

Product Information

Product Description

SANAVITA Pregnancy Test is a rapid urine test used for qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

Product Properties

SANAVITA Pregnancy Test is an in-vitro diagnostic medical device for self-testing. The test can be carried out from the first day of delay in period. In case of pregnancy, women develop the hormone human chorionic gonadotropin (hCG), which can be detected in the urine. SANAVITA Pregnancy Test contains antibodies, which react with this hormone showing the result in analog form. All SANAVITA Pregnancy **Test** types have a shelf life of 2.5 years.

Applicable Product Standards

The conformity assessment procedure was carried out according to Annex IV (excl. Chapter 4 & 6) of IVDD 98/79/EC. All applicable harmonized standards are fulfilled.

Product Specifications and Components*

Strip (10 mIU, 20 mIU)

Types

Cassette (1 Cassette)



Ministick (10 mIU, 20 mIU)



Stick (10 mIU, 20 mIU)



Standard Packaging

1 Test device packed in a pouch with a desiccant bag. Secondary packaging: Consumer Box incl. pouch+ leaflet

1 Test device packed in a pouch with a pipette and a desiccant bag. Secondary packaging: Consumer Box incl. pouch+ leaflet

1 Test device packed in a pouch with a desiccant bag. Secundary packaging: Consumer Box incl. pouch+ leaflet

1 Test device packed in a pouch with a desiccant bag. Secundary packaging: Consumer Box incl. pouch+ leaflet

Sensitivity and Accuracy

Sensitivity: 10 mlU/ml, 20 mlU/ml

Accuracy: > 99%

Sensitivity: 20 mlU/ml Accuracy: > 99%

Sensitivity: 10 mIU/mI, 20 mIU/mI

Accuracy: > 99%

Sensitivity: 10 mIU/mI, 20 mIU/mI

Accuracy: > 99%





^{*} Customized packaging options and individual cap colors upon request.