

Purpose

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

Background

One of the key elements of quality assessment for the National Cancer Screening Program is to routinely assess the laboratory's HPV detection rate ('positivity rate'). Laboratories are expected to compare the HPV detection rate in samples of at least 2000 specimens against National benchmarks.

The Register produces overall and stratified benchmarks which will allow laboratories to assess their detection rates against National averages.

The calculation of the HPV detection rate will include all satisfactory screening samples, with the rate being defined as:

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

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

Work instructions

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

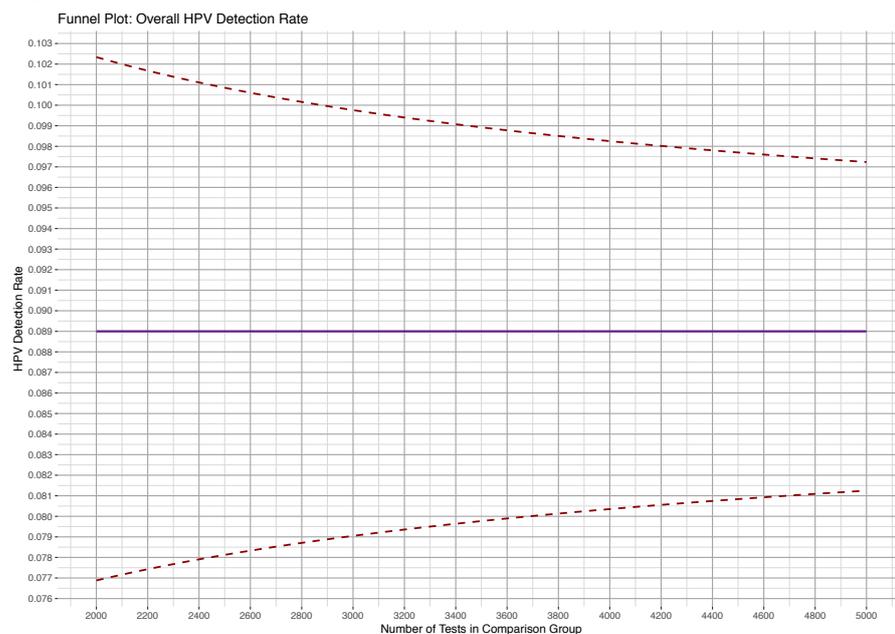
- Activity Steps 1: Using the Funnel Plot.
- Activity Steps 2: Determining HPV Positivity relative to the Benchmark.
- Activity Steps 3: Using the CSV Files.

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 dashed red lines indicate the 95% 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 = 0.089 (8.9%)



Activity Steps 2: Determining HPV positivity relative to the benchmark

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

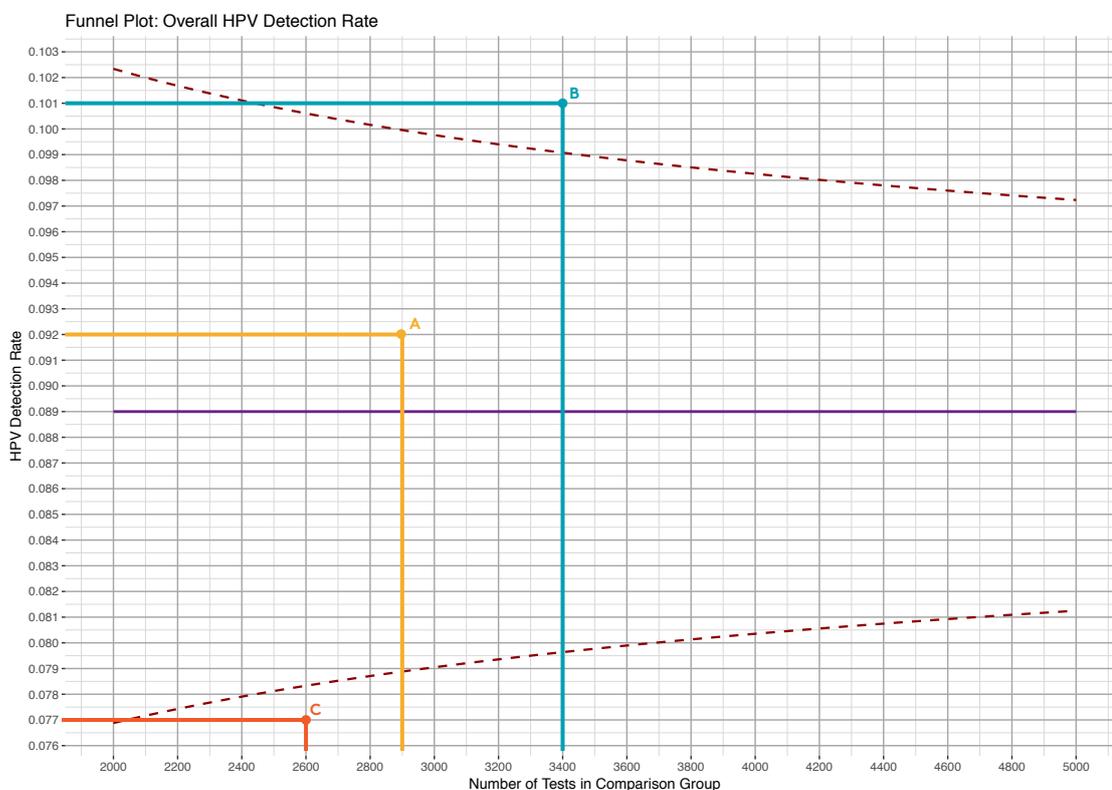
- Use the X-axis to identify the number of tests in your batch.
- Use the Y-axis to identify the detection rate in your batch.

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: 2900 samples in batch, detection rate = 0.092, 9.2%).

If the points falls above the upper dashed line, it should be considered significantly higher than the National Benchmark (Figure 2, Point B: 3400 samples in batch, detection rate = 0.101, 10.1%).

If the point falls below the lower dashed line it should be considered significantly lower than the National Benchmark (Figure 2, Point C: 2600 samples in batch, detection rate = 0.077, 7.7%).

Where a point is significantly higher or lower than the benchmark, action should be taken in accordance with the *Guidelines for Managing the HPV Positivity Rate Quality Assurance Process*.

Activity Steps 3: Using the CSV files

Use the CSV files 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 CSV files provided.

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

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 was 2135 samples in the batch, the Laboratory should use the limits which correspond to the value of 2150 in the 'SampleSize' 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 'lower' column should be considered significantly lower. Detection rates higher than the value in the 'upper' 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 Managing the HPV Positivity Rate Quality Assurance Process*.

Related documents

Refer to the related documents, as required.

- Guidelines for Managing the HPV Positivity Rate Quality Assurance Process: <https://www.ncsr.gov.au/content/ncsr/en/hpv-positivity-rates.html>

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, some types of HPV can cause cell changes that may lead to cervical cancer.