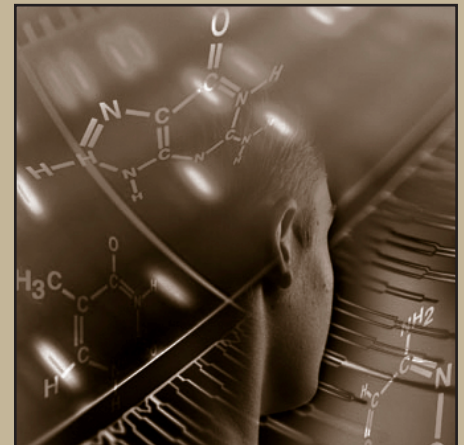
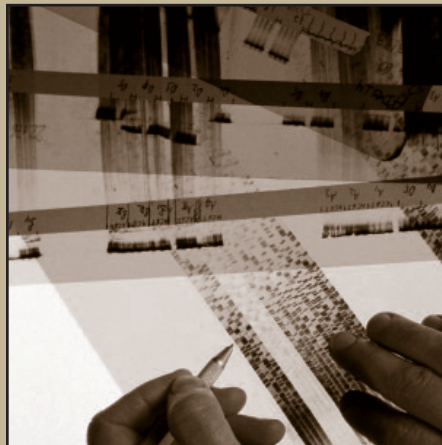
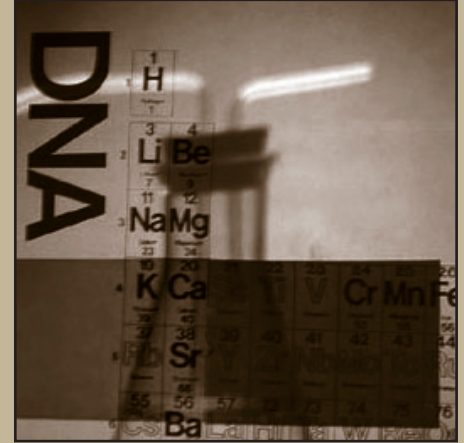
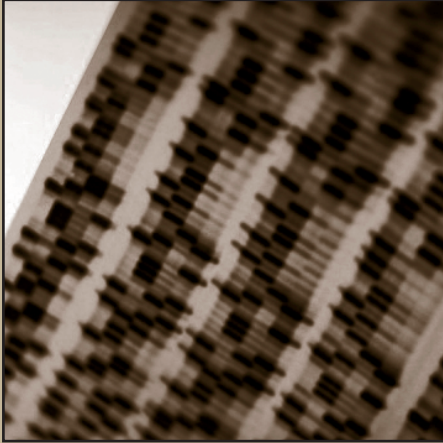



► Genekam Ready to use PCR kits for Human Papilloma viruses (HPV)

Human Papilloma Viruses (HPV)



- High risk group:
HPV-16, 18, 31, 33, 39, 45, 51, 52, 56, 58, 59, 66 and 68
- Low risk group:
HPV-6, 11, 42, 43 and 44
- Other HPV Types: *2, 4 and 7*

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Two steps ahead.

① Human Papilloma Virus (HPV)

SPECIES: Human

SAMPLES: Smears, formalin fixed tissues, genital swabs, biopsies, skin samples, blood (in 70% Ethanol) and other samples

Human Papilloma Viruses (HPV) belong to DNA viruses. There are around more than 100 genotypes of this virus. They cause particularly skin infections. Epidemiological studies clearly demonstrated a high incidence of cutaneous warts on the hands of meat handlers although such warts are considered to be common warts, some of the characteristics may suggest that they are – in part – of a different origin. It has been found that these warts are often difficult to treat and it thought to believe that they develop as a result of transmission of an infectious agent from the meat to hands of meat handler. These warts are usually caused through HPV genotypes 1, 2, 3 and 7. It is considered that HPV may be of animal origin as some studies are indicating the involvement of *bovine papilloma viruses*, but the papilloma viruses are known to be highly species specific and there is no experimental evidence of cross species transmission of these viruses.

HPV causes benign and malignant tumours of skin and mucous membranes. Around 40 different HPV genotypes have been found in anogenital mucosa. They are divided into two groups:

High risk group:

It consists of genotypes: 16, 18, 31, 33, 39, 45, 51, 52, 56, 58, 59, 66 and 68. High risk types are considered oncogenic as they are found in more than 90% of cervical tissues of patients with cervical carcinoma of CIN.

