

INTENDED USE

PRO-Mcomplete™ External Positive Control is intended to provide an external quality control reagent for use with the PRO-Mcomplete™ kit (PL.950-1, PL.950-5, PL.950-10).

PRINCIPLES OF THE TEST

The positive control contains **Alpha-FetoProtein (AFP)** and **Insulin-like Growth Factor-Binding Protein-1 (IGFBP-1)** which, when dispensed into the PRO-Mcomplete™ cassette, produces positive A (AFP), B (IGFBP-1) and C (control) lines in properly functioning tests.

REAGENTS/MATERIALS PROVIDED

- One dropper bottle containing 0.5 ml of positive control sufficient for 1 test.

AFP in the positive control is obtained from human cord serum and the IGFBP-1 is obtained from pooled amniotic fluid. The control reagent is negative for HBs Ag, HIV type 1 and 2 antibodies, HCV, and syphilis.

MATERIALS REQUIRED BUT NOT PROVIDED

- PRO-Mcomplete™ cassettes (PL.951)
- A standard laboratory timer

STORAGE AND STABILITY

The positive control is stable until the expiry date indicated on the bottle when stored at 2-8°C.

PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic use.
- Do not use the reagent beyond the expiry date.
- The positive control contains material of human origin and should be handled as a potential carrier and transmitter of disease. No known test method can offer complete assurance that products derived from human sources will not transmit infectious agents.
- After use dispose of the test cassette according to procedures for potentially infectious waste.

QUALITY CONTROL TEST PROCEDURE

1. The positive control and cassette should be at room temperature prior to testing.
2. Hold the positive control dropper bottle vertically above the sample well (S) on the cassette and dispense three drops by applying gentle pressure on the walls of the bottle. Avoid air bubbles in the sample well or splashes of

liquid into the results window.








3. Start the timer. As the test begins to work, you will see a reddish coloured liquid moving across the membrane.
4. The results should be read after 10 minutes.

INTERPRETATION OF RESULTS

The test is working properly if a band is visible at A, B, and C when using the positive control. Even a faint band should be considered as a positive result.

LIMITATIONS OF THE PROCEDURE

The test procedure must be followed to obtain accurate results.

	= Use by
	= Lot number
REF	= Catalogue number
	= Manufacturer
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use