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IVD CE

REF **PG01003P1**

HPV 2+12

For In Vitro Diagnostic Use

Instruction For Use

Paper copy of insert available upon request

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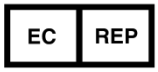
Symbol	Explanation of Symbols
	Manufacturer
	*In Vitro* Diagnostic Medical Device
	Use By
	Batch code
	Reference number
	Date of manufacture
	Temperature limitation
	Sufficient for
	Biological risks
	Consult instructions for use
	Authorized Representative in the European Community
	CE mark
	Keep away from sunlight

Intended Use

The HPV 2+12 Test is an *in vitro* diagnostic test for the qualitative detection of DNA from Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16 and HPV 18 while concurrently detection the rest of the high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

The HPV 2+12 Test is indicated:

(a) To screen patients 21 years and older with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy

(b) To be used in patients 21 years and older with ASC-US cervical cytology results, to assess the presence or absence of high-risk HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy

(c) In women 30 years and older, the HPV 2+12 Test can be used with cervical cytology to adjunctively screen to assess the presence or absence of high risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

(d) In women 30 years and older, the HPV 2+12 Test can be used to assess the presence or absence of HPV genotypes 16 and 18. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

Cervical specimens that may be tested with the HPV 2+12 Test include the following liquid based collection media and collection device:

Cell preservation solution (REF PF04X011)

Endocervical Brush (REF FP01005)

Warning

This test is not intended for use as a screening device for women under age 30 with normal cervical cytology.

The HPV 2+12 Test is not intended to substitute for regular cervical cytology screening.

The HPV 2+12 Test is not intended for use in determining the need for treatment (i.e. excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV 16/18 positive should be monitored carefully for the development of high-grade cervical dysplasia according to current practice guidelines.
The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, hysterectomy, who are pregnant, or who have other risk factors (e.g. HIV+, immunocompromised, history of STI).
The HPV 2+12 Test is designed to enhance existing methods for the detection of cervical disease and should be used in conjunction with clinical information derived from other diagnostic and screening tests, physical examinations, and full medical history in accordance with appropriate patient management procedures.

SUMMARY AND EXPLANATION OF THE TEST

Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer and its precursor cervical intraepithelial neoplasia (CIN). The presence of HPV has been implicated in greater than 99% of cervical cancers worldwide. HPV is a small, non-enveloped, double-stranded DNA virus, with a genome of approximately 8000 nucleotides. There are more than 118 different types of HPV, and approximately 40 different HPVs that can infect the human anogenital mucosa. However, only a subset of approximately 14 of these types is considered high-risk for the development of cervical cancer and its precursor lesionsa-3. In this document "HPV" means "high risk HPV," except where otherwise noted.

Although persistent infection with high-risk (HR) HPV is a necessary cause of cervical cancer and its precursor lesions, a very small percentage of infections progress to these disease states. Sexually transmitted infection with HPV is extremely common, with estimates of up to 75% of all women experiencing exposure to HPV at some point. However, almost all of infected women will mount an effective immune response and clear the infection within 2 years without any long term health consequences. An infection with any HPV type can produce cervical intraepithelial neoplasia (CIN) although this also usually resolves once the HPV infection has been cleared.

In developed countries with cervical cancer screening programs, the Pap smear has been used since the mid-1950s as the primary tool to detect early precursors to cervical cancer. Although it has decreased the death rates due to cervical cancer dramatically in those countries, the Pap smear and subsequent liquid based cytology methods require interpretation by highly trained cytopathologists and have a high rate of false negatives. Cytological abnormalities are primarily due to infection with HPV; however, various inflammatory or sampling variations can result in false positive cytology results. Triage of an abnormal cytology result involves repeat testing, colposcopy and biopsy. A histologically

confirmed high-grade lesion must be surgically removed in order to prevent the development of invasive cervical cancer.

Papillomavirus is extremely difficult to culture *in vitro* and not all patients infected with HPV have a demonstrable antibody response. Nucleic acid (DNA) testing by PCR is a non-invasive method for determining the presence of a cervical HPV infection. Proper implementation of nucleic acid testing for HPV may increase the sensitivity of cervical cancer screening programs by detecting high-risk lesions earlier in women 30 years and older with NILM (negative for intraepithelial lesion or malignancy) cytology and reducing the need for unnecessary colposcopy and treatment in patients 21 and older with ASC-US cytology.

