

WHO Prequalification of Vector Control Products

Considerations for the selection of controls for use in insecticide-treated net (ITN) studies

Factors which may affect the validity of studies using selected controls:

- controls not obtained from a controlled source
- inappropriate storage conditions after receipt
- active ingredient(s) of control does not align with the AI(s) of the ITN under investigation.

1. Purpose

The purpose of reference items (positive and negative controls) in studies is to validate the experimental procedures. The results from controls are used in statistical analyses to make determinations of entomological efficacy, and therefore, it is crucial that the selected controls are appropriate and relevant for the study at hand.

In addition to the requirements described in this document, bodies other than WHO Prequalification of Vector Control Products (PQT/VCP), e.g., WHO Global Malaria Programme or national regulatory agencies, may have specific requirements for controls. Studies that are intended to be submitted to multiple bodies should be designed such that all control requirements are met.

2. Negative controls

All studies must be conducted with a negative control. For the purposes of studies conducted for the prequalification of ITNs, negative controls should be untreated netting samples or constructed ITNs made of polyethylene or polyester. The material of the negative control should be matched to the material of the ITN under investigation wherever possible.

The criteria for the acceptance of negative control results must be clearly stated in the study report.

Negative control results must always be presented.

3. Positive controls

The role of the positive control is to give a consistent, quantifiable signal that can be used to validate experimental procedures. The positive control(s) should be selected based on the intent and design of the study, including the selection of method(s), endpoint(s), and species/strains, to support the assessment of the validity of the study. All positive controls should be prequalified products that have an entomological mode of action and combination of AI(s) (if relevant) consistent with the intended entomological mode of action of the product that is under investigation, e.g., a prequalified pyrethroid-PBO ITN should be used as a positive control for a candidate ITN treated with deltamethrin and PBO. In some cases, if the ITN under investigation contains a novel combination of AIs that has not previously been prequalified, the use of two positive controls may be indicated.

It is critical that the selected positive control(s) is used consistently in all studies for data generation.

4. Documentation of source and storage conditions

The source from which reference items are obtained can influence the results obtained when the items are used in subsequent studies, particularly if the items are obtained from sources that have undocumented and/or uncontrolled storage conditions. It is recommended that reference items are obtained directly from manufacturers.

Reference items should undergo a baseline quality check prior to use in studies to confirm that the items are within specification and to aid with the interpretation of study results. Details of how to perform the baseline quality check are contained in relevant implementation guidance study and method documents.

The means by which reference items were obtained, the number of items obtained, batch numbers, and storage conditions after receipt should be documented and reported, and the certificate of conformity provided.

5. Related documents

- [WHO PQT/VCP Implementation guidance – Regeneration study for ITN fabric](#)
- [WHO PQT/VCP Implementation guidance – Wash resistance study for ITN fabric](#)
- [WHO PQT/VCP Implementation guidance – Semi-field studies for ITNs](#)
- [WHO PQT/VCP Implementation guidance – Long-term community studies](#)
- [WHO PQT/VCP Implementation guidance – Bioassay methods for ITNs: Cone test](#)
- [WHO PQT/VCP Implementation guidance – Bioassay methods for ITNs: Tunnel test](#)
- [WHO PQT/VCP Implementation guidance – Bioassays and semi-field methods for ITNs: IACT](#)
- [WHO PQT/VCP Implementation guidance – Semi-field methods for ITNs: Experimental hut tests](#)