primate and ferret blood can cause positive results.

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: *human hemoglobin* (Sigma Aldrich, H7379).

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

Literature

[1] A. Misencik, D.L. Laux, Validation Study of the Seratec HemDirect Hemoglobin Assay for the Forensic Identification of Human Blood, in: 2007.
[2] M.N. Hochmeister, B. Budowle, R. Sparkes, O. Rudin, C. Gehrig, M. Thali, L. Schmidt, A. Cordier, R. Dirnhofer, Validation studies of an immunochromatographic 1-step test for the forensic identification of human blood, J. Forensic Sci. 44 (1999) 597–602.
[3] 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.
[4] 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.

Symbols


Expiry date


Storage temperature

Lot number

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SERATEC® PSA Semiquant

REF: PSM400F, PSM400F/8, PSM400F/40

Application

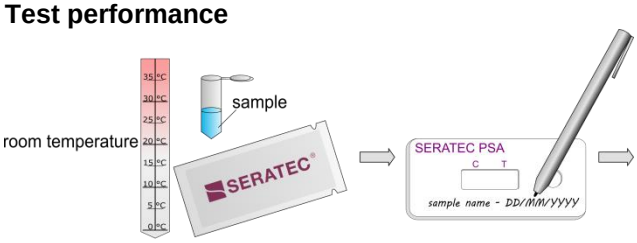
SERATEC® PSA Semiquant is a chromatographic immunoassay for rapid semiquantitative detection of prostate-specific antigen (PSA) to identify seminal fluid in forensic samples. The product contains two monoclonal anti-human PSA antibodies as active components.

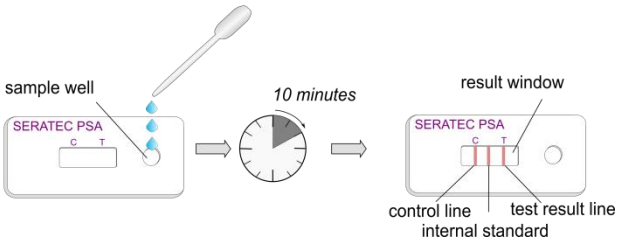
Materials

- 8 or 40 (PSM400F/8, PSM400F/40) individually packaged PSA Semiquant in cassette format with one plastic pipette each
- 15 or 50 ml (PSM400F/8, PSM400F/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

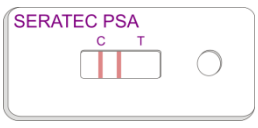
After 10 minutes, up to three lines may be visible in the result window:

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

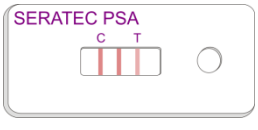
Internal standard: the colour intensity of the line corresponds to a PSA concentration of 4 ng PSA/ml.

Negative result (PSA is not detectable; no PSA in the sample or concentration below the limit of detection):



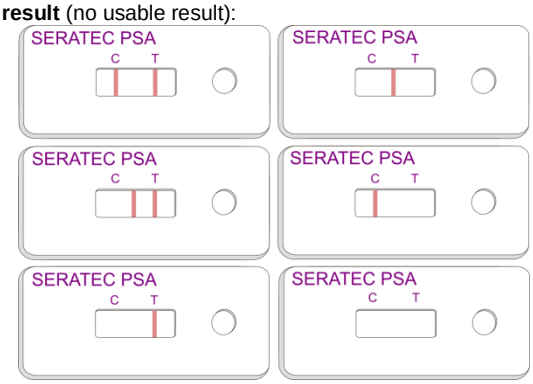
Two lines visible in the result window. The test result line (T) is not visible. The appearing internal standard line and control line (C) confirm that the test has been performed correctly.

Positive result (PSA detectable):



Three lines visible in the result window: the test result line (T), the internal standard line 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) and/or internal standard line 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 1:500 prior to testing. [1]
- 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 PSA Semiquant. 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.[2]
- 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

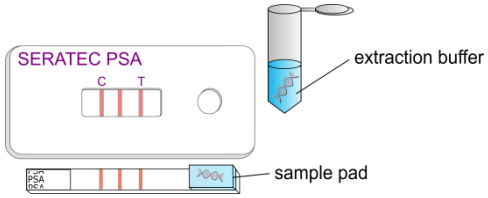
The supplied extraction buffer contains the following constituents (in 1 l distilled H_2O):

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.

