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HIV SELF-TESTING AFRICA

Determination of OraQuick® HIV self-test result stability with delayed visual re-reading: An external quality assurance analysis

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BACKGROUND

- ❖ Due to the nature of self-testing, conventional quality assurance (QA) methodologies conducted in a professional setting cannot be applied.
- ❖ In the absence of an established external quality assurance (EQA) system to support HIVST implementation, the late re-reading of HIVST devices could contribute to the development of a robust EQA system.
- ❖ Initial research in Malawi found a high level of visual stability on delayed re-reading of OraQuick® kits stored in sub-optimal conditions prior to testing¹.
- ❖ Currently several studies are re-reading used test devices to monitor HIVST self-tester interpretation. There are no available data on the appropriateness of this model.
- ❖ We evaluated the visual stability of late re-reading of used OraQuick® HIVST devices in different environmental conditions after testing to determine whether late re-reading of returned devices may offer a possible external quality assurance approach.

METHODS

- ❖ A panel of 444 OraQuick® HIVST devices (OraSure Technologies, Bethlehem, PA, USA) was established using a plasma matrix comprising HIV reactive (n= 148), HIV weak-reactive [reactive sera diluted 1:16] (n=148) and HIV non-reactive (n=148) results.
- ❖ Kits were read at 20 minutes in accordance with the manufacturer instructions for use, by three independent laboratorians blinded to the initial results and each other. Results were recorded as non reactive, or graded as weak reactive or reactive in comparison to the control line intensity.
- ❖ Devices were incubated for 6 months under four different conditions: temperature low/ humidity low, temperature low/ humidity high, temperature high/ humidity low, temperature high/ humidity high.
- ❖ Baseline defined as 30°C, humidity 20%.
- ❖ Kits were re-read daily for a week (excluding weekends), weekly for a month, and monthly for six months. Consensus between two or more laboratorian re-reads were taken as the true result.
- ❖ Test result transition changes between interpretations were estimated using a multi-stage Markov model.

RESULTS

- ❖ 43/144 'true' non-reactive HIVST devices (29.24%) changed to 'false' weak-reactive result across all conditions. Figures 1 and 2
- ❖ Earliest changes in results were observed on Day 4 (n=9). Figure 2