Low risk group:

This consists of genotypes: 6, 11, 42, 43 and 44. They cause only benign lesions.

There are strong experimental and epidemiologic evidences to the theory that HPV plays a key etiological role to develop cervical neoplasia. However the high prevalence of HPV infection relates to the low incidence of invasive cervical cancer and its precursor lesion. Cervical intraepithelial neoplasia (CIN) suggests that vast majority of women infected with HPV at any given time will not develop CIN stage 3 or cancer. Therefore identification factors leading to development of neoplasia needed to be identified. It is well known accepted fact that persistent infection with certain HPV genotypes is one of biggest factor contributing to the development of cervical cancer. These HPV genotypes detected in more than 90% of all cervical cancer cases are non classified as human carcinogen. Because the distribution and prevalence of HPV vary according to the geographical region and prevalence of HPV may vary from region to region. The available vaccine can confer the type specific immunity, therefore the need for HPV genotyping in routine screening population is increased, moreover HPV infection is known to be etiologic for the development of cervical cancers and their precursors, as infection by particular types of HPV increases the risk of developing invasive disease.

HPV-16 is the most prevalent type worldwide. However the second most prevalent is **HPV-18** in western countries, where as in Asia it is **HPV-58**. Multiple HPV genotypes have been reported to occur in 10 to 20% HPV positive cases.

Till today HPV testing has been done with *Pap smear cytology test* for diagnosis of cervical cancers to improve screening sensitivity and negative predictive value. In reality, HPV testing is now recommended for patients with cytological abnormalities based on guidelines issued through world wide recognised institutes. Moreover the importance of HPV-genotyping in diagnostic practices is increasing recognised in distinguishing high risk infections and the development of cancer intervention strategies since vaccine availability. Based on these facts, genotyping of HPV in clinical field is regarded not only as an important diagnostic tool for cervical cancer but also as means providing valuable information necessary for the prevention

As accuracy of the test is one important factor for using Genekam tests, therefore it is decided to offer the tests according to each genotypes against the multiplex testing, where there is chance that test does not detect all genotypes present in the sample

and treatment of HPV. In world, cervical cancer affects more than 400 000 women each year and represents the second most common malignancy found after the breast cancer. Cervical cancer screening with Pap smear has a wide impact on the reduction in the incidence of this disease in developed countries, but the sensitivity of cytological tests vary greatly according to the experience of the cytologists and the type of quality control.

Keeping in mind all above asked discussed issues, Genekam Biotechnology AG has decided to develop most reliable and accurate tests, which are based on PCR technology for detecting the HPV in different kinds of samples. The purpose of these tests are to give the best and most accurate results. Moreover in case of doubt, it is suggested to go for genesequencing. This service is available at extra charges.

As accuracy of the test is one important factor for using Genekam tests, therefore it is decided to offer the tests according to each genotypes against the multiplex testing, where there is chance that test does not detect all genotypes present in the sample (as 10–20% samples carry multiple genotypes): moreover one cannot identify the PCR artefacts during multiplex testing as the number of bands may be too many in one sample, if this sample carries more than two genotypes. This is the case many times occurring in reality. Such type of mistakes can lead to wrong vital data, which lead to wrong diagnosis and ultimately wrong therapeutic and preventive measurements. Such mistakes can end in disaster e.g. If some important institute is carrying first genotype prevalence studies of HPV in a particular on demand of Govt. in a particular country in order to implement the new guidelines to prevent and treat the HPV. Therefore it is recommended to carry these studies with simplex PCR test, which checks each genotype in one test or at least to verify the results with multiplex method. with Genekam single genotype detecting assay. Therefore Genekam Biotechnology AG has decided to offer only most accurate, highly sensitive and specific PCR simplex test. Genekam test is a nested PCR test, which in the first step show common HPV and in 2nd step shows the presence

of HPV group specific tests in order to differentiate this. In this way, one detects single genotype through highly sensitive and specific test. To conduct the Genekam PCR test, one needs isolated DNA. The isolation can be done from different samples e.g. smears, formalin fixed tissues, genital swabs, biopsies, skin samples, blood etc. We recommend strongly to add the samples in 70% ethanol in order to inactivate the infectious material.