PRINCIPLES OF THE PROCEDURE

The HPV 2+12 Test is based on PCR amplification of target DNA sequences using both HPV and ß-globin specific complementary primer pairs and real-time detection of cleaved fluorescent-labeled HPV and ß-globin specific oligonucleotide detection probes. The extraction, amplification and detection of ß-globin in the HPV2+12 Test monitors the entire test process. The master mix reagent for the HPV2+12 Test contains primer pairs and probes specific for the 14 high-risk HPV types and ß-globin DNA. The detection of amplified DNA (amplicon) is performed during thermal cycling using oligonucleotide probes labeled with four different fluorescent dyes. The amplified signal from 12 high-risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68), is detected using the same fluorescent dye, while HPV 16, HPV 18 and ß-globin signals are each detected with their own dedicated fluorescent dye.

REAGENTS PROVIDED

Vial Label	Description	Vial Quantity& Reagent Volume
Master Mix	PCR Mix, Primer, Probe	2X500 µL
Positive Control	recombination plasmid with HPV16 target fragment recombination plasmid with HPV18 target fragment recombination plasmid with HPV45 target fragment Human Genome	1X50 µL
Negative Control	Nuclease-free water	1X50 µL

WARNINGS AND PRECAUTIONS

A. FOR *IN VITRO* DIAGNOSTIC USE

B. Do not pipette by mouth.

C. Do not eat, drink or smoke in laboratory work areas. Wear protective disposable gloves, laboratory coats and eye protection when handling specimens and kit reagents. Wash hands thoroughly after handling specimens and test reagents.

D. Avoid microbial and DNA contamination of reagents.

E. Dispose of unused reagents and waste in accordance with country and local regulations.

F. Do not use reagents after their expiration dates.

G. Do not pool reagents.

H. Material Safety Data Sheets (MSDS) are available by request at techsupport@tellgen.com.

J. Specimens should be handled as infectious using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories*- and in the CLSI Document M29-A3.

STORAGE AND HANDLING REQUIREMENTS

A. Store all reagents at -20℃

B. Do not use reagents past expiration date indicated on outside of package.

C. Protect from light.

D. No thaw-freeze for more than 5 times.

E. In transporting the reagent is valid for 4 days at 2-8℃.

F. Once opened, reagent is valid for 7 days at 2-8℃.

G. Prior to use, remove reagents from freezer and allow them to thaw at least 30 minutes at room temperature.

H. Vortex reagents prior to each use.

I. Do not store in frost free freezer.

ADDITIONAL REAGENTS AND MATERIALS

Endocervical Brush (REF FP01005) or other commercial Endocervical Brush.

Cell Preservation Solution (REF PF04X011)

Nucleic Acid Extraction Kit (REF PF03X010)

The Cell preservation solution and Nucleic Acid extraction kit are accessory of HPV 2+12 test kit, not included in HPV 2+12 kit, provided separately.

For other commercial cell preservation solution and DNA extraction kit, customer should make equivalent test prior HPV test process.

MATERIALS REQUIRED BUT NOT PROVIDED

- Biological cabinet
- Real time PCR system
- Vortex mixer
- Real time PCR reaction tubes/plates
- Pipettes (0.5µl – 1000µl)
- Sterile filter tips for micro pipettes
- Sterile microtubes
- Disposable gloves, powderless
- Biohazard waste container
- Refrigerator and freezer
- Tube racks
- Desktop microcentrifuge for "eppendorf" type tubes (RCF max. 16,000 x g)

Compatible Instruments:

Open real time PCR machine with channels FAM,VIC/HEX,ROX/CY5,i.e ABI 7500, Roche 480,etc.

SPECIMEN COLLECTION, TRANSPORT, STORAGE

The importance of proper specimen collection and submission cannot be overemphasized. At least one half to two thirds of false negatives are the result of patient conditions present at the time of sample collection and submission and the skill and knowledge of the individual who obtains the specimen.

To optimize collection conditions, a woman should:

1. Schedule an appointment approximately two weeks (10-18 days) after the first day of her last menstrual period.
2. Not douche 48 hours prior to the test.
3. Not use tampons, birth control foams, jellies or other vaginal creams or vaginal medications for 48 hours prior to the test.
4. Refrain from intercourse 48 hours prior to the test.

Specimen Collection

A sterile, or single-use bivalve speculum of appropriate size is inserted into the vagina without lubrication. Warm water may be used to facilitate insertion of the speculum. The position of the speculum should allow for complete visualization of the os and ectocervix, wipe away the cervical discharge around the cervix with a cotton swab. Sampling of the

cervix orifice requires insertion of the endocervical brush into the endocervical canal until only the bristles closest to the hand are visible. The brush is rotated 45-90° and slowly drawn out, place it in cell preservation solution; break off the endocervical brush along the fold of the brush handle around the tube mouth, leave the brush head in the cell preservation liquid tube, tighten the tube cap, properly mark the specimen and keep the tube in upright state. Detect the specimen as soon as possible. The specimen in the cell preservation liquid can be stored for seven days at room temperature, two months at 2~8℃ and six months -20℃ or below (no verification data of stability for more than six months); no repeated thawing and froze for more than five times.

