

GenomEra GBS Assay Kit

Sensitive and fast detection of Group B Streptococcus (GBS) during pregnancy and at the time of delivery





Why choose our test?

The GenomEra® GBS Assay Kit is a qualitative molecular assay indicated for the rapid identification of antepartum and intrapartum colonization of Group B Streptococcus (GBS, *Streptococcus agalactiae*) in pregnant women. The assay simplifies and speeds up GBS testing by providing reliable results from vaginal-rectal swab samples in less than one hour.

Key benefits of the test

- Sensitive and specific test to reliably detect GBS from vaginal rectal samples
- Fast results enable detection of GBS carriage at the time of delivery
- Easy to use system that can be adopted to bedside testing at maternity wards

GBS, a gram-positive bacterium, is the leading cause of neonatal infections associated with high morbidity and mortality. Using molecular assays like the GenomEra GBS Assay Kit can help to reduce the risk of neonatal infection, allowing for prompt treatment and improved outcomes.

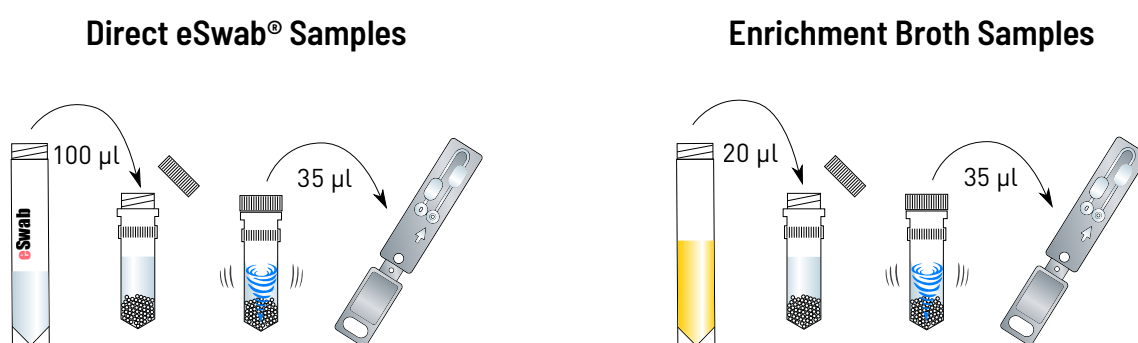
Key facts

- Short hands-on time combined with rapid and automated PCR testing – results for four samples in 50 minutes
- Suitable for direct vaginal-rectal samples and selective broth enrichment cultures
- Unique sample preparation protocol lowers the risk of PCR inhibition due to mucus in the specimen
- Easy-to-use, automated GenomEra molecular diagnostic system with minimal risk of contamination

Assay principle

The GenomEra GBS assay is based on end-point PCR that detects a specific region of the *S. agalactiae* genome utilizing the GenomEra CDX System. The kit is suitable for vaginal-rectal swab specimens in Copan eSwab® transport medium collected from pregnant intrapartum or antepartum women, and for enrichment broth cultures of vaginal-rectal swab specimens collected from antepartum women. The assay contains a very simple sample preparation and yields reliable results in less than one hour.

Test procedure



Clinical performance

The clinical performance of the GenomEra GBS Assay Kit was evaluated for vaginal swab enrichment cultures at one hospital laboratory in Finland (n = 282) and one in Israel (n = 90) (Table 1). Additionally, the test was evaluated for vaginal-rectal swab samples in Denmark at two sites (n = 361), in Finland (n = 267) and in Lebanon (n = 177) at one site (Table 1). Besides this, the test has shown good clinical performance in clinical studies (e.g. Nielsen et al., 2020).

	Sample size (n)	Sensitivity (% , n)	Specificity (% , n)	PPV (%)	NPV (%)
Overnight enrichment broth cultures	396	98.0 (97/99)	98.3 (288/293)	95.1	99.3
Four-hour enrichment broth cultures	114	96.4 (27/28)	96.5 (83/86)	90.0	98.8
Vaginal-rectal swab	805	83.1 (162/195)	96.6 (564/584)	89.0	94.5

Table 1. The GenomEra® GBS Assay Kit proved to be highly sensitive and specific in clinical use. PPV, positive predictive value; NPV, negative predictive value.

* The combined reference standard was established by defining true positives as either culture-positive samples or culture-negative samples where GBS PCR assays were positive



Ordering information

To place an order, please contact your local distributor at uniogen.com/distributors/

Product name	Product code
GenomEra GBS Assay Kit, 20 tests	CDX-60-01-20
GenomEra GBS Assay Kit, 40 tests	CDX-60-01-40
GenomEra CDX System	CDX-10-020

Manufacturer

Uniogen Oy
Tykistökatu 4
FI-20520 Turku, Finland
Tel: + 358 20 7188 380
info@uniogen.com
uniogen.com

Distributor



GenomEra® products carry the Finnish Key Flag Symbol, a valued and trusted symbol of Finnish origin.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen Oy.

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