

BLUESTAR® Identi-HEM®

Rapid test For the Detection of
Human Haemoglobin
For Use in Forensic Medicine

Instructions for Use

BLUESTAR® - Updated 2019.10.22

INTENDED USE

BLUESTAR® Identi-HEM® allows the rapid detection of human haemoglobin (which is the main component of blood) for forensic use. It could be used directly in scenes crime or in any place where the presence of human blood has to be accurately investigated thanks to the specific components supplied into the kit.

PRINCIPLE

Haemoglobin is one of the main elements of blood. This protein is a choice marker for blood detection even when the quantity is very low. Moreover, thanks to the use of monoclonal antibodies, obtained from very complex cell culture techniques, immunology methods, used also in forensic medicine, provide both very high sensitivity and high specificity for human blood detection.

BLUESTAR® Identi-HEM® is a rapid, qualitative immunochromatographic test, in a device, for specific detection of human haemoglobin.

This method uses a unique combination of monoclonal antibodies bound to colloidal gold and polyclonal antibodies bound onto a solid phase in order to selectively identify, with high sensitivity and specificity, human haemoglobin.

After being collected with the provided swab, the sample is placed into an extraction buffer. After the sample has been dispensed on the cassette, the extraction medium is absorbed through migration, the antibodies bound to the colloidal gold then bind to the haemoglobin to form an antibody-antigen complex.

This complex then binds to the anti-haemoglobin antibodies present into the test area, and then a wine-coloured line appears. If there is no haemoglobin, no coloured line appears in the test area.

The mix keeps on migrating onto the membrane, goes beyond the test area, and then binds to the reagents into the control area to produce a wine-coloured line, guaranteeing the reaction performed correctly.

KIT CONTENTS

Each kit contains all the components needed to perform 6 or 24 tests according to product reference:

Ref. VD-HEM-6: 6 x BLUESTAR® Identi-HEM® tests
Ref. VD-HEM-24: 24 x BLUESTAR® Identi-HEM® tests

Quantity	Component
6 or 24	BLUESTAR® Identi-HEM® device
6 or 24	Collection tube (bottle type) containing 2 ml extraction buffer
6 or 24	Sterile swab
1	Instructions leaflet

STORAGE AND STABILITY

- All the components of BLUESTAR® Identi-HEM® kit should be stored at room temperature (4°C to 30°C).
- **DO NOT FREEZE**
- The BLUESTAR® Identi-HEM® test is stable until the expiry date mentioned on the test foil pouch.

PRECAUTIONS

- This test is only for forensic medicine use.
- Carefully read the use instructions before using the test.
- Handle all the samples as if they would contain infectious agents. When the test is completed, discard the samples and swabs with all the necessary precautions.
- Wear protection clothes, such as laboratory coats and single-use gloves to test the samples. Avoid any contact with the hands, eyes or nose when collecting and testing the samples.
- The extraction buffer, containing sodium azide 0.02%, may irritate the skin, eyes or mucosa. Immediately wash the contaminated areas if the solution touches the skin.
- Do not eat, drink, or smoke into the area where the samples and reagents are handled.
- Do not use the test after the expiry date mentioned on the test packaging label.
- Do not use a test if its foil pouch is damaged.
- Use the swabs provided with the kit.

SAMPLE COLLECTION AND PREPARATION

1. The samples should be collected under standard collection conditions (aseptically and so as to avoid any contamination). Each sample should be treated as if it was potentially infectious.
2. Use the swabs provided with the test to collect the sample.
3. Ensure not to break the collection tube tip.
4. Unscrew the cap of the tube, by keeping it vertically in order not to spill the extraction buffer.
5. Collect the samples of the presumed blood trace with the sterile swab provided with the test (in case of dry sample, it is possible to previously humidify the swab with the extraction buffer contained into the collection tube.)
6. Immerse the swab, by vigorously shaking it for 10 seconds, into the tube containing the buffer so that the sample is correctly mixed with the buffer.
7. Remove the swab from the plastic tube while squeezing it against the tube wall to extract the most liquid possible.
8. Dispose of the swab, then rescrew the cap back onto the tube.
9. The collected sample is stable at room temperature (4°C to 30°C) **but should be tested within 7 days**.

PROCEDURE

1. Before starting the assay, make sure all the samples and BLUESTAR® Identi-HEM® reaction devices are at room temperature.
2. Remove the reaction device from its protective pouch by tearing along the notches.
3. Break the collection tube tip (Fig. 1), then squeeze the tube to dispense **4 drops** of the obtained solution into the reagent device well (Fig. 2).

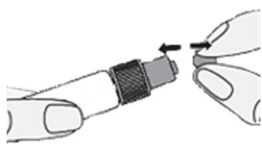


Fig. 1

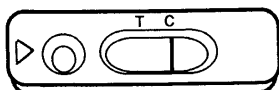


Fig. 2

4. Read the results 10 minutes after the sample was added.

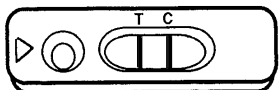
RESULT INTERPRETATION

Negative

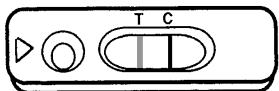


Only one coloured line appears into the control zone (C), indicating the test was correctly performed and the reagents correctly work.
No line appears into the test zone (T).

Positive



In addition with the coloured line into the control zone (C), a coloured line clearly visible also appears into zone (T), indicating the sample contains human haemoglobin.



Even a very pale line should be interpreted as a positive result.

Invalid



If no coloured line appears into the control zone (C), the test is invalid. In this case, it is recommended to restart the test with a new device.

TEST PERFORMANCES

Sensitivity

The BLUESTAR® Identi-HEM® test can detect very low quantities of haemoglobin.
After dilution into the extraction buffer, the minimum haemoglobin level detected by the BLUESTAR® Identi-HEM® test is 0.01 µg/mL.

Cross-reactivity

The BLUESTAR® Identi-HEM® test is manufactured using 2 highly sensitive and specific antihuman haemoglobin monoclonal antibodies.

Ox, pig, rabbit, horse and sheep haemoglobin (ie whole blood) does not react with BLUESTAR® Identi-HEM®. Moreover, the human blood components such as albumin, haptoglobin, myoglobin and transferrin also result in negative results.

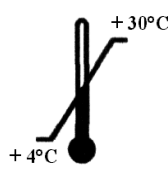
Hook effect

Very high-level haemoglobin samples resulted in positive results up to 2 mg/ml after dilution into the extraction buffer. Nevertheless, too concentrated samples may result in negative results because of the hook effect, a phenomenon very well known in immunologic assays.


In case of doubt for some samples, it is then necessary to retest after 1/100 or 1/1,000 dilution.

BIBLIOGRAPHY


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- 2- **Sidney J. Winaver, Paul Sherlock, David Schottenfeld and Daniel G. Miller.** "Clinical trends and topics : Screening for colon cancer." *Gastroenterology*, volume 70: 783-789. 1976
- 3- **S.J. Winaver, S.D. Leidner, D.G. Miller, D. Schottenfeld, B. Belfer, R.C. Kurtz, P. Sherlock and M. Stearns.** "Results of a screening program for the detection of early colon cancer and polyps using fecal occult blood testing." *Abstracts of paper*, Volume 72 (n°5): A-127/1150. 0..1977
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Temperature limitation
+4°C — +30°C



Please read instructions leaflet



Do not reuse

Ref. VD-HEM-6: 6 x BLUESTAR® Identi-HEM® tests
Ref. VD-HEM-24: 24 x BLUESTAR® Identi-HEM® tests

Made in EU.

BLUESTAR

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