

BabySafe™

17-OHP Rapid Diagnostic Test



Parameter	17-OHP
Intended Use	BabySafe™ 17-OHP Rapid test kit is an <i>in-vitro</i> diagnostic immunochromatographic assay for the semi-quantitative detection of 17 α -hydroxyprogesterone (17-OHP) in New Born whole blood samples. This is a screening test.
Principle	BabySafe™ 17-OHP Rapid Test Cassette (Whole Blood) is Semi-Quantitative membrane-based immunoassay for the detection of 17 α -OH Progesterone(17-OHP) in new-born whole blood samples. This test is based on competitive inhibition assay. There are two components, one is conjugate pad containing Anti-17-OHP antibody conjugated to colloidal gold and other is 17-OHP immobilized on to the membrane at test zone "T". Cases in which, 17-OHP is very high in specimen, specimen will flow through the membrane assembly of the device, 17-OHP in the specimen binds to the highly specific antibody for 17-OHP colloidal gold conjugate and travels on the membrane due to capillary action. Since conjugate is already saturated with 17-OHP, it will not bind to Capture test line and move further. Samples in which 17-OHP is in normal levels or lesser, the conjugate will have enough binding sites to bind to capture as it travels across test region "T". Based on the concentration of 17-OHP present in the specimen, colour intensity of the Test "T" will vary. The colloidal gold conjugate and unbound complex moves further to the reference region (R) that contains pre-calibrated for rabbit globulin corresponding to 50ng/ml,17-OHP immobilized on the membrane. The intensity of the coloured band formed at the reference region (R) corresponds to a17-OHP concentration of 50ng/ml. The unreacted conjugate and unbound complex, if any, move further on the membrane and are subsequently immobilized by the agglutinating sera for rabbit globulin coated on the membrane at the control region (C), forming a pink to pink-purple coloured band. The intensity of the coloured band formed at the control region(C) corresponds to a 17-OHP concentration of 15ng/ml.
Kit Components	Materials Provided A. Individual pouches, each containing: 1. Test Device: Membrane assembly pre-dispensed with 17-OHP (indicator) colloidal gold conjugate, 17-OHP (capture) and Agglutinating sera for rabbit globulin coated at the respective regions. 2. Desiccant pouch. B. Assay buffer bottle. C. Package insert.
Pack size	10/25 Tests

Key Distinctions

-  Onsite test- Results in 25 minutes at the newborn baby's bed side. Enables bedside testing.
-  Semi-quantitative estimation of analyte concentration.
-  Visual Test that can be performed at Birthing centres, Clinics and Hospital -attached labs.
-  Uses 10 µl heel prick whole blood sample, Minimizes discomfort to the newborn baby, eases sample collection process.
-  Room temperature storage therefore Flexibility of remote distribution and storage.