

Clearview[®] Simplify D-dimer Control Set

Product Number: 6101KCV

Positive and Negative Control Set for use with Clearview Simplify D-dimer.

INTENDED USE

The D-dimer control set consists of unassayed Positive and Negative Control intended for use with Clearview Simplify D-dimer test kits to verify that the tests have worked correctly. The controls are intended to monitor for gross systematic errors only.

REAGENTS

Positive Control: a solution containing purified human D-dimer fragment, 5 mg/mL BSA and 0.1% sodium azide.

Negative Control: a buffer solution containing 5 mg/mL BSA and 0.1% sodium azide.

The Controls are ready to use. No dilution is necessary.

Warnings And Precautions

For In Vitro Diagnostic Use Only.

Harmful if swallowed (R22). Avoid contact with skin and eyes (S24/25). Do not empty into drains (S29). Wear suitable protective clothing (S36).

CAUTION: Controls contain sodium azide (0.1%) as preservative. Do not ingest or allow to contact skin or mucous membranes. Sodium azide may form explosive azides in metal plumbing. Use proper disposal procedures.

CAUTION: The Positive Control contains components of human origin. Each individual blood donation intended for the production of this reagent is tested for Hepatitis B antigen, anti-HCV, anti-HIV1 and anti-HIV2. Only donations with negative findings are employed. As complete absence of infectious agents can never be assured, all materials derived from human blood should be treated as potentially infectious and handled with due care following the precautions recommended for biohazardous material.

Storage And Stability

Storage: Store at 2°C to 8°C. DO NOT FREEZE.

Stability: Refer to vial labels for expiration date.

PROCEDURE

Materials Provided:

Positive Control: 1 x 0.8 mL; Yellow Cap

Negative Control: 1 x 0.8 mL; Black Cap
Instructions for Use.

Material sufficient for 20 tests.

Materials Required but Not Provided:

Clearview Simplify D-dimer Kit -
Inverness Medical - 6100KCV / BBIInternational - 505285

Disposable gloves

Stopwatch or timing device

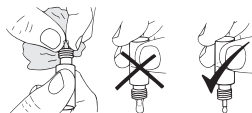
Tissue (for wiping dropper bottle tips)

Important!

- Equilibrate controls to room temperature (20°C to 25°C) before use.
- Prior to each use, the dropper bottle tips must be wiped dry with a tissue.
- Dropper bottles must be held vertically when dispensing drops of control.
- Allow Control and Buffer drops to fall onto the membrane at the sample well. Do not touch Control or Buffer drops, or bottle tips directly to the membrane.

For correct drop delivery...

Wipe tip dry prior to use



Assay Procedure

1. The Controls should be treated as patient samples. Refer to the Clearview Simplify D-dimer Instructions for Use for the proper test procedure and interpretation of results.
2. Holding the bottle vertically, **apply 2 drops of control** to the sample window.
3. Holding the bottle vertically, apply 2 drops of Clearview Simplify Buffer to the sample window.
4. Leave the test device lying flat for the development period and read the result at 10 minutes.

Quality Control

To confirm the proper functioning of the Clearview Simplify D-dimer test system it is recommended that both Positive and Negative Controls be tested at regular intervals in conformance with local, state and/or federal regulations or accreditation programs.

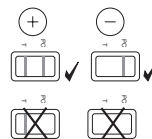
EXPECTED VALUES

The Positive Control should produce a weak to moderate positive result on the test line (T) combined with a clearly visible PC line.

The Negative Control should yield negative results, that is, only a PC line should be present with no line visible on the Test (T) zone.

If these results are not observed, it may be an indication that:

- An error in technique has been made
- The Clearview Simplify D-dimer device has not performed properly, or
- The Controls are not functioning correctly



North American Customers:

Distributed by Inverness Medical, 2 Research Way, Princeton, NJ 08540 USA.
Manufactured by BBIInternational, Dundee, DD2 1NH, UK.

Technical Support

Further information can be obtained from www.clearview.com, or your distributor.

Phone **1-877-441-7440**

Customers outside North America:

Phone **1-321-441-7200**

To reorder

Please call **1-877-441-7440** or **1-321-441-7200**
(press 1 for Customer Service)



BBIInternational (BBI), Dundee, DD2 1NH, UK

Advice Line

Further information can be obtained from your distributor, or call Inverness Medical Technical Support on:

International: **+44 (0)1234 835959**

www.clearview.com



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