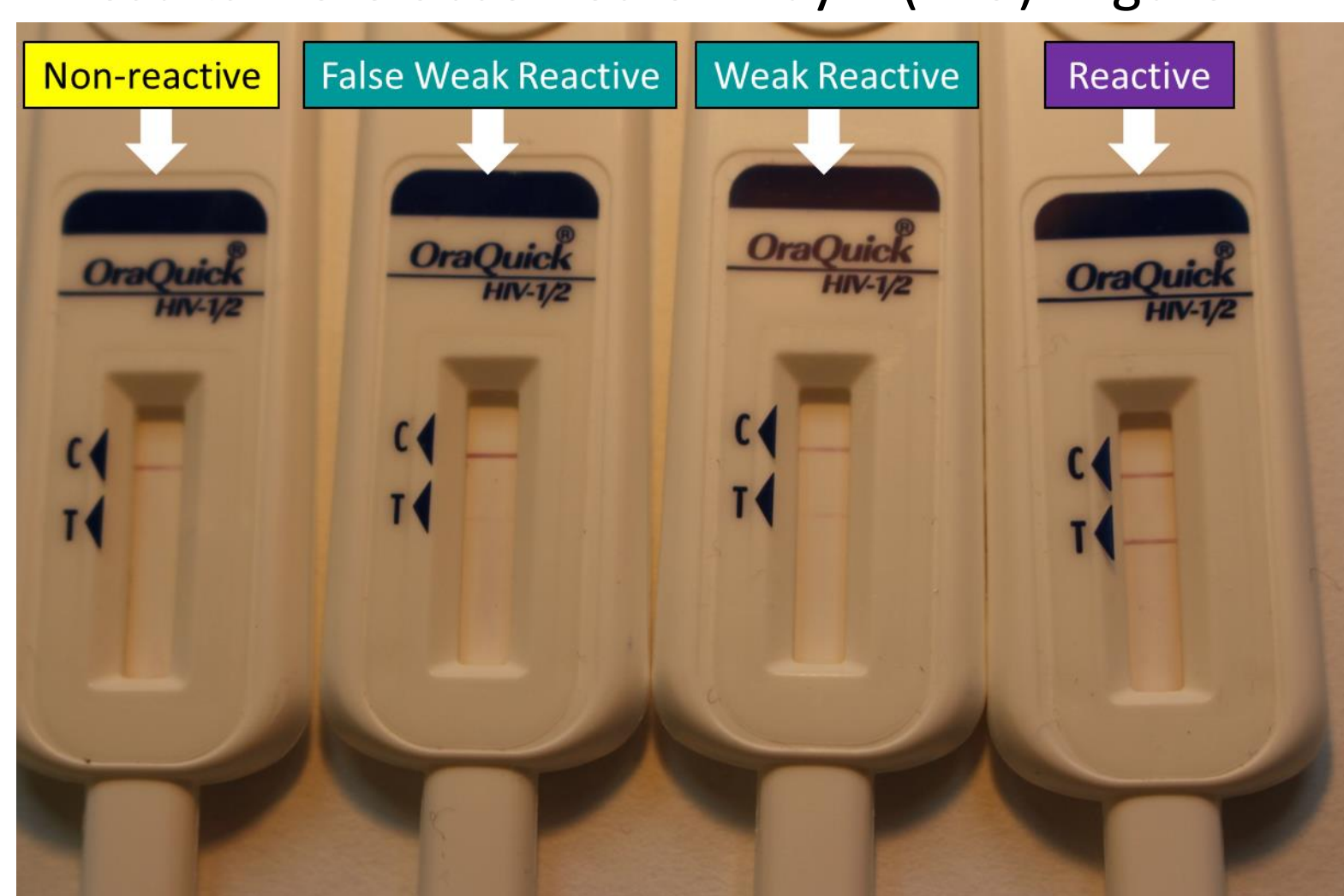


Figure 1. OraQuick HIV self test devices. Re-read result interpretation. False weak reactive were recorded and analysed as a weak reactive result.

- ❖ There was dynamic movement between non-reactive and weak-reactive states over time.
- ❖ No devices with an initial reactive result changed to a non reactive. Figure 2.

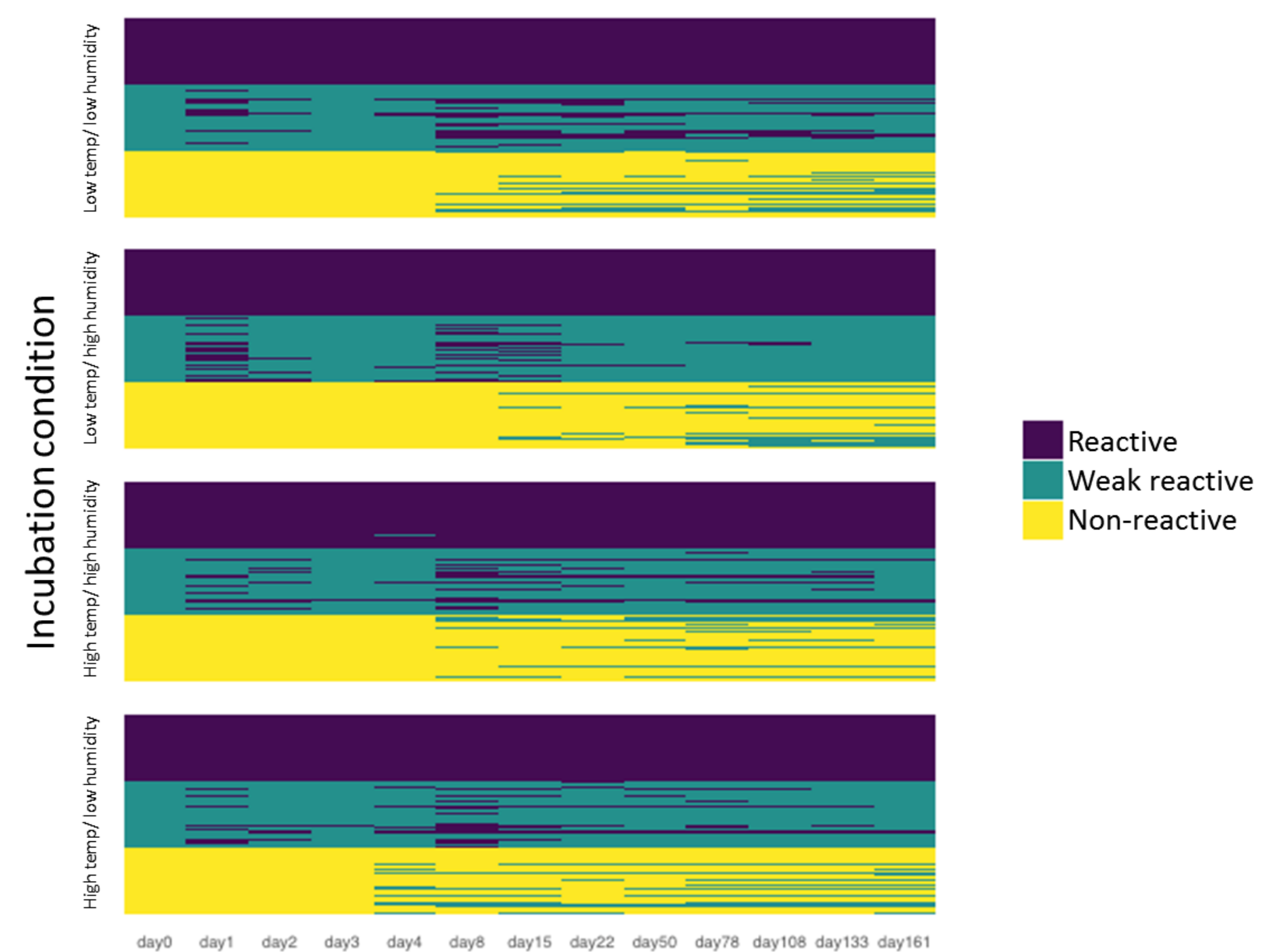


Figure 2. Heat map to illustrate the transitions of re-read result change over the study period. The incidence of false reactive is highlighted here as a 'green' (weak reactive) result against the yellow (non-reactive) conditions.

