



## NeoMass CAH

**Second Tier LC-MS/MS Kit for Confirmation  
of Congenital Adrenal Hyperplasia from  
Dried Blood Spots**

## CE-IVD Kit for Steroid Profiling in CAH Diagnosis

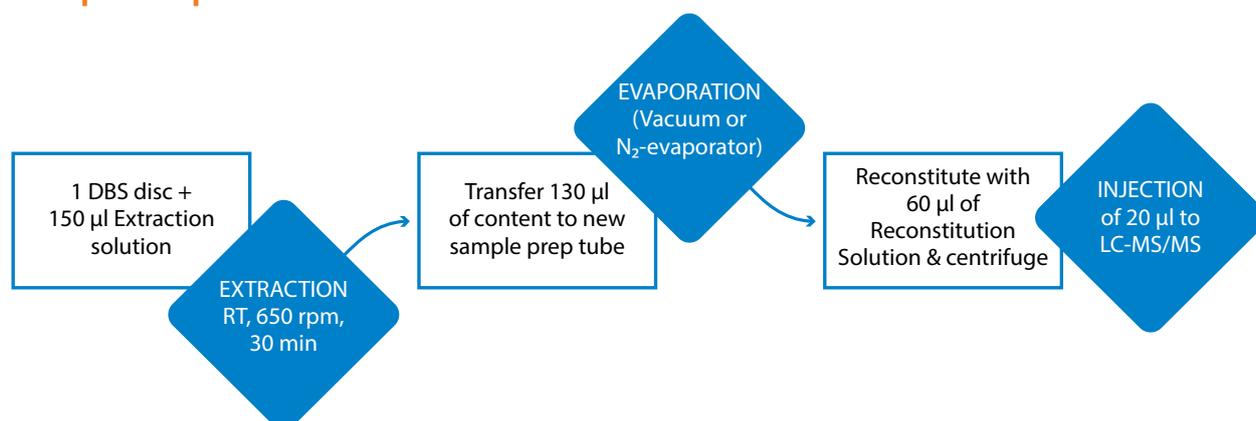
Congenital adrenal hyperplasia (CAH) refers to a group of autosomal recessive disorders that impair steroid biosynthesis and are associated with abnormal cortisol production. In around 95% of all cases this disease is caused by a deficiency in 21-hydroxylase. This enzyme converts 17-Hydroxyprogesterone in few biosynthetic steps into Aldosterone and Cortisol. As a consequence, CAH results in the inability to produce the above mentioned mineral and glucocorticoid which leads to insufficiency of the adrenal glands and to an overproduction of steroid hormone precursors. Finally, the result of

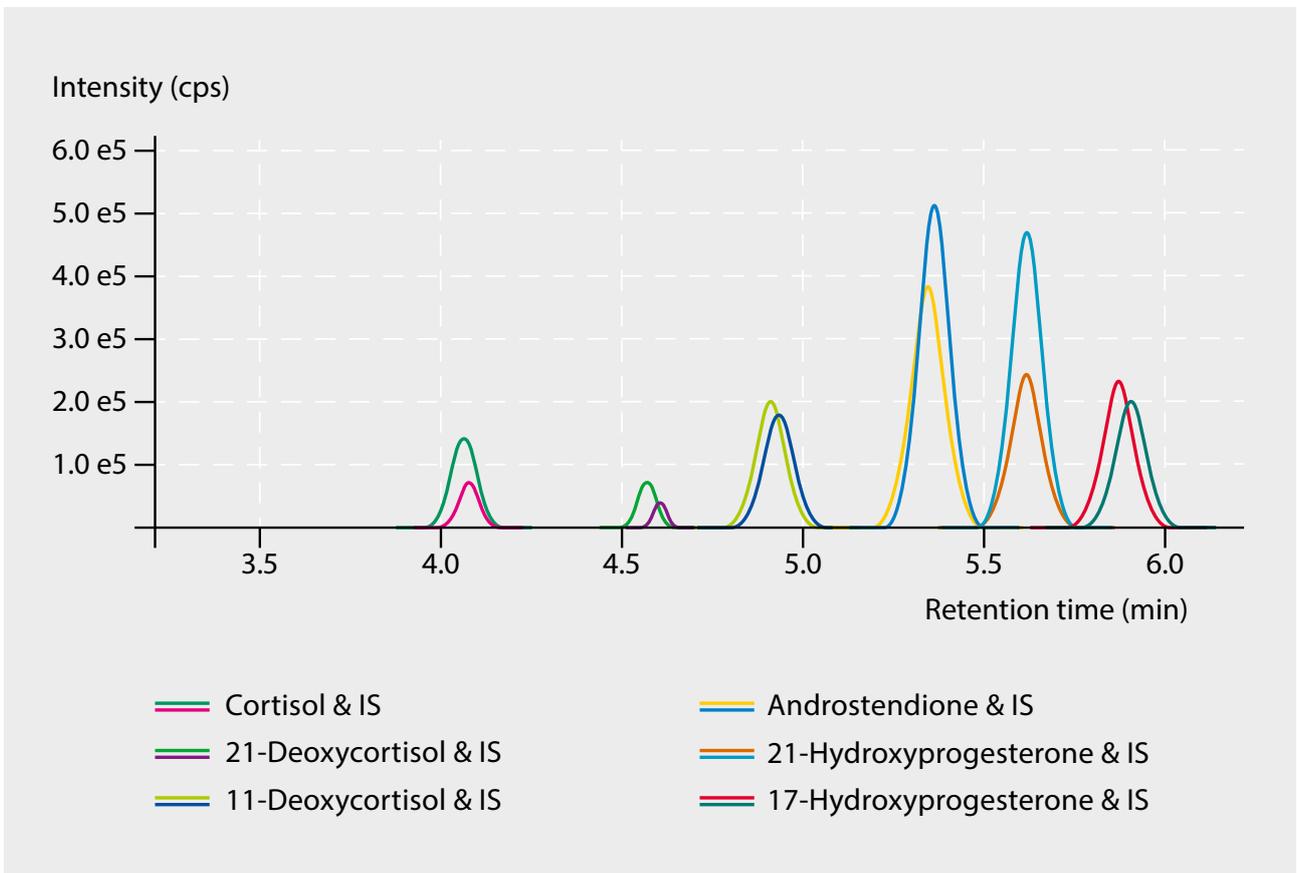
this accumulation is an increased production of androgens in both sexes. Therefore, CAH is the most common cause of genital ambiguity in newborns and affects approximately 1 of 15,000 live births worldwide.