Specimen Transport

Cervical specimens collected in cell preservation solution can be transported 2-30℃ in 4 days. Transportation of HPV specimens must comply with country and local regulations for the transport of etiologic agents.

Specimen Storage

Cervical specimen collected in the cell preservation solution can be stored for seven days at room temperature, two months at 2~8℃ and up to six months at -20℃ or below (no verification data of stability for more than six months); no repeated thawing and froze for more than five times.

TEST PROCEDURE

DNA Extraction

DNA should be extracted from Cell Preservation Solution (REF PF04X011) using the Nucleic Acid Extraction Kit (REF PF03X010) or other proper commercial DNA extraction kit.

PCR reagent preparation

a) Take **HPV 2+12** test kit out from the refrigerator, and place them under room temperature for 30mins until they are fully thawed;

b) Prepare PCR reaction tubes according to the number of samples. For example, if there are 16 samples (combined with a positive control and a negative control), then a total of 18 PCR reaction tubes are needed. Properly mark the samples.

Note: Do not mark on the cap of PCR reaction tubes which might influence the collection of fluorescence signal.

Note: Do not wear gloves with talcum powder.

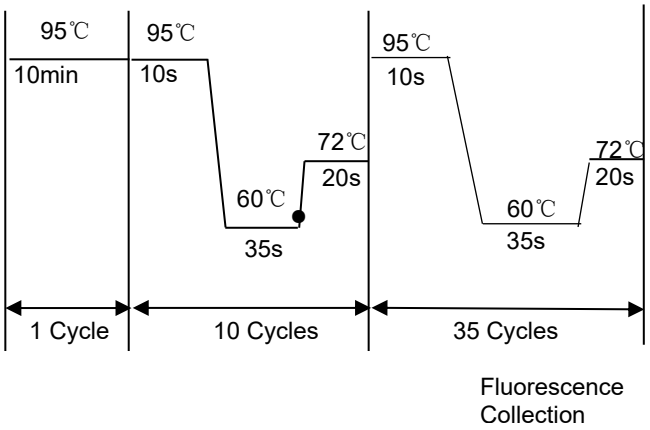
c) Each PCR reaction has a total volume of 25μL, add 5.0μL extracted DNA sample to PCR tube containing 20μL reaction, tighten the cap and slightly flick the bottom of the tube; centrifuge it for 10 seconds at 2,000rpm to concentrate the reaction solution at the bottom of the PCR reaction tube, ensuring that there are no bubbles in the reaction solution.

PCR amplification:

a) Fluorescence channel selection: FAM, HEX/VIC, ROX, Cy5.

(Note: Set "Passive Reference" as "none" for ABI 7500).

b) Setting of amplification procedure:



Note: Some Real Time PCR machines might need to be properly adjusted according to above procedure. For details, please consult Tellgen technical service or local distributor.

Note: It is strongly recommended that no attempt to open the cap of PCR tube after detection, thus to prevent pollutant contamination.

Interpretation of Results

1. Baseline and threshold setting:

Baseline: Adopt the fluorescence signal of 1~5 cycles as the baseline.

Threshold: Set the threshold line exceed the peak of the amplification curve of the negative control, and Ct as Undet (no Ct value).

2. Control:

Ct values of Negative Control should be Undet (no Ct value).

Ct values of Positive Control should be ≤ 30.

3 .Data Analysis:

Fluorescence Channel	VIC	ROX	FAM	CY5
Detection target	HPV16	HPV18	HPV (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68)	β-Globin
CT Value	Undet or >30	Undet or >30	Undet or >30	≤ 32
HPV2+12 test result	HPV 16 Negative	HPV 18 Negative	HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 DNA were undetectable or below the pre-set threshold.	Valid
CT Value	≤30	≤30	≤30	Undet or >32
HPV2+12 test result	HPV 16 Positive	HPV 18 Positive	Specimen is positive for the DNA of any one of, or combination of the following high risk HPV types: 16, 18, 31, 33, 35, 39, 45, 51, 52. 56. 58, 59, 66, 68.	Results are invalid. Original specimen should be re-tested to obtain valid result

Note: A negative result does not preclude the presence of HPV infection because results depend on adequate specimen collection, absence of inhibitors and sufficient DNA to be detected.

