

1. Purpose

This document is for Laboratory personnel comparing Human Papillomavirus (HPV) detection rates for the National Cancer Screening Register (NCSR).

2. Background

One of the key elements of quality assessment for the National Cervical Screening Program is to routinely assess the laboratory's HPV detection rate ('positivity rate') and unsatisfactory rate.

Action 3.02 from [Requirements for cervical screening \(Second edition 2024\)](#) is as follows:

The laboratory has process to review its Human Papillomavirus 16, 18 and non 16 or 18 detection rates at least quarterly and:

1. Monitor the positivity rate and the unsatisfactory rate for clinician-collected and self-collected specimens
2. Benchmark its rates against current rates reported from the National Cancer Screening Register

Further details about how laboratories should fulfill this requirement are in the NCSP Guidelines for Handling HPV Detection Rates document.

This document outlines the steps laboratories are required to routinely undertake HPV positivity monitoring of screening tests, using rates reported by the NCSR for internal benchmarking purposes, and undertake

investigations if rates fall outside the 99% confidence interval reported by the Register.

As per the NCSP Guidelines for handling HPV Detection rates, the benchmark for unsatisfactory rates for clinician-collected specimens is in line with the numerical standard for Program Indicator 1 – **see Appendix 1: Program Indicators of the Requirements for cervical screening (Second edition 2024):**

The percentage of clinician collected laboratory specimens that are reported as unsatisfactory for HPV NAT testing should not exceed 0.5%.

The unsatisfactory rate for self-collected specimens is for monitoring only, as these are largely influenced by factors outside laboratory control.

The Register produces overall and stratified benchmarks for the positivity rates which will allow laboratories to assess their positivity rates against National averages. The rates are reported for clinician-collected and self-collected specimens separately.

The calculation of the HPV positivity rate will include all satisfactory screening samples for a given collection method, with the rate being defined as:

$$\text{HPV Detection Rate} = \frac{\text{Number of HPC positive screening tests}}{\text{Total number of satisfactory screening tests}}$$

Where the number of positive screening tests is calculated as the sum of 16/18 positive and other oncogenic HPV types.

3. Work instructions

When you are required to compare HPV detection rates, follow the instructions listed below:

- **Activity Steps 1:** Using the Funnel Plot.
- **Activity Steps 2:** Determining HPV Positivity relative to the Benchmark.
- **Activity Steps 3:** Using the data tables

Activity Steps 1: Using the Funnel Plot

Laboratories should compare the HPV detection rate using the funnel plot provided (see **Figure 1**).

The horizontal line (purple) corresponds to the National Benchmark for HPV positivity.

The red lines indicate the 99% confidence intervals for rates which should be considered significantly higher (above the upper line) and significantly lower (below the lower line).

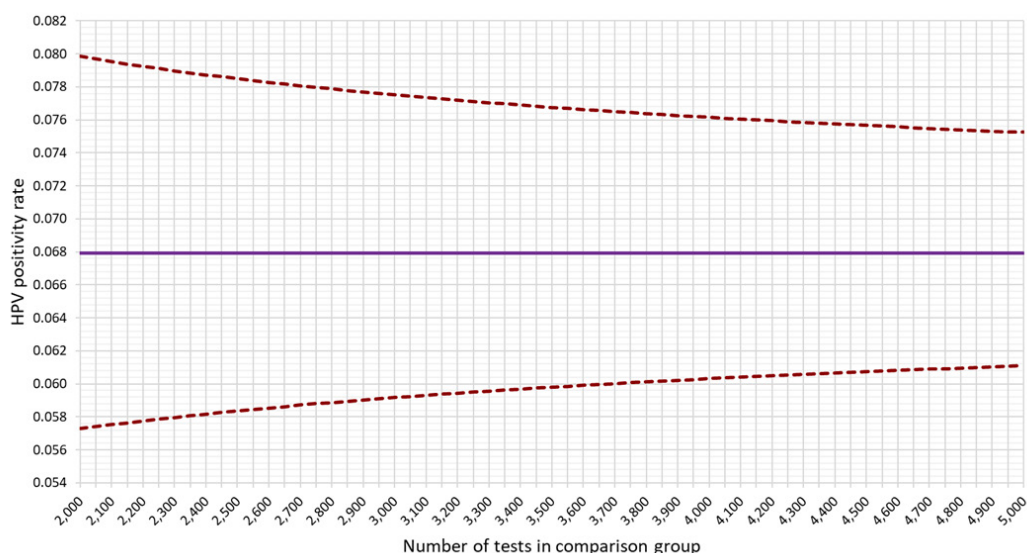


Figure 1: Sample Funnel Plot, National HPV Detection Rate for clinician-collected samples = 0.068 (6.8%)

Activity Steps 2: Determining HPV positivity relative to the benchmark

To use the graph to determine HPV positivity relative to the benchmark:

- Use the X-axis to identify the number of tests in your batch.
- Use the Y-axis to identify the detection rate in your batch.

Where the detection rate falls outside the charted zone, it should be considered to be significantly higher (if above plotted range) or significantly lower (if below the plotted range).

The point which corresponds to the number of tests and detection rate in your batch should be located on the chart (**Figure 2**).

