en

*care*HPV® Test Training Panel

Intended Use

For laboratory training purposes only.

Not for use in diagnostic procedures.

The *care*HPV Test Training Panel (known as the training panel) is intended for use in conjunction with the *care*HPV Test, which is a chemiluminescent test for the qualitative detection of human papillomavirus (HPV) DNA in cervical or vaginal specimens. The training panel provides a source of characterized samples for laboratory training.

Summary and Explanation

The training panel is designed as an aid to train and validate new users on the proper techniques and procedures required when testing specimens with the *care*HPV Test.
The training panel consists of 8 samples of known concentrations of HPV DNA. These samples are to be tested as specimens with the *care*HPV Test. Because the type of DNA per target is known, the training panel can be used to ensure that predicted results are obtained.

Refer to care*HPV Test Kit Handbook* for detailed instructions on assay performance and procedures.

Principle of the Procedure

The *care*HPV Test uses the same Hybrid Capture® 2 technology developed for the *digene*® HC2 High-Risk HPV DNA Test. The *care*HPV Test is a nucleic acid hybridization assay with signal amplification that uses microplate chemiluminescent detection.

When specimens containing high-risk HPV DNA are present, the HPV DNA hybridizes to complementary RNA from the probe mix. The magnetic microparticle solid support displays anti-DNA:RNA hybrid antibodies that capture the DNA:RNA hybrids, allowing separation and removal of unbound non-specific material. Next, alkaline phosphatase-linked anti-hybrid antibodies are added to bind and detect the captured hybrids. Further washing removes unbound alkaline phosphatase conjugate, leaving alkaline phosphatase that is bound in proportion to the amount of hybridized HPV DNA. Finally, a chemiluminescent substrate is added that is hydrolyzed by the bound alkaline phosphatase to produce light in direct proportion to the amount of alkaline phosphatase present, which correlates with the amount of hybridized HPV DNA present.

The signal produced by the hydrolyzed substrate is measured to give a result in relative light units (RLU) quantified by a luminometer. A RLU value equal to or greater than the cutoff value (CO) means that the specimen contains sufficient amount of high-risk HPV DNA to be considered clinically positive. A RLU value below the CO means that the specimen contains insufficient or no high-risk HPV DNA and is considered clinically negative.

Materials Provided

- 4 x 1.5 ml *care*HPV Test Training Panel A (TP**A**)
- 4 x 1.5 ml *care*HPV Test Training Panel B (TP**B**)
- 8 *care*HPV Training Brushes
- 1 Instructions For Use (IFU)

Materials Required but Not Provided

- *care*HPV Test Kit
- All materials required as listed in care*HPV Test Kit Handbook* but not provided are required to use this training panel.

Warnings and Precautions

Do not use product if package damaged.

Do not re-use.

Observe all safety precautions stated in care*HPV Test Kit Handbook* when using the training panel.

- Observe all handling precautions as stated in care*HPV Kit Test Handbook* when using the training panel.
- Do not use after the expiration date indicated next to the ⌛ symbol on the package label.
- The training panel samples contain sodium azide, which may react with lead or copper plumbing to form highly explosive metal azide compounds. Upon disposal, flush with large amounts of water.
- Dispose of all training panel samples, reagents and other potentially contaminated materials in accordance with national and local regulations.

*care*HPV Test Training Panel A
Warning! Causes mild skin irritation. If skin irritation occurs: Get medical advice/ attention.

*care*HPV Test Training Panel B
Warning! Causes mild skin irritation. If skin irritation occurs: Get medical advice/ attention.

Reagent Storage and Handling

Upon receipt, store the training panel at 4–25°C. Product stored as directed will retain the expiration date printed on the package label.

Procedure

Important points before starting:

- The training panel samples are handled in a similar manner as patient specimens. The training panel does not contain clinical specimens.
- To simulate specimens, a *care*HPV Training Brush must be inserted into each training panel sample.
- The plate layout of the training panel samples is designed by the trainer and entered onto the *care*HPV Test Data Recording Sheet. Columns 1–5 of the microplate are used, so that 34 wells are used for training panel samples. TPA samples should be added to 26–28 wells and TPB samples should be added randomly and evenly dispersed to 6–8 wells (see Figure 1 for an example layout).

	1	2	3	4	5
A	NC	TP**B**	TP**A**	TP**A**	TP**A**
B	NC	TP**A**	TP**A**	TP**B**	TP**A**
C	NC	TP**A**	TP**A**	TP**A**	TP**A**
D	PC	TP**A**	TP**B**	TP**A**	TP**A**
E	PC	TP**A**	TP**A**	TP**A**	TP**B**
F	PC	TP**B**	TP**A**	TP**A**	TP**A**
G	TP**A**	TP**A**	TP**A**	TP**B**	TP**A**
H	TP**B**	TP**A**	TP**A**	TP**A**	TP**A**

Figure 1. Plate layout for testing a training panel.
NC = Negative control; PC = Positive control;
TP**A** = *care*HPV Test Training Panel A samples;
TP**B** = *care*HPV Test Training Panel B samples.

Preparing specimens:

1. Into each training panel sample, insert one *care*HPV Training Brush, snap off the shaft at the score line and cap the tube securely.
2. Arrange the training panel samples in a foam specimen tube rack, alternating between Sample A and Sample B.
3. Number each pair of A and B samples consecutively to give them a unique ID for tracking (see Figure 1) and enter the IDs on the Assay Data Recording Sheet (refer to care*HPV Test Kit Handbook*).

To validate that a trainee can perform the *care*HPV Test:

1. The trainer prepares the training panel and performs a demonstration of the *care*HPV Test for the trainee.
2. The trainee prepares the training panel and performs the *care*HPV Test while the trainer observes.
3. The trainee prepares the training panel and performs two *care*HPV Test runs without assistance from the trainer.

Interpretation of Results

The interpretation of results and assay calibration verification must be performed as described in care*HPV Test Kit Handbook* prior to analyzing the results of the training panel.

To validate performance of the *care*HPV Test, the trainee's results must have a 94% agreement (no more than 2 discrepant results) between the observed results and the expected results.

The expected results of the training panel samples are as follows:

Traning panel sample	Concentration of HPV DNA	Expected result
A	0 pg/ml	Negative
B	10 pg/ml	Positive

Limitations

All limitations described in care*HPV Test Kit Handbook* apply to the use of the training panel.

Ordering information

Product	Contents	Cat. no.
*care*HPV Test (96)	Assay reagent kit for detection of 14 high-risk HPV genotypes	614015
*care*HPV Test Training Panel	8 samples of known HPV DNA concentrations and 8 *care*HPV Training Brushes	619029

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN® kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
GERMANY

REF 619029

HB -1924-002 1104860 154043066 10/2016