

Size : 137 x 218 mm

Seroquant 17-OHP

Lyophilized Control set for Neonatal 17-OHP assay

INTENDED USE

17-OHP Controls are intended for use as quality control materials in the routine monitoring of precision and accuracy of Neonatal 17-OHP immunoassay.

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.

PRODUCT DESCRIPTION

Seroquant 17-OHP controls are prepared in a synthetic buffered matrix. Each control is a lyophilised, buffer-based material containing 17 α -hydroxyprogesterone (17-OHP) at Low and High concentration levels. Stabilizers and preservatives are added to maintain analyte integrity during storage.

PRINCIPLE

Quality control materials are analyzed along with patient samples to verify the reliability of assay performance. Results should fall within the assigned range for the respective control level. Deviations may indicate reagent deterioration, calibration errors, or instrument malfunction.

PRESENTATION

REF	547020201
Pack Size	2x0.1 ml
Control Level-I	0.1 ml
Control Level-II	0.1 ml
PACKAGE INSERT	01 No.

REAGENTS PROVIDED

Component	Description	Quantity
17-OHP Control – Level 1 (Low Level)	Lyophilized, buffer-based control containing 17-OHP at a low concentration	1 vial
17-OHP Control – Level 2 (High Level)	Lyophilized, buffer-based control containing 17-OHP at a high concentration	1 vial

MATERIAL REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Calibrated pipettes and tips
- 17-OHP assay reagents and analyzer

PROCEDURE

1. Remove the vial from 2–8 °C and allow it to reach room temperature.
2. Add 0.1 ml of distilled or deionized water to the vial.
3. Gently swirl (do not shake) until completely dissolved.
4. Allow to stand for 5 minutes before use.
5. Mix gently before each use.
6. Run the controls in the same manner as patient samples according to the instructions of the 17-OHP assay kit.

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

Size : 137 x 218 mm

STORAGE AND STABILITY

Condition	Stability
Unopened (lyophilised)	Stable until expiry when stored at 2–8 °C.
After reconstitution	Stable for 2 days at 2–8 °C.

PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- Avoid microbial contamination.
- Do not interchange caps or mix controls from different lots.
- Protect reconstituted material from contamination, evaporation, and repeated freeze–thaw cycles.
- Discard vials showing turbidity or precipitate after reconstitution.

LIMITATIONS

- Control values are method- and instrument-dependent and may vary between assay systems.
- Not intended for calibration or standardization purposes.
- Results outside the assigned range may indicate procedural or reagent issues that require investigation.










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. Krone, N., & Arlt, W. (2009). Genetics of congenital adrenal hyperplasia. Best practice & research. Clinical endocrinology & metabolism, 23(2), 181-92.
2. The Basic Concepts of Quality Control Reference: Interval Studies, Diagnostic Efficiency, and Method Evaluation in Quality Control Ayed Dera <http://dx.doi.org/10.5772/intechopen.76848>
3. Data on file: Zephyr Biomedicals.

SYMBOL KEYS

 Temperature limitation	 Manufacturer	 Batch Number/ Lot Number
 Use by	 Consult Instructions for use	 <i>In vitro</i> Diagnostic Medical Device
 Date of Manufacture	 Catalogue Number	 This way up



Manufactured by:

Zephyr Biomedicals

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