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.[3,4]



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.

Background

Prostate-specific antigen (PSA) is a glycoprotein produced in the prostate. It is secreted into the seminal fluid for liquefaction and reaches concentrations of 0.2 to 3.0 mg/ml. These high levels as well as the fact that PSA only occurs in very low concentrations (0.0 – 1.25 ng/ml[5,6]) in female vaginal secretions make **PSA a suitable marker for the detection of small quantities of seminal fluid**. The benefits in forensic application compared to other detection methods are:

- Easy handling without additional equipment – directly at the crime scene or in the laboratory.
- A quick and reliable result after 10 minutes.
- Detection of PSA is also possible in cases where no sperm cells can be found (e.g. after a vasectomy).[7]
- High stability of PSA – positive detection could be obtained with 30-year-old samples.[7]
- Detection of PSA in vaginal swabs up to 27 hours after sexual intercourse.[5,7]
- Higher specificity of PSA for the detection of seminal fluid compared to "acid phosphatase tests".[6,7]
- In simulated samples of vomit, PSA was detectable for up to 4 hours.[8]
- Greater reliability in the detection of PSA in vaginal swabs compared to semenogelin.[9]

Note: Besides seminal fluid, PSA occurs in other body fluids and secretions/excretions, e.g. blood, urine, stool.[10,11] The recommended sample dilution (see sample preparation) reduces the probability that samples not containing any seminal fluid show a positive test result. More information on PSA in body fluids as well as recommendations on the use of SERATEC® PSA Semiquant in forensic biology have been gathered by the manufacturer in a freely available document and can be found in the references. [1,2,12]

Sensitivity

SERATEC® PSA Semiquant can be used to detect quantities of min. 1 ng/ml human PSA. The **high dose hook effect** will not impact a positive test result. Seminal fluid diluted in the range between 1:1 and $1:10^6$ is successfully detected in the recommended extraction buffer.

Specificity

SERATEC® PSA Semiquant does not show any cross-reactivity with other proteins in seminal fluid. No cross-reactivity was observed with seminal fluid from other mammals (dog, cat, horse, bull, pig, ram and others). [7,13] A possible exception is seminal fluid 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 WHO-standard: *PSA NIBSC Code 96/668 and 17/102*.

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

Literature

[1] D.L. Laux, S.E. Custis, Forensic Detection of Semen III . Detection of PSA Using Membrane Based Tests : Sensitivity Issues with Regards to the Presence of PSA in Other Body Fluids, in: 2004.
[2] D.L. Laux, A.J. Tambasco, E.A. Benzinger, Forensic Detection of Semen II, in: 2008.
[3] 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.
[4] 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.
[5] M. Macaluso, L. Lawson, R. Akers, T. Valappil, K. Hammond, R. Blackwell, G. Hortin, Prostate-specific antigen in vaginal fluid as a biologic marker of condom failure, Contraception. 59 (1999) 195–201.
[6] M.L. Lawson, M. Maculuso, A. Bloom, G. Hortin, K.R. Hammond, R. Blackwell, Objective markers of condom failure, Sex. Transm. Dis. 25 (1998) 427–432.
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[8] S. McWilliams, B. Gartside, Identification of Prostate-Specific Antigen and Spermatozoa from a Mixture of Semen and Simulated Gastric Juice, J. Forensic Sci. 54 (2009) 610–611. doi:10.1111/j.1556-4029.2009.01008.x.
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[10] S. Bolduc, L. Lacombe, A. Naud, M. Grégoire, Y. Fradet, R.R. Tremblay, Urinary PSA: a potential useful marker when serum PSA is between 2.5 ng/mL and 10 ng/mL, Can. Urol. Assoc. J. J. Assoc. Urol. Can. 1 (2007) 377–381.
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[12] SERATEC GmbH, Summary about PSA in body fluids, n.d. http://www.seratec.com/docs/user_instructions/psa_in_body_fluids.
[13] R. Miteva, S. Yotov, P. Georgiev, I. Fasulkov, DETERMINATION OF SPECIES SPECIFICITY OF PROSTATE- SPECIFIC ANTIGEN (PSA) IN SEMEN, in: 2006.

Symbols


Expiry date


Storage temperature

Lot number

* As of June 2019