- ❖ No statistically significant differences in the hazard of transition between storage conditions for any group when compared to baseline conditions. Figure 3.

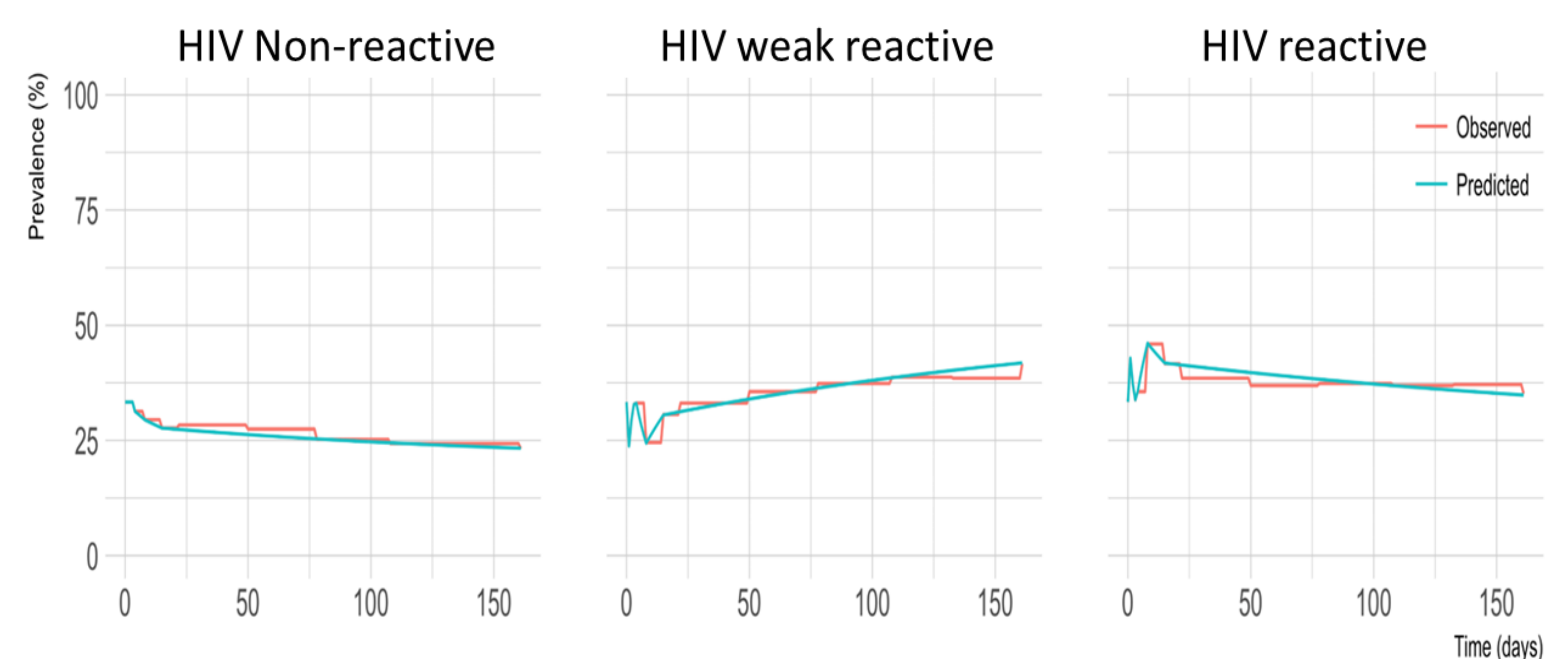


Figure 3. Observed and predicted changes in HIVST re-read status. Red lines are observed values. Blue lines are predicted values from hidden Markov multistage transition model, adjusted for the effect of storage conditions.

CONCLUSION

- ❖ There is a high incidence of OraQuick® HIVST device results changing from 'true non-reactive' to 'false weak reactive' results over 6-months, making late re-reading at this stage an inaccurate option for EQA monitoring.
- ❖ These changes not only require a more nuanced approach to EQA models but also have the potential to cause misinterpretation and misunderstanding to self-testers who do not dispose of their HIVST device immediately after testing.

- ❖ Programmes scaling up the use of HIVST, need to ensure clear messages are disseminated about read times to avoid confusion among self-testers who fail to dispose of their test device.
- ❖ Studies using returned used HIVST devices for 'late' visual re-reading for the monitoring of HIVST test results, may overestimate the true HIV positivity prevalence in a testing population.

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