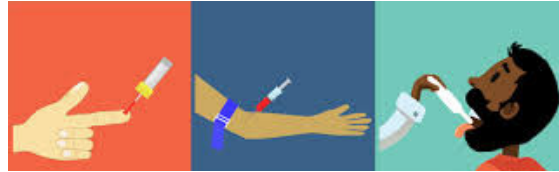


WHO's guidance on post-market surveillance for HIV self-testing

WHO's department of Essential Medicines and Health Products supports end-users, including HIV self-testers, to conduct post-market surveillance of in vitro diagnostics (IVDs).



Seminar description:

Post-market surveillance of IVDs is the action of detecting, investigating, and acting on of any issue related **to safety, quality, or performance** of an IVD after it has been placed on the market.

Common complaints that should be reported for HIV IVDs for self-testing include:

- false negative test results
- false positive test results
- invalid results (when neither a reactive or non-reactive result can be read)
- defective or missing reagents/consumables that mean the IVD can't be used.

Complaints should be reported back to the location where the HIV self-test was distributed (e.g. pharmacy, health clinic). These complaints are then reported back to the IVD manufacturer for their investigation and corrective action, if needed.

Who should attend?

Testing providers (end-users, including HIV self-testers) and manufacturers of IVDs

When?

Tuesday 11 December at 19: 30 – 21:00 in the Niger/Enugu Room

What will you learn?

- How to use WHO guidance on post-market surveillance of IVDs for HIV self-testing.
- How to report complaints for HIV IVDs used for self-testing.