



Parameter 17 α -OH Progesterone (17OHP)

Intended Use The Born Safe™ Neonatal 17-OHP ELISA is an enzyme immunoassay for the quantitative determination of 17 Alpha-Hydroxyprogesterone in blood samples dried on Whatman S&S 903 filter paper. This test is intended as a screening method for the determination of 17-OHP concentrations in newborn dried blood spot specimens as an aid to the diagnosis Congenital Adrenal Hyperplasia (CAH).

Principle The essential reagents required for an enzyme immunoassay include antibody, enzyme- antigen conjugate and native antigen. Upon mixing the antibody with blood spot containing the antigen, a reaction results between the antigen and the antibody. After a short period, the enzyme conjugate is added (This delayed addition permits an increase in sensitivity for low concentration samples and better precision). Upon the addition of the enzyme conjugate, competition reaction results between the enzyme analog and the antigen in the sample for a limited number of antibody binding sites (not consumed in the first incubation). Simultaneously, the immune complex is immobilized through the interaction with Anti-Rabbit antibody coated to the well. Unbound reactants (17-OHP and 17-OHP-HRP) are removed at the end of the incubation time. A substrate is then reacted with the enzyme bound on the wall of the microwells. The enzymatic reaction is terminated with an acid. The end product is measured at 450 nm. The 17-OHP of the unknown sample is determined using a calibration curve generated with known concentration of 17-OHP.

Kit Components Reagents








- 17OHP Calibrators –Dried Blood Spots in Aluminium pouch (One row of six spots levels-1x6): Six (6) levels of 17OHP calibrators in dried blood spots (adjusted to 55% hematocrit) at approximate concentrations of 0 (C0), 5 (C1), 12 (C2), 24 (C3), 53(C4) and 120 (C5) ng/ml spotted on Whatman S&S 903 filter paper. Store at 2-8°C. Desiccant is included. Preservative has been added.
 Note 1: The Lot Specific calibrators are whole human blood based, were calibrated against the 5th ISNS Reference Preparation for Neonatal Screening (5th ISNS-RPNS), RIVM, Bilthoven, Netherlands.
 Note 2: The exact 17OHP values are printed on the lot specific value sheet included in the kit. (Above values given are for illustration purpose only.)
- 17OHP Controls –Dried Blood Spots in Aluminium pouch (One row of two spots –1 x 2) Two levels of whole human blood controls with different concentrations of 17OHP spotted on Whatman S&S 903 filter paper. Store at 2-8°C. Desiccant is included Preservative has been added.
 Note 1: The controls are whole human blood based, were manufactured to fall within significant clinical ranges.
 Note 2: The exact values are printed on the lot specific value sheet included in the kit.
- 17OHP Enzyme Reagent – 14.0 ml/vial
 One (1) vial contains enzyme 17OHP horseradish peroxidase (HRP) conjugates in buffer, and preservative. Store at 2-8°C.
- 17OHP Antibody Reagent – 14.0 ml/vial
 One (1) vial containing Antibody to 17OHP in buffer, and preservative. Store at 2-8°C.
- Coated Microtiter plate: One 96-well microplate coated with Anti-rabbit antibody and packaged in an aluminium bag with a drying agent. Store at 2-8°C.

17-OHP

- Wash Solution Concentrate – 22.0 ml
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-30°C.
- Substrate Solution – 15.0 ml/vial
One (1) vial containing tetramethylbenzidine (TMB) and hydrogen peroxide (H₂O₂) in buffer. Store at 2-8°C.
- Stop Solution – 7.0 ml/vial
One vial containing a mineral acid. Store at 2-8°C.
- Sealing Tapes- 3 nos.
- Product Instructions- Details of the Kit and testing methodology.

Pack size	96 Tests
Linearity	0-255 ng/ml

Key Distinctions

 Born Safe 17OHP is Indian FDA approved, ISO certified.  Comprehensive External Clinical Evaluation, exclusively on neonatal population:>3200 samples.  Absolute Compliance with Lab QMS trend (e.g. CDC-PT/QC).  Born Safe 17OHP Calibrators are traceable to international CRMs e.g. 5th ISNS-RPNS, are validated by CDC samples.  Excellent correlation to other commercial Colorimetric & Fluorometric assays and CDC target values.  Born Safe kits are available both in smaller (96T) and in larger pack sizes (192T) suitably fitting into the requirements of every NBS Lab.  Manufactured in India Plant, hence efficient management of supply & logistics across country.