

HiKaryoXL™ PHA-M Solution

With 0.1mg per ml PHA-M in sterile tissue culture grade water

Product Code: TCL061

Intended Use:

HiKaryoXL™ PHA-M Solution is a mitogen recommended for stimulation of peripheral blood lymphocytes during short term in vitro culture for cytogenetic studies.

Principle and Interpretation:

Phytohemagglutinin (PHA-M) is a lectin extracted from red kidney bean *Phaseolus vulgaris*. PHA-M is the most common mitogen used for the stimulation of cell division in lymphocyte cultures. PHA-M is a mucoprotein consisting of two subunits, a leucoagglutinin (PHA-L) and an erythroagglutinin (PHA-E). Leucoagglutinin is responsible for mitogenic property of PHA-M as it has high affinity for lymphocyte surface receptors.

TCL061 is a sterile filtered solution of 0.1mg per ml PHA-M in sterile tissue culture grade water.

Composition:

0.1 mg/ml PHA-M in sterile tissue culture grade water.

Type of Specimen:

Clinical samples - Blood

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling as per established guidelines^{1,2}.

1. Disinfect the vacutainer by applying 70% isopropyl alcohol to the rubber stopper.
2. If using blood collection tube containing suitable anticoagulant (EDTA), disinfect the tube by applying 70% isopropyl alcohol.
3. Wait for 1 minute.
4. Palpate vein before disinfection of venipuncture site.
5. Cleanse the site with 70% isopropyl alcohol.
6. Starting at the center, swab the site concentrically with tincture iodine or chlorhexidine.
7. Allow the disinfectant to dry.

Note: Do not palpate the vein at this point without sterile gloves.

8. Collect the required volume of blood by venipuncture.
9. Mix gently by inverting tube 2 – 3 times to avoid coagulation.
10. After venipuncture, remove iodine from the skin with alcohol.
11. Sterilize the needle, syringe and other materials used for blood collection by autoclaving before discarding.

Warning and Precautions:

In Vitro Diagnostic Use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow proper aseptic techniques while handling specimens and cultures. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets.

Directions:

Add 10ml of TCL061 per 50ml of culture medium.

Limitations:

Not applicable.

Quality Control:

Appearance

Colorless, clear solution.

Sterility

No bacterial or fungal growth is observed after 14 days of incubation, as per USP specification.

Performance Tests

1. **Peripheral blood performance test**
Passes
2. **Mitotic index (Test lot)**
≥ 0.010
3. **Mitotic index (Control lot)**
≥ 0.010

Storage and Shelf Life:

Store at -30°C to -10°C. Avoid repeated free thaw cycles.

Shelf life of the product is 24 months.

Use before expiry date given on the product label.

Disposal:

User must ensure safe disposal by autoclaving and / or incineration of used or unusable preparations of this product. Follow established laboratory procedures for disposing infectious materials. The materials that come into contact with clinical samples must be decontaminated and disposed of in accordance with current laboratory techniques ^{1,2}.

References:

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
2. Jorgensen, J. H., Pfaller, M.A., Carroll, K.C., Funke, G. Landry, M.L., Richter, S.S and Warnock., D.W. (2015), Manual of Clinical Microbiology, 11th Edition. Vol. 1.



In vitro diagnostic medical device



CE Marking of Conformity



Consult instructions for use



Do not use if package is damaged



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Disclaimer:

Revision date: 03/2025

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