

HPV High Risk with 16/18 Genotype - SurePath

Order Name: HPV Hi/16/18 SP

Test Number: 5522580 Revision Date: 01/01/2025

| TEST NAME           | METHODOLOGY     | LOINC CODE |
|---------------------|-----------------|------------|
| HPV Genotype 16 PCR | Qualitative PCR | 61372-9    |
| HPV Genotype 18 PCR | Qualitative PCR | 61373-7    |
| HPV Other High Risk | Qualitative PCR | 70061-7    |
| HPV Source          | Prompt          |            |

| SPECIMEN REQUIREMENTS |                               |                                 |                                          |                       |
|-----------------------|-------------------------------|---------------------------------|------------------------------------------|-----------------------|
| Specimen              | Specimen Volume (min)         | Specimen Type                   | Specimen Container                       | Transport Environment |
| Preferred             | 2 mL (1 mL)                   | PAP specimen                    | ThinPrep PreservCyt solution             | Room Temperature      |
| Alternate 1           | 2 mL (1 mL)                   | PAP specimen                    | SurePath Liquid Pap Container (Pap Prep) | Room Temperature      |
| Instructions          | Notes: 1 mL (Note: This volur | me Does NOT allow for repeat te | sting.)                                  |                       |

Notes: 1 mL (Note: This volume Does NOT allow for repeat testing.)

Specimen Type: ThinPrep(R) vial or SurePath(TM) vial

Specimen Storage: Maintain liquid-based cytology specimens at room temperature. date of collection prior to performing the cobas(R) HPV test.

ThinPrep(R) specimens should not be frozen.

Specimen Collection: BRUSH/SPATULA TECHNIQUE: Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush 1/4 to 1/2 turn in one direction. Do NOT over-rotate the brush. Then, rotate the brush in the PreservCyt(R) solution 10 times while pushing against the wall of the ThinPrep(R) vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep(R) vial 10 times and discard the spatula. Tighten the cap on the ThinPrep(R) container so that the torque line on the cap passes the torque line on the vial. SUREPATH(TM) VIAL: When using the SurePath(TM) vial, the cervical broom must be used for specimen collection. Insert the broom into the cervical os and rotate five times. Place the broom head into the CytoRich(TM) preservative fluid in the SurePath(TM) collection vial. Tightly cap the vial.

Specimen Stability: Ambient: Not Available, Refrigerated: Not Available, Frozen: Not Available

| GENERAL INFORMATION |                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |  |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| Expected TAT        | 2 - 4 days                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |  |
| Clinical Use        | This test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high-risk types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 without further specific differentiation.  Limitations: 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. |  |  |
| CPT Code(s)         | 87626                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |  |
| Service Provided By | labcorp Oklahoma, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |  |