

Size : 137 x 218 mm



17-OHP

**Rapid test for detection of 17 Alpha-hydroxyprogesterone (17-OHP)  
in Human whole blood**

**DEVICE**

**INTENDED USE**

The **BabySafe™ 17-OHP** Rapid test kit is an *in-vitro* diagnostic immunochromatographic assay for the detection of 17 $\alpha$ -Hydroxy-Progesterone (17-OHP) in Human Whole Blood samples. This is a screening test. **BabySafe™ 17-OHP** Rapid test results of new born whole blood samples can be quantified using **BabySafe™ Analyzer**.

**SUMMARY**

17-OHP is an intermediate hormone in the production of cortisol by the adrenal glands.

The 17-OHP (17-hydroxyprogesterone) test is a blood test that measures the level of a hormone crucial for cortisol production. The 17-OHP test is a standard part of newborn screening to check for CAH (Congenital Adrenal Hyperplasia), a genetic disorder affecting hormone production. A high 17-OHP level, often detected in the initial screening, does not automatically confirm CAH and requires follow-up testing, especially because levels can be elevated in premature or stressed infants. If confirmed, CAH can be life-threatening in newborns, so prompt diagnosis through additional tests is crucial.

The test also helps diagnose CAH in children and adults, investigate certain types of infertility in women, and monitor CAH treatment.

**BabySafe™ 17-OHP** is a screening test wherein 17-OHP Rapid test results can be quantified using **BabySafe™ Analyzer**.

**TEST PRINCIPLE**

The **BabySafe™ 17-OHP** Rapid Test Device (Whole Blood) is membrane-based immunoassay for the quantitative determination of 17 $\alpha$ -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 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 purple coloured band.

**PRESENTATION**

REF	526020008	526020024
E	8 T	24 T

**REAGENTS AND MATERIAL SUPPLIED**

**BabySafe™ 17-OHP Kit contains:**

- Individual pouches, each containing:
  - 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.
  - Desiccant pouch.
- BUF**: Assay buffer bottle.
- QR Code card for calibration.
- Package insert.

**MATERIAL REQUIRED BUT NOT PROVIDED**

- BabySafe™ Analyzer** (Cat. No.: 853BSA00002)
- Micropipette, Micropipette Tips, Gloves, Alcohol swab, Sterile blood lancet (0.85 mm- 2 mm max depth) and stopwatch.

\*\* For premature neonates, a lancet depth of 0.85 mm is recommended.

**TEST KIT STORAGE AND STABILITY**

- Store the sealed pouches and assay buffer at 4°C to 30°C. DO NOT FREEZE.
- The test kit is stable until the expiration date marked on the RDT box and /or the packaging of the individual components when stored as specified.

**WARNINGS AND PRECAUTIONS**

- Read the instructions carefully before performing the test.
- For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
- Do not use the kit beyond expiry date and do not re-use the test device.
- Do not intermix reagents from different lots.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

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- Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS#7646-79-9) should be kept to minimum. Inhalation / swallowing may cause harm.
- Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
- Scan QR code card specific to the lot you are using.
- Assay buffer contains Sodium Azide(0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing system and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

#### **SPECIMEN REQUIRED**

##### **Capillary Whole Blood Sampling by Heel Prick:**

- Blood samples should ideally be collected between the third and fifth day of baby's life (48 to 120 hrs after birth) by Heel prick. However, in some screening programs the sampling timing may vary. Consult local regulations for appropriate timing for specimen collection.
- Blood from the new-born's Heel should be collected **ONLY** from the medial (closest to the body center-line) or lateral portion (furthest from the body center-line) of the planter surface (walking surface).
- Clean the skin with an alcohol swab and allow to air-dry.
- Puncture the infant's Heel with a sterile lancet to the depth of approximately 0.85 mm - 2.0 mm. Puncturing deeper than 2.0 mm on small infants may cause bone damage. (Reference: WHO Guidelines for Paediatric and Neonatal patients sampling).
- Puncture infant's heel with one quick, continuous and deliberate stroke, to achieve a good flow of blood and to prevent the need to repeat the puncture.
- Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris (sloughing skin). Collect 10 µl of blood sample with the help of a Micropipette (10 µl) from a large well-formed drop of blood.
- Avoid squeezing the heel too tightly because this dilutes the specimen with tissue fluid (plasma) and increases the probability of haemolysis.
- When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding.

##### **Venous blood:**

- Fresh whole blood collected in EDTA. Freezing is not recommended. With the help of micropipette transfer 10 µl whole blood in to the test cassette 'A' region.

