Quality Management systems for non-laboratory settings – Toolkit

How to document problems with RDTs for post-market surveillance

World Health Organization

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Post-market surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from in vitro diagnostic medical devices (IVDs) that have been placed on the market, and to identify the need to take any action.

Users of IVDs, both healthcare professionals and lay providers, and their clients will be first to notice any problems with RDTs used in non-laboratory settings.

It is critical that users quickly document the problem and report to the manufacturer or local authorised representative. The manufacturer can then investigate by retesting retained samples of the lot, and determining if other users have experienced the same problem with the RDT.

1. How to detect a product problem

False negative or false positive results will be detected if a person is retested, at the same site or a different site, and gets different results with another product.

Quality issues are often an early warning and should be reported to the manufacturer. For example when the buffer bottle contains less volume than expected, it may not lead immediately to a false negative or positive but it may have a health impact if no buffer is left to run the RDT.

IVD problems that should be notified to manufacturers for post-market surveillance	
Factors affecting the patient (safety)	● Any false negative result ● Any false positive result ● Non-reproducible results (on the same product) ● Indicated from results of external quality assessment (proficiency testing) or quality control
Factors affecting the test kit (quality)	● Packaging – damaged, defective, suspect tampering ● Labelling – insufficient instructions for use, illegible ● Sampling – device doesn't collect/transfer specimen ● Liquid – leak, splash ● Environmental – noise, temperature, humidity/moisture, microbial growth, dust affecting functionality ● Increased rate of invalid or unreturnable test results ● Obviously incorrect, inadequate or imprecise result or readings ● Unable to obtain reading

Note: this is not an exhaustive list, any problem for an IVD can be notified to the manufacturer.

2. How to document the product problem
    1. Gather supporting information

- Product details (lot number, expiry date)
- Take photographs of labelling and devices as well as any accessories
- Take and store samples of the affected product (at least one test kit box)
- State when and where the test kits were received
- State how the test kits were stored until use
- Describe exactly what happened; what is the product problem
- If misdiagnosis (false negative, false positive), by providing testing results on other product or reference methods.

3. Who to tell about the product problem

- User/testing provider feedback should be filled. See 6.1.2. User feedback form
- Send to the legal manufacturer (details on test kit label or instructions for use) and local authorized representative.
- Users can inform/copy the national regulator for medical products (and/or national disease programme) for their awareness. But they will need to forward the form onto the manufacturer for the investigation.

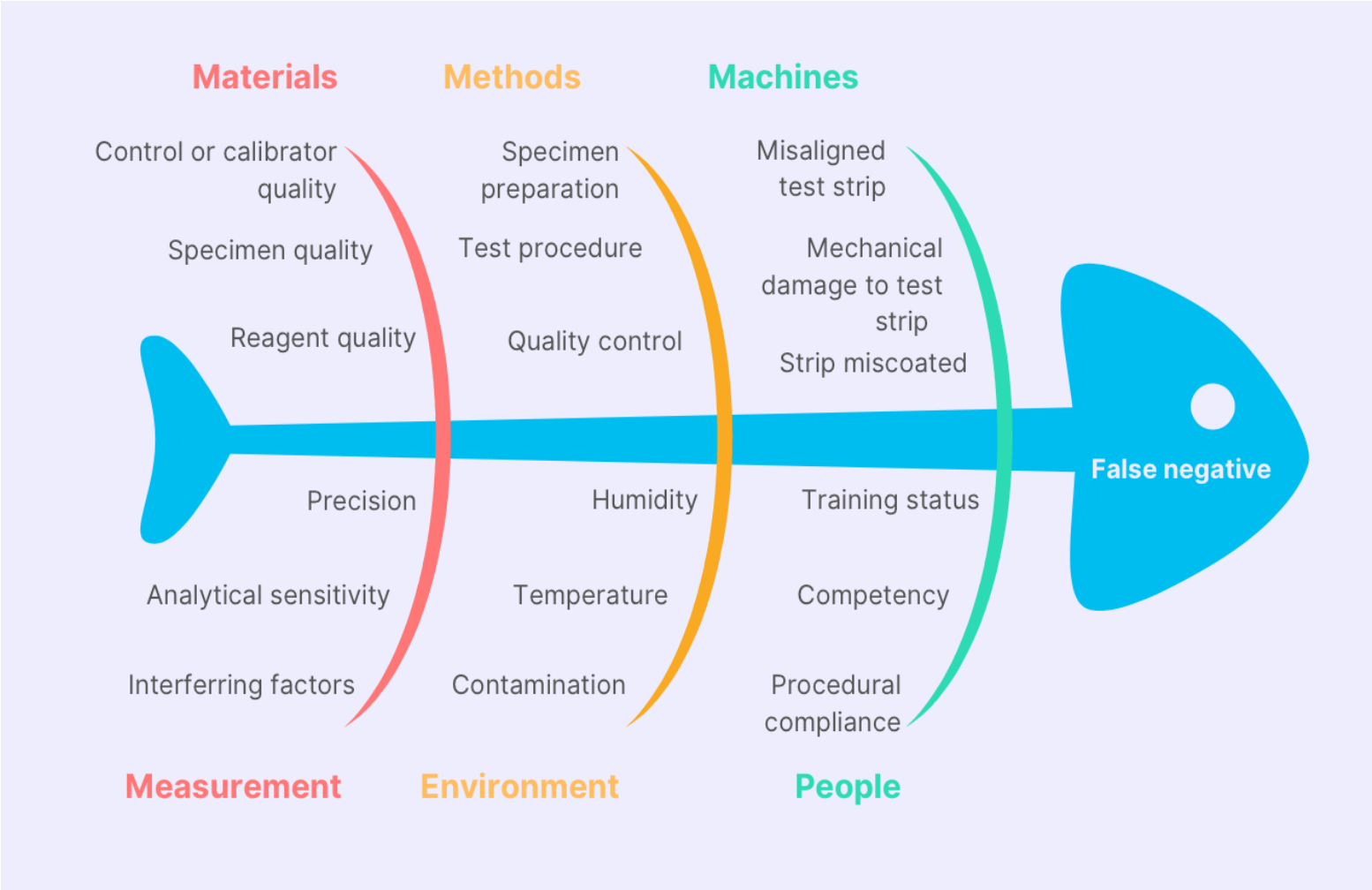
How to investigate problems with RDTs for post-market surveillance

It is the responsibility of the manufacturer to fully investigate any problems reported by users/testing providers.

The manufacturer is best placed to investigate any problems as they know how the product was made, how the components of the product were sourced, if any other users had the same problem with the same lot or same product, etc.

They are expected to investigate and report certain problems/incidents to the national regulatory authority for medical products. An incident report should outline the root cause for the observed problem. A fishbone diagram is a useful way to demonstrate which root causes have been ruled out; with evidence.

The following fishbone diagram is an example for false negative RDT results.



The following potential root causes should be investigated and ruled out so that the definitive root cause can be determined.

- Environment: Focuses on external conditions affecting test performance
- Materials: Covers all reagents and physical components
- Methods: Addresses procedural aspects
- Machines: Relates to equipment and technical issues
- Measurements: Focuses on analytical performance
- Personnel: Covers human factors

For more information: WHO Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics