Human papillomavirus (HPV) gDNA Reference Standard

【PRODUCT SPECIFICATION】

Catalog ID	IB-GW-IPF001～IB-GW-IPF025
Specification	1.0E+07 ~ 4.0E+07copies/mL, 100 μL/tube (Measured by QX200 Droplet Digital PCR)

【INTENDED USE】

Human papillomavirus (HPV) gDNA reference standard is formulated for use with targeted quantitative or qualitative detection of HPV DNA in cervical specimens. This product is a new quality control that randomly integrates the full-length sequence of HPV into the human genome to monitor the accuracy and sensitivity of HPV nucleic acid detection assay.

The product contains eighteen high-risk HPV types: 16/18/26/31/33/35/39/45/51/52/53/56/58/59/66/68/73/82 and seven low-risk HPV types: 6/11/42/43/44/81/83.

For Research Use Only. Not for diagnostic procedures.

【PRINCIPLES OF THE PROCEDURE】

The product is ready-to-use in HPV nucleic acid detection following DNA isolation; no further purification or DNA isolation is required. It includes human genomic DNA in a 1 mM Tris, 0.1 mM EDTA, 10 mM NaCl, pH 8.0 aqueous buffer, compatible with PCR-based target amplification and other nucleic acid detection methods.

【APPEARANCE & COMPONENTS】

The product is a clear liquid.

The product is human genomic DNA in a 10 mM Tris / 1 mM EDTA, pH 8.0, aqueous buffer.

【STORAGE INSTRUCTIONS】

Ambient shipping, store refrigerated at 2-8°C, valid for 36 months.

Note: Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

【PROCEDURE】

Follow the instructions for unknown specimens provided by the test kits or the laboratory's standard operating procedures.

Mix the product tube by vortexing to ensure a homogeneous solution and spin down briefly. The HPV gDNA reference standard should be integrated into library preparation after the DNA isolation step. This product must undergo PCR amplification and data analysis in parallel with the test specimens. Refer to your routine assay procedures to determine the required amount of material.

Quality Control

The HPV gDNA reference standard is formulated using digital PCR quantitation to include the HPV types listed in Table 1 at expected HPV copy numbers. Deviations from these targets may occur and should be investigated. Each laboratory should qualify the use of each lot with each assay system before routine use.

【EXPECTED RESULTS】

The specific detection value of each HPV type will vary among different assays, procedures, lot numbers, and laboratories. Each laboratory should establish its own range of acceptable values. Table 1 lists the HPV copy numbers present in the product defined by digital PCR.

【INTERPRETATION OF RESULTS】

The analytical results obtained from this product are integral for the precise evaluation of the assay's capacity to detect specific HPV types. The primary assessment should involve ascertaining the positivity or negativity of the results. A satisfactory positive result validates the assay's functionality in detecting the target HPV type, while a satisfactory negative result confirms the assay's specificity and the absence of interference or cross-reactivity. Discrepancies in results, notably inconsistent positive or negative outcomes that diverge from established expectations, signify a substantial issue warranting thorough investigation. Potential factors contributing to these discrepancies may include the degradation of test kit reagents, inaccuracies due to operator error, malfunctioning of laboratory equipment, or contamination of reagents. Furthermore, it is essential to acknowledge that in the case of qPCR, differential detection values, exemplified by Ct or Tm values, are anticipated when utilizing diverse test kits. For routine quality control purposes, laboratories must establish and rigorously adhere to a defined range of acceptable detection values, ensuring steadfastness and reliability in the assay results.

【LIMITATIONS OF THE PROCEDURE】

The HPV gDNA Reference Standard MUST NOT be substituted for control reagents provided with manufactured test kits.

Test procedures provided by manufacturers must be followed closely. Deviations may result in unreliable results. The HPV gDNA reference standard is not a calibrator and should not be used for assay calibration. It also does not evaluate specimen extraction methods.

Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

【WARNINGS AND PRECAUTIONS】

For Research Use Only. Not for use in diagnostic procedures.

CAUTION: Handle the HPV gDNA Reference Standard as if capable of transmitting infectious agents. It is manufactured using processed human genomic DNA.

Safety Precautions

Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens [1]. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use The HPV gDNA Reference Standard beyond the expiration date. Avoid contamination of the product when opening and closing the tubes.

【SUMMARY】

A well-designed routine quality control standard operating procedure enhances confidence in the reliability of results obtained from unknown specimens. The use of independent reference materials can provide valuable insights into assay sensitivity, specificity, precision, and bioinformatics pipeline analysis.

【REFERENCES】

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

【MANUFACTURER】

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Table 1: The Human papillomavirus (HPV) gDNA Reference Standard

No.	Cat.	Product name	HPV copy number (copies/mL)
1	IB-GW-IPF001	Human papillomavirus (HPV16) gDNA Reference Standard	4.0E+07
2	IB-GW-IPF002	Human papillomavirus (HPV18) gDNA Reference Standard	4.0E+07
3	IB-GW-IPF003	Human papillomavirus (HPV26) gDNA Reference Standard	3.0E+07
4	IB-GW-IPF004	Human papillomavirus (HPV31) gDNA Reference Standard	4.0E+07
5	IB-GW-IPF005	Human papillomavirus (HPV33) gDNA Reference Standard	3.0E+07
6	IB-GW-IPF006	Human papillomavirus (HPV35) gDNA Reference Standard	4.0E+07
7	IB-GW-IPF007	Human papillomavirus (HPV43) gDNA Reference Standard	3.0E+07
8	IB-GW-IPF008	Human papillomavirus (HPV44) gDNA Reference Standard	4.0E+07
9	IB-GW-IPF009	Human papillomavirus (HPV45) gDNA Reference Standard	4.0E+07
10	IB-GW-IPF010	Human papillomavirus (HPV52) gDNA Reference Standard	4.0E+07
11	IB-GW-IPF011	Human papillomavirus (HPV58) gDNA Reference Standard	4.0E+07
12	IB-GW-IPF012	Human papillomavirus (HPV59) gDNA Reference Standard	4.0E+07
13	IB-GW-IPF013	Human papillomavirus (HPV66) gDNA Reference Standard	2.0E+07
14	IB-GW-IPF014	Human papillomavirus (HPV68) gDNA Reference Standard	4.0E+07
15	IB-GW-IPF015	Human papillomavirus (HPV73) gDNA Reference Standard	4.0E+07
16	IB-GW-IPF016	Human papillomavirus (HPV82) gDNA Reference Standard	4.0E+07
17	IB-GW-IPF017	Human papillomavirus (HPV11) gDNA Reference Standard	4.0E+07
18	IB-GW-IPF018	Human papillomavirus (HPV53) gDNA Reference Standard	4.0E+07
19	IB-GW-IPF019	Human papillomavirus (HPV81) gDNA Reference Standard	4.0E+07
20	IB-GW-IPF020	Human papillomavirus (HPV6) gDNA Reference Standard	1.0E+07
21	IB-GW-IPF021	Human papillomavirus (HPV39) gDNA Reference Standard	4.0E+07
22	IB-GW-IPF022	Human papillomavirus (HPV42) gDNA Reference Standard	1.0E+07
23	IB-GW-IPF023	Human papillomavirus (HPV51) gDNA Reference Standard	4.0E+07
24	IB-GW-IPF024	Human papillomavirus (HPV56) gDNA Reference Standard	4.0E+07
25	IB-GW-IPF025	Human papillomavirus (HPV83) gDNA Reference Standard	4.0E+07