#### **ASSAY PREPARATION**

##### **Before testing:**

1. To calibrate the **BabySafe™ 17-OHP** kit, scan the QR code card provided with the kit.
2. Bring the kit components of **BabySafe™ 17-OHP** device to ambient temperature before testing.
3. **BabySafe™** Test device should be used within 30 mins once the foil pouch is opened.
4. Check that the device packaging is not damaged. (If damaged, discard the device packaging and use another test).
5. Open the device packaging by tearing along the notch indicated and check the desiccant. (If it shows saturation i.e. colour changed from blue to pink or colourless), discard the device and take another device packaging. If the colour of the desiccant does not show any colour change the device can be used for the test.
6. Throw the desiccant in the non-sharp disposal container.
7. Take the device and place it on the horizontal surface.
8. The device will have:
  - A result window (marked as C & T).
  - A sample port marked "A".
  - A circle well for buffer marked "B".
9. Write the patient name or patient identification on the device.
10. Put the gloves. Use new pair of gloves for each patient.

#### **TEST PROCEDURE**

##### **Capillary whole blood Sample from Heel prick**

1. Wear gloves.
2. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
3. Wipe the complete area to be pricked with the alcohol swab.
4. Wait until the area has completely dried (minimum 30 seconds).
5. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the blood).
6. Take the safety-seal lancet. Carefully check the puncture site.
7. Detach the cap of the lancet. Puncture the infant's Heel (from medial or lateral portion of plantar surface) with a sterile Lancet (0.85 mm-2 mm). Dispose the lancet immediately into the sharps box.
8. Make sure a well-formed drop of blood is present.
9. If there is no well-formed drop of blood, repeat the prick at some other area.
10. Use a new lancet and choose a different puncture site.
11. Collect 10 µl of blood sample with the help of a Micropipette (10 µl) from a large well-formed drop of blood. Take the alcohol swab you put aside (step 5). Press it to the site of pricking to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container. Use a separate micropipette tip for each patient to avoid any contamination.

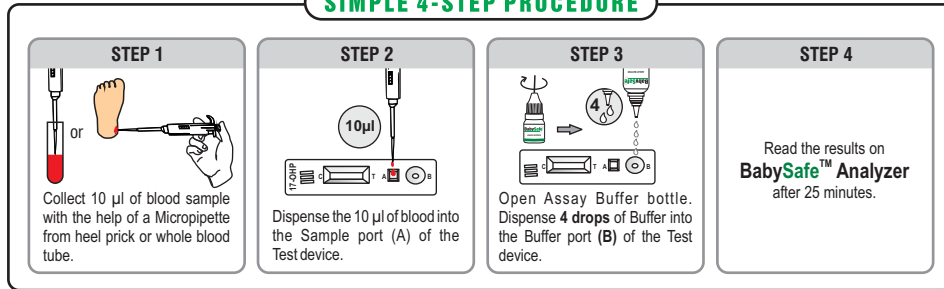
Size : 137 x 218 mm

12. Dispense 10 µl blood sample in the sample port 'A', followed by the addition of 4 drops of the Assay buffer in port 'B' (**Do not move the device after addition of Assay buffer**).
13. Read the result in 25 minutes on **BabySafe™ Analyzer**. Do not read and interpret after 25 minutes.

**Venous whole blood**

1. Wear Gloves.
2. Collect fresh whole blood by standard venipuncture procedure into tube containing anticoagulant (EDTA).
3. Mix the tube gently.
4. Perform steps 11 -13 of the previous section ("Capillary whole blood from heel prick").
5. **Storage duration:** If assays are not completed immediately, Whole blood samples should be stored at +2°C to +8°C no longer than 24 hours.

**SIMPLE 4-STEP PROCEDURE**



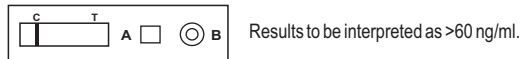
**Quantitative result interpretation using BabySafe™ Analyzer:**

The test results can be read and quantified using **BabySafe™ Analyzer** (Cat. No.: 853BSA00002). Please refer the User manual of **BabySafe™ Analyzer** for procedural details.

