Understanding the NPAAC *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)*

The NPAAC Tier 4 document *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)* has been recently published. The Requirements set out the minimum requirements for best practice in relation to HPV NAT and gynaecological LBC services by laboratories participating in cervical screening program. The document provides guidance for the additional steps laboratories must take when using HPV NAT alone as a primary screening test in a population of both vaccinated and unvaccinated women and form the basis for laboratory accreditation in this area.

The Introduction of the document provides a background to the changes to the Cervical Cancer Screening Program and the basis for the development of the quality standards. In view of the extent of change, there have inevitably been questions and concerns raised. The following summarises some of the common questions and attempts to provide answers and explanations.

Frequently Asked Questions

Q. S5.5 requires laboratories to compare their rates of HPV detection in screening tests with the rates most recently reported by the NCSR. The current collection medium our lab uses can only be used for LBC for 6 weeks according to the product insert. What if our test numbers fall below 2000 in a 6 week period?

The Standard does not preclude changing to a collection medium with a longer specimen preservation time, possibly facilitated through refrigeration.

It does not preclude a laboratory from validating their current collection medium for a longer specimen preservation time themselves, as long as it complies with the NPAAC *Requirements for the Development and Use of In House In Vitro Diagnostic Devices* and they register the in house IVD with TGA on their list of IVDs.

It does not preclude preparing LBC slides on all specimens and examining them only if HPV positive or on review if required.

There is a recommendation that the comparison should occur at least quarterly so that if laboratories are anticipating very low numbers of screening HPV NAT, consideration should be given to referring these out to another laboratory as a send away test.

Q. S5.5. Why was this standard included?

The change to HPV NAT as the primary screening test is a pioneering initiative without a history of its use as a single screening test internationally. Whilst the requirement for assessing positivity of a minimum of 2000 samples is based on a large scale clinical trial, the longitudinal follow up for the trial is not yet complete. It is possible to monitor test performance at the bench with control material but this would not monitor the whole screening episode including specimen collection, collection media quality, transport and storage etc. This was determined as the best available measure of overall performance for HPV detection in the current setting.

Q. S5.5. How was the 2000 number arrived at?

This was derived as the number of tests needed to reach a statistically robust sample of screening results tests based on best available evidence which was the HPV incidence in preliminary data from the COMPASS trial of Australian women. If a smaller number of samples were to be used there would be an increased risk of a sample set falling outside of the acceptable positivity rate and therefore have the potential to cause increased retesting by laboratories.

Q. S5.5. What will happen when test numbers fall to a low level in 2 years because of the change to a 5 year screening interval?

It is planned to begin a review of the Standards in 2018 which will include reviewing the effectiveness of this quality measure informed by the very large body of data which will accumulate in the first months of testing in the real environment of the Screening Program in operation. This should guide the Standard development to cover the period of low volume testing.

Q. S5.5. Our lab only does diagnostic testing, do we have to do this?

The Standard only applies to HPV NAT as a routine screening episode, not symptomatic women, test of cure, self collected tests etc.

Q. S5.5 Must the minimum 2000 test volume be tested in the same laboratory ie a single site?

Yes. This measure was intended to monitor performance of each testing laboratory, similar to the Performance Measures for Cytology in the current Cervical Screening Program.

Q. To which of the reports from the NSCP on the national positivity rate do we compare the positivity rate of the 2000 samples tested in our laboratory?

The NCSR is currently working on developing a tool which would allow laboratories to enter their data and assess it against the most current NCSR data. The NCSR will normally collate data every quarter but for the first quarter of the new program data will be made available monthly with the first batch of positivity data to available in December, 2017

Q. If our detection rate is out of range do we have to retest immediately?

The laboratory should first follow the procedures set out in Appendix A.

Q. What if the positivity rate is higher than the NSCP national average?

The occurrence should be reported to the NCSP Quality and Safety Committee but there would not be a requirement for immediate action by the laboratory. The Committee was more concerned about false negative tests occurring in the context of a longer screening interval of 5 years. Women who have a positive HPV test will have had reflex LBC +/- colposcopy but will not have a definitive clinical intervention unless an actual abnormality is confirmed. A persistent high level of positivity could be investigated and compared to the HPV NAT user group.

Q. Is there guidance on performance measures for diagnostic tests – is there some information available?

The NPAAC drafting committee considered this but the HPV and LBC positivity rates for women in the diagnostic setting are influenced by many clinical and treatment related factors and the detection rate would give little indication of laboratory performance.

Q. What quality measures are in place for self collected tests?

This again is a pioneering initiative within the NCSP and will be carefully monitored by the Quality and Safety Committee of the NCSP. Performance Measures may be developed later when there is sufficient data to support them.

Q. How will NSCP establish the initial reference value against which the laboratory's positivity rate is compared?

The NCSR will examine the rates within the first 4 weeks of the Program in operation and determine this figure.