

## PILL PROTECT<sup>®</sup>: Risk estimate for the development of thromboembolic event when using oral combined contraception

### Thromboembolic events

The use of oral combined contraception or hormone replacement increases the risk to develop thromboembolic events. Prevalence of such event associated with combined contraception is estimated to 1 in 1000 women (Bitzer et al. 2012). In Switzerland, each year, about 400 women develop a deep vein thrombosis (DVT) associated with the use of oral contraception. This prevalence increases with age and with the presence of other behavioral factors such as smoking and overweight.

Genetic risk factors play also an important role in the development of thromboembolic events (60% of total risk). Two major variations are associated with a high risk for thrombosis: Leiden mutation in the gene coding for Factor V and another polymorphism in the gene coding for Factor II (G20210A) also called prothrombin. However, other genetic variants are also important and their combined presence can increase further the total risk of the disease.

### PILL PROTECT<sup>®</sup> test

Pill Protect<sup>®</sup> is an innovative medical test, marked CE-IVD, which estimates the risk of thromboembolic event associated with oral combined contraception. This test includes the detection of specific genetic variations that affect thrombosis occurrence when using combined contraception such as Factor-V Leiden and Factor II-G20210A, but also other variants associated with coagulation and hormone metabolism. The test also includes risk measurement that takes into account these genetics variants and also clinical factors such as age, BMI, smoking status and family history of thromboembolic events. The test also integrates the risk inherent to various compound present in most contraceptive pills on the market.

Pill Protect<sup>®</sup> test was validated using a retrospective study that included 1600 women taking oral combined contraception. Half of them had developed thromboembolic event. Pill Protect<sup>®</sup> detected 6x more women with elevated risk among cases than the current approach based on a medical questionnaire (weight, smoking status, family and personal history). (McDaid et al., 2017, *Risk prediction of developing venous thrombosis in combined oral contraceptive users, PLoS One*)

Pill Protect<sup>®</sup> test costs 270 CHF. It is reimbursed for any woman who uses or wishes to use a combined contraception and has contracted a PRIMEO complementary insurance of Helsana. These genetic analyses are performed once in a lifetime in a simple and non-invasive fashion (buccal swab).