Results	Interpretation
<15 ng/ml	Presumptive Negative
15-50 ng/ml	Borderline Positive
>50 ng/ml	Presumptive Positive

**NOTE:** The device measuring range is between 1.8 ng/ml – 60 ng/ml.

**No Test Line:**



**Invalid Result:**



**PERFORMANCE CHARACTERISTICS**

**Internal Evaluation:** In an in-house study, the performance of **BabySafe™ 17-OHP** was evaluated using a total 100 samples collected from the locally available tertiary care center and were tested in parallel on ELISA system. Out of which 1 was clinically 17-OHP positive, 2 borderline positive and remaining 97 were known Negative specimens. The results of the evaluation are as follows:

SPECIMEN DATA	17-OHP	BabySafe™ 17-OHP	BornSafe™ 17-OHP
No. of specimens tested	100	100	100
No. of positive specimens	01	01	01
No. of Borderline positive specimens	02	02	02
No. of negative specimens	97	97	97

Based on this evaluation **BabySafe™ 17-OHP** has 100% correlation with licensed reference system, **BornSafe™ Neonatal 17-OHP**.

**External Evaluation:** In a NABL accredited reputed reference laboratory in India, **BabySafe™ 17-OHP** (Device) were evaluated with 100 nos. of whole blood samples derived from new born. Results were obtained as below:

SPECIMEN DATA	17-OHP	BabySafe™ 17-OHP	BornSafe™ 17-OHP
No. of specimens tested	100	100	100
No. of borderline and positive specimens	1	1	1
No. of negative specimens	99	99	99

Size : 137 x 218 mm

Based on this evaluation **BabySafe™ 17-OHP** have 100% correlation with licensed reference system, BornSafe™ Neonatal 17-OHP (Enzyme immunoassay for the quantitative determination of 17-OH Progesterone (17-OHP)).

**LIMITATIONS OF THE PRODUCT**

1. The test procedure, precautions and interpretation of results for this test must be followed while testing.
2. The **BabySafe™ 17-OHP** is for in vitro diagnostic use only. The test should be used for the detection of 17-OHP in whole blood specimens only.
3. Test kit directly exposed to sunlight and heat can lead to wrong results.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Values expressed is in ng/ml of whole blood.
6. This test does not determine the absolute value of 17-OHP in specimen.
7. This test is designed for full-term, normal weight babies. Hence, interpretation should be done very carefully and needed to be confirmed with confirmatory assay.
8. Elevated concentrations of 17-OHP are not as per diagnostic of CAH the circulating 17-OHP concentration may be elevated in infants who are pre-term, under stress, have respiratory disorders or other severe illness.

**REMARKS**

1. **BabySafe™ 17-OHP** is a first-line screening test. If the result is negative but symptoms develop later, positive results should be confirmed with more sensitive and confirmatory assays.
2. In cases of IEMs, toxic metabolites and by-products can only be detected biochemically about 12 hours after the baby's first feed.
3. Infants screened before 24 hours of life should be re-screened by 2 weeks of age to detect possible missed cases.
4. Screening performed between 2 and 7 days of age provides the earliest results, allowing initiation of specific therapy or special elimination diets if the baby tests positive.
5. Cord blood is not suitable for newborn Screening since it is taken before the baby takes first breast milk.
6. Use of hemolyzed samples can produce reddish background which can interfere with results interpretation.
7. All samples tested as Borderline or presumptive positive, necessitate confirmation using more sensitive confirmatory assays (e.g. Steroid Profiling) & further correlating test results to clinical status of specimens from new born less than 48 hours after birth, premature, low birth weight and hospitalized sick new born.
















**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

(1). WHO Guidelines for Paediatric and Neonatal patients sampling. (2). Nimkarn S, Gangishetti PK, Yau M, et al. 21-Hydroxylase-Deficient Congenital Adrenal Hyperplasia. 2002 Feb 26 [Updated 2016 Feb 4]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. Gene Reviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1171/>. (3). Krone N, Roscher AA, Schwarz HP, Braun A. (1998) Comprehensive analytical strategy for mutation screening in 21-hydroxylase deficiency. Clin Chem . 44:2075–2082. (4). Speiser, P. W., Azziz, R., Baskin, L. S., et.al. (2010) Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 95(9), 4133-60. (5).Krone, N., & Art, W. (2009). Genetics of congenital adrenal hyperplasia. Best practice & research. Clinical endocrinology & metabolism, 23(2), 181-92. (6).Data on file: Zephyr Biomedicals.

**SYMBOL KEYS**

 Temperature Limitation	 Manufacturer	 Batch Number / Lot Number	 Device	 <small>HARM. 322 S23-46-61</small> Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
 Use by	 Consult Instructions for use	 Contains sufficient for <n> tests	 Assay Buffer	
 Date of Manufacture	 Catalogue Number	 This side up	 Do not reuse	
 In vitro Diagnostic Medical Device	 Do not use if package is damaged			



Manufactured by:

**Zephyr Biomedicals**

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