AN IMPLEMENTABLE AND SUSTAINABLE QUALITY ASSURANCE PROGRAM FOR OV16 SEROLOGY-BASED RAPID TESTS

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BACKGROUND

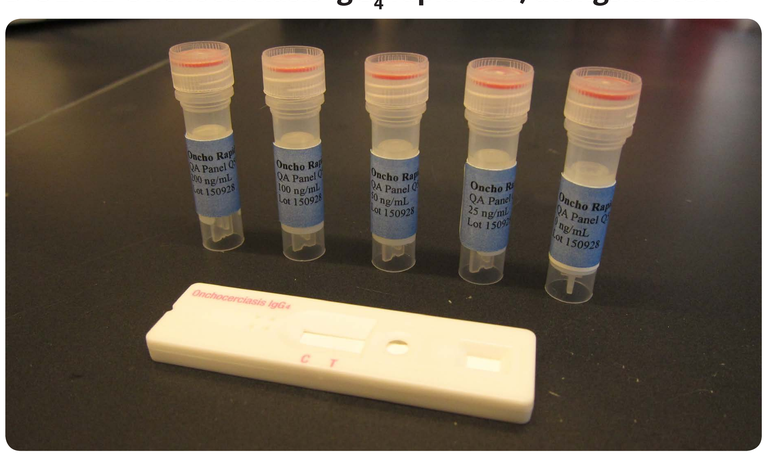
The availability of an Ov16 serology-based rapid test has highlighted important issues around uptake and appropriate use. The commercial availability of a rapid test does not guarantee high-quality results will be obtained when used by a program. There are many steps involved in selecting a test, how and when testing will occur, performing the test, reporting results, and how the results are used to inform control and elimination programs. At each step of the process, there is the potential that something can go wrong. Confidence in the testing process, including test quality, performance, and accurate results, is important to consider when national onchocerciasis control and elimination programs (NOCPs) use test results for action. A quality assurance (QA) program will help to assure NOCPs that the tests are functioning as intended, results are of high quality, and additionally provide an opportunity for feedback to the test manufacturer.

QA PROGRAM MODULES

Six modules have been developed to support a QA program:

1. **Operator training** to familiarize those involved in the testing process with the proper use of the test.
2. **Operator proficiency** to qualify trained individuals to conduct the test.
3. **Quality assessment** to demonstrate performance with country-specific samples, as necessary.
4. **Lot testing** to confirm that the tests perform as intended when received in-country from the manufacturer.
5. **Quality control** to increase confidence that the test system is working as intended at the point of use.
6. **Post-market surveillance** to monitor the performance of the product during routine use.

Figure 1. **Quality assurance panel tubes for the SD BIOLINE Onchocerciasis IgG_4 rapid test, alongside test.**



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QA TOOLS

In support of the QA program modules, PATH has developed tools to facilitate operator training and proficiency, quality assessment, lot testing, quality control, and post-market surveillance. These tools include training aids—videos, instructional materials, sample panels, and data collection forms; and quality assessment aids—sample panels, quality control samples, and data collection forms. **The quality assurance tools are freely available to NOCP staff from PATH's website or by contacting PATH's offices.** Sample panels were designed to be renewable and sustainable by using a recombinant monoclonal human IgG_4 antibody instead of patient samples. Quality assurance tools are available in English and French and may be translated in additional languages.

Table 1. **Panel specifications for rapid serological test supporting QA program modules 1-3.** The quality assurance tools are freely available to NOCP staff from PATH's website or by contacting PATH's offices.

	Training Panel	Proficiency Panel	QA Panel
Purpose	Teach and inform individual test users how to properly conduct the test.	Provide assurance that the user correctly interprets the test results.	Affirm test performs as intended. Panel should not be prepared by test manufacturer.
Intended user	Individuals who will be collecting samples for testing, conducting the test in the field or laboratory, and/or interpreting results.	Trained individuals who will be collecting samples for testing, conducting the test in the field or laboratory, and/or interpreting results.	Highly trained and proficient operators of the test, generally at the program reference laboratory.
Contents (Panel members)	High to low positive, negative.	Mixture of range of positives and negatives.	Range of positives, very low positive, and negative.
Shipping conditions	Ambient	Ambient	Ambient
Storage conditions	2°C-8°C.	2°C-8°C.	2°C-8°C.
Setting	Conducted where the test is intended to be used, or as close to this as possible.	Conducted either in a controlled laboratory setting or where test is intended to be used.	Conducted in a controlled laboratory settings or similar controlled setting.
Recommended use	Training technical personnel in the performance of tests.	Panel is blinded and must be run and read correctly to be qualified as a proficient operator.	Assessment of all lots of tests prior to use.
What happens to results	Results indicate the success of training materials and the ease with which an individual runs the test without error.	Records of operator proficiency assessment should be maintained by the program using the tests.	Testing should be 100% complete with expected results before routine testing is conducted. Results are collected over time and used to determine functional issues with the test, including lot variability.

IMPLEMENTING A QA PROGRAM

The guidelines are designed for policymakers and program planners wishing to implement a QA program for an Ov16 serology rapid testing program. The QA program is intended to be utilized by and implemented completely or by module with NOCPs in conjunction with test manufacturers and other key international stakeholders.

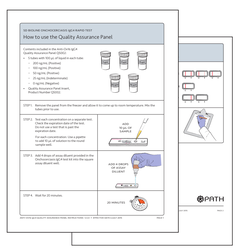
Early adopters of Ov16 serology-based rapid testing have piloted modules of the QA program. Test users were trained by a variety of mechanisms including in-person training, remote training by teleconferences and/or video conferences, and QA program material review. Feedback from QA program implementers has indicated that the methods are acceptable. The feedback is also used to iteratively improve the QA program and will seed future implementation.

Implementation of the QA program or modules by NOCPs should be simultaneous with the adoption of Ov16 rapid testing. The elements and reagents required for such a QA program are presented here. Stakeholder support for the QA program and reliable availability of the sample panels and supplemental materials are needed to make it sustainable.

Figure 2. **Quality Assurance Panel training document for the SD BIOLINE Onchocerciasis IgG_4 rapid test.**

Product inserts for:
- Training Panel
- Proficiency Panel
- Quality Assurance Panel

Instruction materials for:
- Training Panel and results interpretation
- Proficiency Panel and results recording
- Quality Assurance Panel and results recording
- Training video and PowerPoint for SD BIOLINE Onchocerciasis IgG_4 rapid test



CONCLUSIONS

Guidelines for organizing a QA program for Ov16 serological rapid tests are now available for implementation with the adoption of Ov16 rapid testing. Tools to support the test and program are available and have been used by early adopters in NOCPs.

FOR MORE INFORMATION