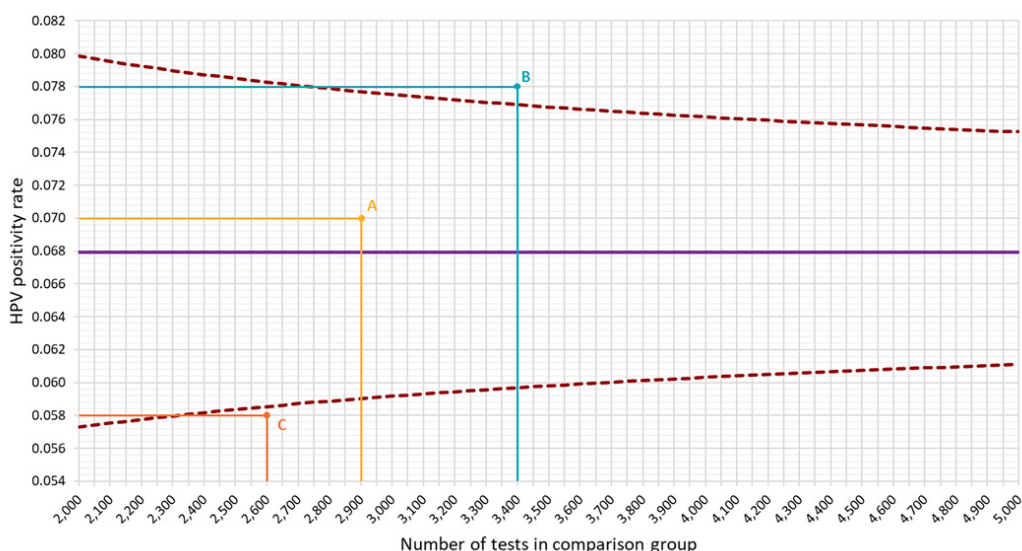


Figure 2: Sample Scenarios for in range, significantly high and significantly low HPV detection rates



If the point falls between the red dashed lines, it should be considered in range and no further action is required

- **Figure 2, Point A:** 2,900 samples in batch, detection rate = 0.070, 7.0%.

If the points falls above the upper dashed line, it should be considered significantly higher than the National Benchmark:

- **Figure 2, Point B:** 3,400 samples in batch, detection rate = 0.078, 7.8%.

If the point falls below the lower dashed line it should be considered significantly lower than the National Benchmark:

- **Figure 2, Point C:** 2,600 samples in batch, detection rate = 0.058, 5.8%.

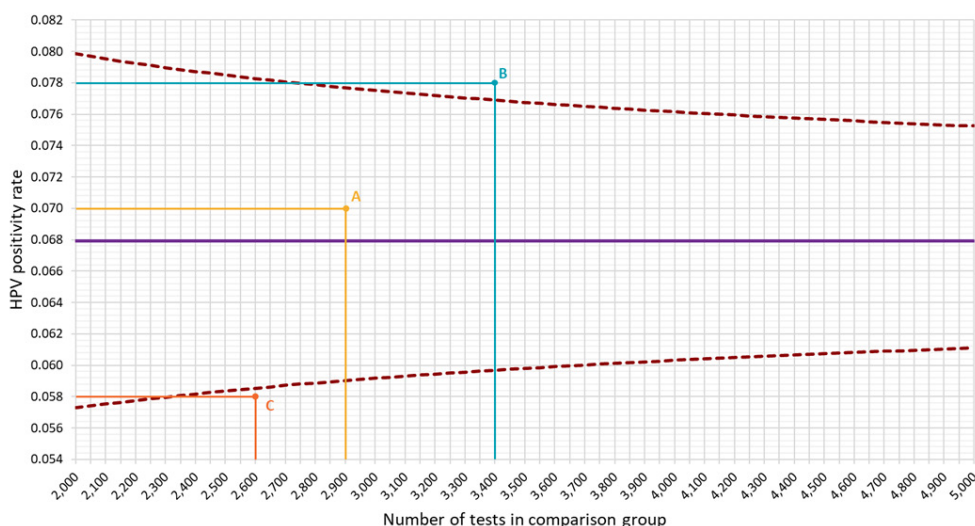


Figure 2: Sample Scenarios for in range, significantly high and significantly low HPV detection rates

Where a point is significantly higher or lower than the benchmark, action should be taken in accordance with the Guidelines for Handling HPV Detection Rates.

Activity Steps 2: Using the data tables

Use the data tables to determine HPV positivity relative to the benchmark, as described below.

For purposes of automation, or if the point for your batch falls close to the lines, it may be preferable to use the data tables provided.

Laboratories should identify the numbers of samples in their batch using the column 'Sample size'.

The number of samples in the batch is given in increments of 50 – Labs should use the number which corresponds closest to their sample size. For example, if there were 2,135 samples in the batch, the Laboratory should use the limits which correspond to the value of 2150 in the 'Sample size' column.

Laboratories can then compare their detection rate to the lower and upper values in their respective columns.

Detection rates lower than the value in the '99%CI lower limit' column should be considered significantly lower.

Detection rates higher than the value in the '99% CI upper limit' column should be considered significantly higher.

Where a point is significantly higher or lower than the benchmark, action should be taken in accordance with the Guidelines for Handling HPV Detection Rates.

Related documents

- Guidelines for Handling HPV Detection Rates

Definitions

- Human Papillomavirus (HPV): The human papillomavirus (HPV), which is a common infection in females and males, and certain types are spread through sexual contact. In a small number of women or people with a cervix, some types of HPV can cause cell changes that may lead to cervical cancer.