Actim® PROM Controls

R_x ONLY

For *In Vitro* Diagnostic Use

INTENDED USE
The Actim PROM Controls are intended for use as external controls with the Actim PROM test. The controls may also be used to demonstrate negative results and weak and strong positive results.

SUMMARY AND EXPLANATION
The Actim PROM Controls contain one vial each of negative (-), low positive (+) and high positive (++) controls, and reconstitution solution for use in verifying the performance of the Actim PROM test.
The Actim PROM Controls can be used in place of patient samples, in which case the results aid in interpretation of a positive and negative result and verify test and operator performance.

PRINCIPLE OF THE TEST/METHOD
The Actim PROM Controls kit is designed for use as external quality control samples with the Actim PROM test.

REAGENTS AND COMPONENTS
The Actim PROM Controls kit consists of one of each of the following components:
1. Actim PROM Negative Control (0 µg/L)
2. Actim PROM Low Positive Control (~40 µg/L)
3. Actim PROM High Positive Control (~250 µg/L)
4. Actim Reconstitution Solution
5. Instructions for use

The Positive Controls consist of purified human insulin-like growth factor binding protein-1 (IGFBP-1) in a buffered protein solution with BSA and Thimerosal as preservative. The Negative Control consists of the same matrix without added antigen. All components include preservative (please see the warnings and precautions section).

Materials needed but not provided:
- Actim PROM test kit
- Pipette (to measure 500 µL of solution for accurate dispensing of Reconstitution Solution)
- Timer or stopwatch

PRECAUTIONS AND WARNINGS
- The controls are intended for professional *in vitro* diagnostic use only.
- The controls are designed for use only with the Actim PROM test.
- The lyophilized controls contain <0.01%, the reconstitution solution contain <0.01% and the reconstituted controls contain <0.02% reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Skin Sens 1). May cause an allergic skin reaction (H317). Avoid breathing mist/vapour (P261). Contaminated work clothing should not be allowed out of the workplace (P272). Wear eye protection/protective gloves/protective clothing (P280). If skin irritation or rash occurs: Get medical advice/attention (P333+P313). Take off contaminated clothing and wash it before reuse (P362+P364). Dispose of contents/container in accordance with local regulation (P501).
- Before use, ensure that the package and vials are intact. Do not use a control if the vial is damaged.
- Do not use the controls before they have been completely reconstituted.
- Test controls at room temperature to ensure optimal results with the Actim PROM test.
- Carefully follow the instructions for use of the Actim PROM Controls and Actim PROM test to ensure correct results.
- Do not use the Actim PROM Controls after the expiration date, which is printed on the labels of the kit components.
- Laboratories should follow the guidelines or requirements of Federal, State and/or Local regulations or accrediting organizations in the use of controls.
- The IGFBP-1 antigen in the Positive Controls has been shown to be negative for HBsAg, HIV type 1 and 2 antibodies, HCV and syphilis. Nevertheless, such tests are unable to prove the complete absence of viruses, and **therefore the controls should be treated as potentially infectious.**
- Dispose kit and used contents in accordance with Federal, State, and Local requirements.

STORAGE AND STABILITY
Store the components at 2–25°C (36–77°F). Unopened, each component can be used until the expiration date marked on the component.
After reconstitution, the controls can be stored for 24 hours at 18–30°C (64–86°F) or for 7 days at 2–8°C (36–46°F).

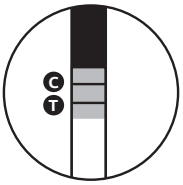
TEST PROCEDURE
Reconstitution
1. Unscrew the cap and open the vials by carefully removing the grey stopper.
2. Reconstitute the controls by adding 500 µL of Reconstitution Solution to each of the vials. When pipetting, avoid the risk of contamination by changing the pipette or its tip after each addition.
3. Close the stopper and allow the vial to reconstitute for at least 15 minutes. Be sure the lyophilized material is completely dissolved before use.

Testing
Note: Each Actim PROM test requires approximately 150 µL of sample. Before placing

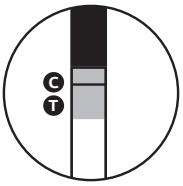
the Actim PROM test in the control vial, ensure that the volume of control solution is sufficient.

1. If stored refrigerated, allow the Actim PROM test to reach room temperature before use. Open the foil pouch containing the dipstick. Do not touch the yellow sample area at the lower part of the dipstick. Identifying marks may be written on the upper turquoise part of the dipstick. The dipstick must be used as soon as possible after its removal from the foil pouch.
2. Place the yellow sample area (the lower end of the dipstick) into the control vial and hold it there **until you see the liquid front enter the result area.** Remove the dipstick from the solution and place it on a non-absorbent flat surface. Start the timer.
3. The result can be interpreted as positive as soon as two blue lines become visible in the result area. Negative results should be read at 5 minutes. **Do not interpret results after 5 minutes.**

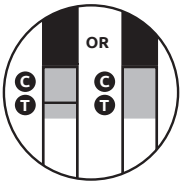
INTERPRETATION OF THE RESULT



POSITIVE
Two blue lines appear. One line should be in the test line area T and the other in the control line area C.
Note: The intensity of the line in the test line area T may vary. Any test line appearing at or before the 5 minute read time can be considered a positive result, assuming a control line is also present. Disregard any lines seen after 5 minutes.



NEGATIVE
One blue line appears in the control line area C.



INVALID
Control line fails to appear. Repeat using another dipstick. If the test result cannot be interpreted clearly (e.g. if the lines are blotched or uneven) it is recommended that the test be repeated. If the problem persists, discontinue using the test kit and contact Technical Support (see below).

LIMITATIONS

- The controls are to be used with the Actim PROM test only.
- The Actim PROM Controls are not to be used as quantitative calibrators.

EXPECTED VALUES

The Actim PROM Controls will provide examples of negative, low positive and high positive results. The Negative Control gives a negative test result. The Low Positive Control gives a weak positive result. The High Positive Control gives a strong positive result.
The failure to obtain expected results indicates that the test was not performed properly or that the test reagents were not functioning properly.
If the controls do not perform as expected, repeat the test. If expected results are not obtained after repeating the test, please contact Technical Support (see below).

TECHNICAL SUPPORT:

United States Technical Support: Tel: +1 844 465 6442 or contact your local distributor.

EXPLANATION OF SYMBOLS

Use by YYYY-MM-DD
REF Catalog number
LOT Batch code
Manufacturer
IVD *In Vitro* Diagnostic Medical Device
Temperature limitation
Consult instructions for use
5 PP Polypropylene
20 PAP Corrugated Cardboard
22 PAP Paper

Distributed by:
Hologic, Inc.
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REF **30800ETUS**

Actim® PROM Controls

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