## Post-market surveillance – how to detect problems for HIV self-testing test kits

- Check the packaging is not damaged.
  - *If any damage – please report as the product may be falsified or defective*.

- Check the expiry date has not passed or been obviously manipulated.
  - *If any evidence of manipulation – please report as the product may be falsified*.

- Check the labelling and make sure the name of the manufacturer and their address are clearly stated.
  - *If these details are not present – please report as the product may be falsified*.

- Read carefully the instructions for use that come within the test kit.

- Conduct test and use a timing device to wait the time indicated by the manufacturer before reading the final result.
  - *If the HIVST test result is invalid*, please report as the product may be defective (or the test procedure may have been unsuccessful).
  - *When a test result is not clearly HIV-negative or clearly HIV-positive, usually because the control line is missing.*

- When you go to a facility for additional testing to determine your HIV status, the result may be different to your self-testing result, for example:
  - HIVST result is positive but additional testing is HIV-negative, or;
  - HIVST result is negative but additional testing is HIV-positive;
  - *When HIVST results are not the same as results of additional testing at health facility (i.e. are discrepant), please report this to staff at the testing facility.*

1 When a test result is not clearly HIV-negative or clearly HIV-positive, usually because the control line is missing.
Post-market surveillance – how to report problems for HIV self-testing test kits

When to report a problem?
When any of the following occurs or might have occurred:

Happened to me
- False negative test result
- False positive test result

Happened to the test kit
- Invalid test result (not HIV-negative or not HIV-positive as control line is missing)
- Damaged packaging, e.g. foil pouch, buffer bottle, desiccant.
- Missing components, e.g. transfer device, instructions for use.

Note: This is not an exhaustive list, report any issue that you suspect might affect the test result.

What to report?
Document exactly what happened, for example:
- When, where, and from whom you received the test kit;
- How did you store the test kit until you used it;
- When did you open the packaging to conduct the test;
- What is the lot number/expiry date (take a photograph of labelling);
- Describe exactly what happened;
- If the result of the test was invalid or you can’t interpret it, take a photograph of the test.

Who to report to?
Report as soon as you can so that the manufacturer can start their investigation.
- Return to the place where you received/bought the test kit with details as per “what to report”;
- They will report to the manufacturer, and to the national regulatory authority in your country.
- Use WHO’s complaint form http://www.who.int/diagnostics_laboratory/postmarket/en/

What next?
Assist with the manufacturer’s investigation
- Retain the test kit, any consumables such as the buffer vial, and its packaging including the labelling. Put into a plastic bag or a box, and label with date and contents;
- Be ready to send the test kit back to the local distributor, along with the photographs.

Act on field safety notices
- There may be certain changes to the product or the labelling such as the test procedure.
- There may be a recall of the affected product, usually restricted to certain lots of product.

Where do I find any current product alerts for test kits intended for HIV self-testing?
http://www.who.int/diagnostics_laboratory/procurement/complaints/en/