4. It should be positive for any specimen resulting with CT≤ 5 or re-test the specimen after 100 folds dilution.

Quality Control

External Control

Negative Control

The Negative Control must be run on each test and results must be 'Valid'.

Positive Control

The Positive Control must be run on each test and results must be 'Valid'.

Internal Control

The concurrent extraction, amplification and detection of β-globin in the **HPV 2+12** Test monitors the entire test process. The results for each specimen must be positive.

Limitations

1. The HPV2+12 Test detects DNA of the high-risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. This test does not detect DNA of HPV low-risk types (e.g. 6, 11, 42, 43, 44) since there is no clinical utility for testing of low-risk HPV types.
2. The HPV 2+12 Test for detection of human papillomavirus types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 is not recommended for evaluation of suspected sexual abuse.
3. Test only the indicated specimen type. The HPV 2+12 Test has only been validated for use with cervical specimens collected in Cell preservation solution using endocervical brush.
4. Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances.
5. Prevalence of HPV infection in a population may affect performance. Positive predictive values decrease when testing populations with low prevalence or individuals with no risk of infection.
6. Infection with HPV is not an indicator of cytologic HSIL or underlying high-grade CIN, nor does it imply that CIN2-3 or cancer will develop. Most women infected with one or more high-risk HPV types do not develop CIN2-3 or cancer.
7. A negative high-risk HPV result does not exclude the possibility of future cytologic HSIL or underlying CIN2-3 or cancer.
8. β-globin amplification and detection is included in the HPV2+12 Test to differentiate HPV negative specimens from those that do not exhibit HPV signal due to insufficient cell mass in the specimen. All HPV negative specimens must have a valid β-globin signal within a pre-defined range to be identified as valid negatives by the real time PCR system.
9. Reliable results are dependent on adequate specimen collection, transport, storage and processing. Follow the procedures in this package insert.
10. Good laboratory practices and careful adherence to the procedures specified in this package Insert are necessary to avoid contamination of reagents.
11. Use of this product must be limited to personnel trained in the techniques of PCR and the use of the real time PCR system.

12. Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology differences.

13. The effects of other potential variables such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables have not been evaluated.

14. Though rare, mutations within the highly conserved regions of the genomic DNA of Human papillomavirus covered by the HPV 2+12 Test's primers and/or probes may result in failure to detect the presence of the viral DNA.

15. The presence of PCR inhibitors may cause false negative or invalid results.

16. Cervical specimens often show visibly detectable levels of whole blood as a pink or light brown coloration. These specimens are processed normally on the compatible real time PCR system. If concentrations of whole blood exceeds 2.5% (dark red or brown coloration) in Tellgen's Cell preservation solution, there is a likelihood of obtaining a false-negative result. The HPV 2+12 Test performance has not been validated with Tellgen Cell preservation solution specimens which have been treated with glacial acetic acid for removal of red blood cells. Any such processing of Tellgen Cell preservation solution specimens prior to HPV testing would invalidate the HPV 2+12 Test results.

17. Cross-contamination of samples can cause false positive results.

Performance Characteristics

1. Detection of national reference panel: Using the complete Human Papillomavirus genome genotyping national reference panel (360003-201101) as the detection reference panel, Tellgen provide the HPV 39, HPV 51,HPV 52,HPV 56 and HPV 68 as the positive control. The detection results of product appearance, CT value of Internal control, coincidence rate of positive control, coincidence rate of negative control, reproducibility, the limit of detection and positive and negative control all conform with regulations.

2. Appearance: All components shall be complete, intact, no liquid leakage; packaging and labelling should be clear and legible; the amount of each component not less than the label indicated loading volume.

3. CT value of Internal Control: Less than 32.

4. Coincidence rate of positive control: The national genotyping reference panel or standardized enterprise genotyping control (concentration as 500copies/test) is used for the detection of 14 HPV types within the detection range of the kit (HPV16, 18, 31,

33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68), and the results are positive and corresponding HPV types are correct.

5. Coincidence rate of negative control:

   a) The national genotyping reference panel or standardized enterprise genotyping control exclusive the detection range of kit is used for the detection of kit, no cross reaction in high-risk HPV genotypes and the cross reaction rate of low-risk types should be no higher than 10.0%.

   b) The national negative reference panel or standardized enterprise negative control is used for detection purpose, and the results of various HPV types are all negative.

6. Reproducibility: The references of high-risk types HPV16, HPV18 and HPV45 (concentrations all set at 100copies/test and 500copies/test) are respectively detected repeatedly for ten times, and the results of corresponding HPV types are all positive and the variation coefficient of Ct value (CV,%)≤5%.

