



CER818 – HPV High Risk Testing

- HPV High Risk Rapid Test:**
- Easy to handle
 - Quick test result
 - Robust
 - Affordabel
 - Blood-based test – without genital contact!

Cervical Cancer Screening Using A Single Drop Of Blood

Cervical cancer is a leading cause of cancer-related death in women worldwide. To change this, the World Health Organization (WHO) has defined several global goals to eradicate the disease. Due to the complexity of existing smear based approaches, a screening coverage of 70% seems to be the most ambitious target.

In this respect, easy-to-use blood-based HPV detection methods, such as the CER818 lateral flow rapid test, could be of critical importance to change this situation, and to enable a 'see and treat' approach.

NEAR PATIENT CARE DIAGNOSIS

- ! More than 600,000 new cervical cancer cases annually
- ! Minimum 342,000 women die of the disease
- ! Women in low- or middle-income countries (LMICs) still suffer most from the disease
- ! WHO screening goal 70%
- ! WHO vaccination and treatment goal 90%

Moving From Smear To Blood Based Cervical Cancer Screening

CER818 Clinical Performance



CER818: A Highly Specific and Sensitive HPV L1 High-Risk Serological Lateral Flow Rapid Test for Early Detection of Cervical Cancer and Its Precursor Lesions (*Bräutigam et al, IDOG, 2024*)



Scan QR code for the scientific paper

Discriminating HPV Driven Disease From Sub-Clinical, Latent HPV Infection



Within minutes the CER818 rapid test detects HPV L1 specific antibodies, which are specific for clinically relevant HPV High Risk driven disease.

HPV DNA positive, but healthy asymptomatic women are tested negative for HPV L1 antibodies, due to the latent, subclinical infection.

Technical Details

Name	CER818 HPV High Risk
Analytical specificity	HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 68 and 73
Sample	Serum / whole blood
Test result	Within 15 minutes
Format	Quantitative (CE IVD marked) Qualitative (under development)
Storage	At 2–8°C

Clinical Performance Data

✓ **Sensitivity**
 CIN1/2 100%
 CIN3..... 86.6%
 Cervical Cancer 82.4%

✓ **Specificity**
 20–29y 96.6%
 30–39y 92.1%
 40–49y 95.0%
 50–59y 97.5%

✓ **ROC curve analysis**
 Area under curve
 CIN1+ 0.923
 CIN2+ 0.910

✓ **Predictive values**
 PPV 93.23%
 NPV 94.02%

