

PRO·Mcomplete™ External Positive Control



pro-lab.com/resources



1

REF PL.953

INSTRUCTIONS FOR USE

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).

PRINCIPLE 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™ Test Cassette, produces positive A (AFP), B (IGFBP-1) and C (control) lines in properly functioning tests.

MATERIALS PROVIDED

One dropper bottle containing 0.5 ml of positive control sufficient for 1 test. AFP and IGFBP-1 are recombinant proteins dissolved in a buffer with preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

- PRO·Mcomplete™ Test Cassette (PL.951), included with PRO·Mcomplete™ Test Kits (PL.950-1, PL.950-5, PL.950-10)
- A standard laboratory timer

STABILITY AND STORAGE

Reagent should be stored at 2-8°C. **Do not freeze**. Product stored under these conditions will be stable until the expiry date shown on the product label.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use the reagent after the expiration date shown on the product label.
- Universal precautions should be taken in handling, accessing and discarding all clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.
- The procedures, storage conditions, precautions, and limitations specified in these directions must be followed to obtain valid test results.

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.

AVAILABILITY

Cat. No	Description
PL.950-1	PRO-Mcomplete™ Test Kit (1 test)
PL.950-5	PRO-Mcomplete™ Test Kit (5 tests)
PL.950-10	PRO-Mcomplete™ Test Kit (10 tests)

SYMBOLS GLOSSARY

Symbol	Meaning
	Manufacturer
	Use-by date
	Lot number
	Catalogue number
	Temperature limit
	Consult instructions for use or consult electronic instructions for use
	In vitro diagnostic medical device
	Contains sufficient for <n> tests
	Do not reuse

Pro-Lab Diagnostics U.K.

3 Bassendale Road, Bromborough,
Wirral, Merseyside CH62 3QL
United Kingdom
Tel.: 0151 353 1613
www.pro-lab.co.uk
E-mail: uksupport@pro-lab.co.uk



Pro-Lab Diagnostics Canada

20 Mural Street, Unit #4
Richmond Hill, Ontario L4B 1K3
Canada
Tel.: 905-731-0300
www.pro-lab.com
E-mail: support@pro-lab.com

Pro-Lab Diagnostics U.S.A.

1301 Blue Ridge Drive, Suite #101
Georgetown, Texas 78626-3269
United States
Tel.: 512-832-9145
www.pro-lab-direct.com
E-mail: support@pro-lab.us