7. Limit of Detection (LoD) : The minimum detection limits of the references of the 14 HPV types within the detection range of the kit (i.e., HPV16, HPV18, HPV (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68)) should be less than 100copies/test.

8. Quality control: In quality control detection, the results of HPV16, HPV18 and HPV45 are positive (Ct value of Internal Control≤32).

9. The performance DNA Nucleic Acid Extraction kit have no distinct difference for the kits between from Tellgen with from other companies.

10. Collection of 14 pathogen positive samples with similar clinical symptoms or from similar or the same sampling sites, then detect them all (i.e., two *Mycoplasma urealytium* samples, two *Chlamydia trachomatis* from genital tract samples, two *Candida albicans* samples, two *Neisseria gonorrhoeae* samples, two trichomonas samples, two mildew samples and two *Gardnerella vaginalis* samples), and the results of various HPV types are all negative; 38 samples whose nucleic acid sequences have homological types are selected from exclusive the detection range of the kit for detection purpose (i.e., one sample each type, specifically including HPV6, HPV11, HPV26, HPV40, HPV42, HPV43, HPV44, HPV53, HPV55, HPV61, HPV81, HPV82, HPV83, HPV54, HPV70, HPV72, HPV73, HPV7, HPV10, HPV28, HPV29, HPV30, HPV32, HPV34, HPV67, HPV71, HPV69, HPV78, HPV2, HPV3, HPV13, HPV27, HPV57, HPV75, HPV74, HPV77, HPV84 and HPV94), and the results of various HPV types are all negative; Collecting four samples using vaginal washing fluids in the recent 1~2 days (i.e., two samples using Jie'eryin Lotion and two samples using Fuyinjie Lotion), four samples using vaginal suppositories in the recent

3~5 days (i.e., two samples using Metronidazole Suppository and two samples using Gyno-Daktarin), four HPV positive samples (i.e., HPV16 positive, HPV 18 positive, HPV33 positive and HPV45 positive, respectively; each sample added with a certain amount of healthy human peripheral blood, make each 200ul sample contains 50ul blood) and two HPV positive fester samples from the hospital (should be HPV16 positive and HPV18 positive detected by the hospital), to detect all above samples and the results of corresponding HPV types are all positive; Conclusion is that the kit has an anti-interference action for drugs, blood and fester and has no non-specificity for the detection of other HPV types or of other relevant pathogens of the genital tract.

11. Also collected three HPV16, HPV18, and HPV45 positive samples, mixed and detected them to check the variation coefficient (CV) between the values of single positive samples and mixed positive samples. The verified CV is ≤5%, which represents that there is no mutual interference among the four fluorescence dyes.

12. DNA sequencing analysis as the reference method to verify HPV 2+12, and using HPVL1 region type-specific primer for sequencing; a comparative study is carried out in three provincial hospitals to detect a total of 1,000 samples. After the third-party verification of non-conforming samples, the Kappa value is 0.94, the specificity is 91%, sensitivity is 100%, the coincidence rate for positive is 100%, the coincidence rate for negative is 99.9%, and the total coincidence rate is 98% for clinical statistics of various types, the 95% confidence intervals of coincidence rate（0.97，0.99）.

    Therein:

    HPV16：Kappa value is 1，Sensitivity is 100%，specificity is 99.9%，coincidence rate is 99.9%，95% confidence intervals of coincidence rate（0.99,1.00）；

    HPV18： Kappa value is 1，Sensitivity is 100%，specificity is 100%，coincidence rate is 100%，95% confidence intervals of coincidence rate（0.99,1.00）；

    12 hrHPV: Kappa value is 0.95，Sensitivity is 100%，specificity is 93%，coincidence rate is 98%，95% confidence intervals of coincidence rate（0.97,0.99）；

    Otherwise, statistical analysis detection results comparing with Tellgenplex® HPV 27 genotyping Assay present after detecting total 200 samples that the Kappa value is 1, coincidence rate of positive is 100%, coincidence rate of negative is 100%, total coincidence rate is 100% in clinical statistics.

Reference

1. The current status of development of prophylactic vaccines against human papillomavirus infection Report of a technical meeting, Geneva, 16-18 February 1999，World Health Organization

2. Carcinogenicity of human papillomavirus, Upcoming meetings June 7-14,2005, WHO International Agency for Research on Cancer

3. Munger K,Howley PM. Human papillomavirus immortalization and transformation functions [J] . Virus Res. 2002; 89:213-228.

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Order Information

Cat No.	Products
PG01003P1	HPV2+12

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