



## PROCEDURE FOR THE EVALUATION OF HIV, HBV & HCV DIAGNOSTIC TESTS DEPARTMENT OF BLOOD SAFETY AND CLINICAL TECHNOLOGY, WHO, GENEVA

**Background.** The objective of the evaluations conducted by WHO is to assess the major operational characteristics of commercially available diagnostic assays for the purpose of advising the governments of WHO Member States and other UN agencies, non-governmental organizations and other parties on these issues. The Department of Blood Safety and Clinical Technology (BCT) coordinates the evaluations of the assays. The practical laboratory work involved is carried out by the WHO Collaborating Centre. Simple and Rapid diagnostic devices have been given priority, as information on these devices is in great demand from WHO member states, and particularly from countries with limited infrastructure. However, we also schedule evaluations of ELISA kits throughout each year.

**Procedure.** The procedure has several steps which are set out below.

**1. Formal request.**

The manufacturer or a third party (with the agreement of the manufacturer) requests a formal WHO evaluation of their test kit. Following requests that do not originate from the manufacturer, WHO requires written authorization from the manufacturer for the evaluation to proceed.

**2. Information to be provided to WHO.**

Along with your request to have your test kit evaluated, WHO initially requires the following information on your test kit:

1. A copy of the package insert
2. Accreditation documentation (i.e. GMP certificates) or a license issued by a well-known regulatory authority
3. Data on the performance of the assay from centres of excellence independent of the manufacturer (or third party) .

**3. Review of information by WHO.**

Once a request from a manufacturer (or third party) and information on the kit is received at WHO it is reviewed and if it is appropriate for WHO to evaluate that diagnostic device a Letter of Agreement is drawn up and sent to the manufacturer (or third party).

**4. Letter of Agreement.**

WHO will send a Letter of Agreement and a Request for Evaluation form to the manufacturer (or third party), which also contains information regarding the deposit of the fee for the evaluation (US\$6000 per assay). The manufacturer (or third party) must sign and return the Request for Evaluation form to WHO and deposit the appropriate fee into the WHO account.

**5. WHO Collaborating Centre.**

On clearance of the evaluation fee, WHO will authorise the Collaborating Centre to contact the manufacturer (or third party) to request the dispatch of the test kits and to give precise details for their delivery. The manufacturer (or third party) is required to provide the kits Free Domicile.

The manufacturer (or third party) is free to visit the Collaborating Centre to provide any information and/or training and ensure that the test is carried out according to the instructions.

At the Collaborating Centre, the preliminary assessment (phase I) will use a panel of approximately 400 sera for HIV evaluations and approximately 300 sera each for Hepatitis B and Hepatitis C evaluations. The specimens contained in the panels are of diverse geographical origin. Commercial seroconversion and/or performance panels (BBI) will also be included in the evaluation. Operational characteristics, eg ease of use, storage requirements, equipment required etc, will also be assessed.

**6. Test kit evaluation report.**

On completion of the evaluation, a draft evaluation report is prepared by WHO and sent to the manufacturer for comment. It is requested that the manufacturer's comments on the report should be received by WHO within one month. A final evaluation report will be prepared and forwarded to the manufacturer (or third party) .

**7. Summary reports.**

Data from evaluations are regularly reported in WHO composite summary reports. Manufacturers whose test kits are included in the reports are sent copies. The summary reports are also available through the WHO website, on the BCT webpages.

**8. Bulk Procurement Scheme.**

Manufacturers whose kits meet WHO's criteria are eligible to tender to the WHO bulk procurement scheme. This scheme allows Member States to purchase high quality kits through WHO at a reasonable cost.

For further information please contact one of the following:

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