World Health Organization

# 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[1], 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.

***You can report any complaint back to the place where you received the test kit.**
**This distributor will then report all categories of complaints to the IVD manufacturer, and they will, for certain categories, report to WHO.**

# 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/

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