

CAH -Mass

2nd tier LC-MS/MS Kit for Congenital Adrenal Hyperplasia

17-hydroxyprogesterone, Androstenedione, Cortisol,
11-deoxycortisol and 21-deoxycortisol in Dried Blood Spot Samples



Second-tier Confirmation of
Congenital Adrenal Hyperplasia in newborns

Introduction

Congenital adrenal hyperplasia (CAH) refers to a group of autosomal recessive disorders that impair cortisol biosynthesis. CAH represents a continuous phenotypic spectrum with over 95% of all cases caused by 21-hydroxylase deficiency. CAH owing to 21-hydroxylase deficiency is the most common cause of genital ambiguity in the newborn and is present in about 1 in 15,000 live births worldwide.

Immunoassays are typically used to quantify 17-hydroxyprogesterone (17-OHP) as a marker for CAH in the newborn screening programmes. However, these immunoassays are hampered by cross-reactivity of the antibodies with other steroids, yielding a high rate of false-positive results.

Liquid Chromatography - Tandem mass spectrometry (LC-MS/MS) techniques allows for the simultaneous specific determination of 17-OHP and other steroids related with CAH such as androstenedione, cortisol, 11-deoxycortisol, and 21-deoxycortisol. Application of this technology to the determination of steroids in newborn blood spots significantly enhances the correct identification of patients with CAH and reduces the number of false-positive screening results when implemented as a second-tier analysis performed prior to reporting of initial newborn screen results.

The CAH-Mass kit is designed for accurate and sensitive quantitation of 17-hydroxyprogesterone, androstenedione, cortisol, 11-deoxycortisol and 21-deoxycortisol in dried blood samples using LC-MS/MS.

Sample Treatment:

2 x 3mm punch from DBS sample (calibrator, control, patient)	Add 200 µL Reagent E. Mix for 30 min at 250 rpm	Take 150 µL of extract Evaporate until dryness at 40°C
Add 100 µL of Reagent D. Vortex for 30 seconds.	Centrifuge at 12.000 rpm for 5 minutes. Transfer 80 µL of clean supernatant to vial	Inject 20 µL to LC-MS/MS system.

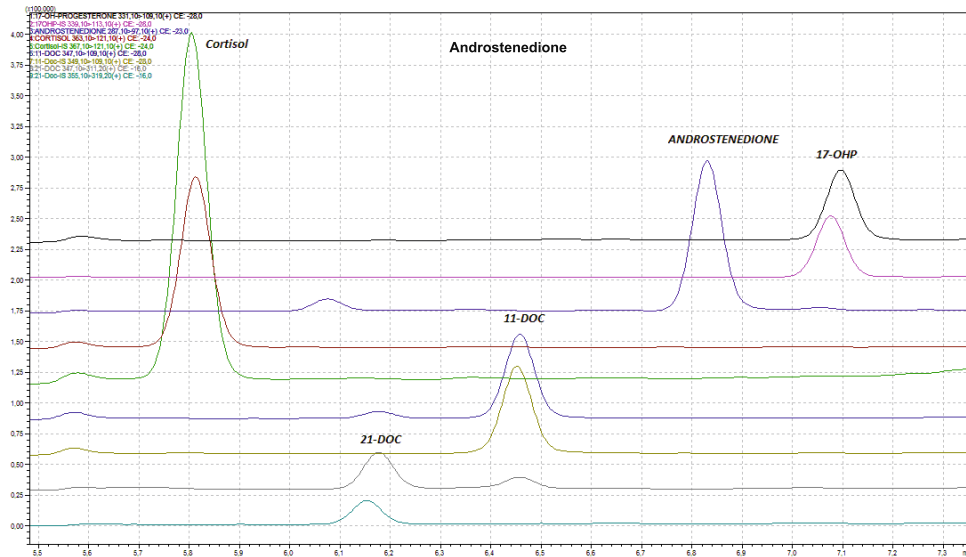
Test Data :

Linearity

Analyte	Linearity (R ² > 0.995)
17-OHP	0.4 - 120 ng/mL
Cortisol	1.3 - 500 ng/mL
Androstenedione	0.4 - 120 ng/mL
11-deoxycortisol	0.5 - 100 ng/mL
21-deoxycortisol	0.7 - 150 ng/mL

Repeatability&Reproducibility

Analyte	Intra-day (%CV)	Inter-day (%CV)
17-OHP	% 5,6	% 8,7
Cortisol	% 3,2	% 7,1
Androstenedione	% 6,2	% 7,8
11-deoxycortisol	% 4,8	% 8,1
21-deoxycortisol	% 6,5	% 9,7



LC-MS/MS Parameters

System	Shimadzu 8050 or higher MS/MS with UHPLC System
Ionization	ESI Positive
Flow	0.4 mL/min, gradient
Column Oven	40°C
Injection Volume	20 µL
Run Time	12 Minutes

Kit Description

DBS Calibrator and Controls Extraction solution with IS Dilution solution
Mobile phase A Mobile phase B Analytical column (must be ordered separately)

Ordering Information

Ordering Information	Tests	Shelf Life
BR130022	CAH-Mass Kit	100 Tests
BR130023	CAH-Mass Kit	500 Tests
BR130023C1	CAH-Mass Kit Analytical Column	

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