Contents of the kit:

- Taq/polymerase ► Buffer solution ► MgCl₂ solution
- Primers ► Positive control ► Negative control
- Loading dye ► Gene ruler (100 bp)
- Manual ► Storage: –20 degree
- Detection will be in gel agarose as gel agarose is quick to make.
- Validation: The PCR kit has been validated for cross reactions with related and non related gene targets. Therefore it will be highly specific. Moreover it has been checked on the samples showing different types of genotypes.

There are two different kinds of HPV kits available from Genekam Biotechnology AG:

❶ To detect the common HPV virus:

It will detect all HPV viruses irrespective of their genotypes. This is double check kit, which detects twice so that one can be sure about the results.

❷ To detect the genotype of HPV:

This kit will be used to detect the genotype e.g. HPV 16 in two steps (called nested PCR). In first step, one will detect the common HPV and in 2nd step, it will detect the specific genotype.

► [List of all HPV-PCR Kits](#)

Keeping in mind all above asked discussed issues, Genekam Biotechnology AG has decided to develop most reliable and accurate tests, which are based on PCR technology for detecting the HPV in different kinds of samples.

▶ **K795 HPV (double check), 100 reactions***

This kit will detect the HPV common in the sample. Therefore it can be used as screening test for all samples to know whether they are positive or negative for HPV. It checks the presence of HPV two times in sample, therefore this is called as double check.

▶ **K796 HPV-2, 100 reactions***

This kit will detect the presence of HPV-2 genotype, which is present in skin lesion usually.

▶ **K797 HPV-4, 100 reactions***

This kit will detect the presence of HPV-4 genotype, which is usually present in the skin lesions e.g. in the hands of butchers.

▶ **K798 HPV-7, 100 reactions***

This kit will detect the presence of HPV-7 genotype, which is usually present in the skin lesions e.g. in the hand of butchers.

▶ **K204 HPV 6/11, 100 reactions***

This kit will detect the presence of HPV-6/11 genotypes, which are present in genital samples. It belongs to low risk group. It may cause the benign tumour.

▶ **K799 HPV-16, 100 reactions***

This kit will detect the presence of HPV-16 genotype, which is present in anogenital samples. This belongs to high risk group and it is most widely spread in the women. It is involved in malignant cervical tumour.

▶ **K800 HPV-18, 100 reactions***

This kit will detect the presence of HPV-18 genotype, which is present in anogenital samples and belongs to high risk group. This is also second most widely spread genotype in the women and is involved in the etiology of malignant cervical tumour.

▶ **K801 HPV-31, 100 reactions***

This kit will detect the presence of HPV-31 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K802 HPV-33, 100 reactions***

This kit will detect the presence of HPV-33 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K205 HPV-35, 100 reactions***

This kit will detect the presence of HPV-35 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K160 HPV-39, 100 reactions***

This kit will detect the presence of HPV-39 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K206 HPV-42, 100 reactions***

This kit will detect the presence of HPV-42 genotype, which is present in anogenital samples and belongs to low risk group. This is involved in the etiology of benign cervical tumour.

▶ **K209 HPV-43, 100 reactions***

This kit will detect the presence of HPV-43 genotype, which is present in anogenital samples and belongs to low risk group. This is involved in the etiology of benign cervical tumour.

▶ **K207 HPV-44, 100 reactions***

This kit will detect the presence of HPV-44 genotype, which is present in anogenital samples and belongs to low risk group. This is involved in the etiology of benign cervical tumour.

▶ **K161 HPV-45, 100 reactions***

This kit will detect the presence of HPV-45 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K162 HPV-51, 100 reactions***

This kit will detect the presence of HPV-51 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K163 HPV-56, 100 reactions***

This kit will detect the presence of HPV-56 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K164 HPV-58, 100 reactions***

This kit will detect the presence of HPV-58 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K165 HPV-59, 100 reactions***

This kit will detect the presence of HPV-59 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K166 HPV-66, 100 reactions***

This kit will detect the presence of HPV-66 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

▶ **K167 HPV-68, 100 reactions***

This kit will detect the presence of HPV-68 genotype, which is present in anogenital samples and belongs to high risk group. This is involved in the aetiology of malignant cervical tumour.

* for human beings only for research use.

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