NeoMass CAH kit allows for the simultaneous specific determination of most clinically relevant steroids related to CAH from dried blood spot samples using LC-MS/MS. This highly sensitive and specific technology significantly reduce false-positive screening results for 17-hydroxyprogesterone.

- ◆ Includes all clinically relevant parameters for CAH steroid profiling: **Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol, 17-Hydroxyprogesterone & 21-Hydroxyprogesterone.**
- ◆ Sample preparation from 1 DBS disc in less than 45 min.
- ◆ Simple sample preparation protocol for reaction tubes or 96-well plates available
- ◆ Isotopically labelled internal standards for all analytes
- ◆ Proven 8-Level DBS calibrators and 3-Level DBS controls prepared according to CLSI
- ◆ Clear and reliable 10 min-chromatographic separation including isobaric compounds
- ◆ Suitable for most mid- and high-sensitive LC-MS/MS instruments
- ◆ All components separately available

### Sample Preparation Procedure





This chromatogram was obtained by analysis of a prepared LabSystems control level II

## LC-MS/MS Parameters

LC-MS/MS	Requires sufficient sensitivity equivalent to Shimadzu 8050
MS/MS Mode	MRM
Ionisation	ESI positive
Flow Rate	0.25 mL/min, binary gradient
Column Temperature	40 °C
Injection Volume	20 µL
Injection Interval	10 minutes

## Performance Data

**Linearity:** Linearity is specified as the range between LLOQ and ULOQ.

**Recovery:** Relative recovery was determined from blood on Dried Blood Spots.

Analyte	Linear range [ng/ml blood]
Androstendione	0,80 - 400
Cortisol	1,30 - 600
11-Deoxycortisol	0,90 - 400
21-Deoxycortisol	0,70 - 300
17-Hydroxyprogesterone	0,90 - 400
21-Hydroxyprogesterone	0,90 - 400

Analyte	Recovery [%]
Androstendione	82
Cortisol	90
11-Deoxycortisol	86
21-Deoxycortisol	95
17-Hydroxyprogesterone	90
21-Hydroxyprogesterone	85

**Reproducibility:** The inter-assay and intra-assay reproducibility were determined according to CLSI guidelines using three different concentrations: C1 (4,44-4,73 ng/ml), C2 (14,8-15,78 ng/ml) and C3 (147,96-157,76 ng/ml).

Analyte	Intra-assay (%CV)			Inter-assay (%CV)		
	C 1	C 2	C 3	C 1	C 2	C 3
Androstenedione	6,60	5,10	5,20	4,00	2,90	3,00
Cortisol	8,60	6,70	5,00	7,00	4,70	4,30
11-Deoxycortisol	6,20	6,30	5,30	5,00	3,50	4,00
21-Deoxycortisol	9,30	7,10	5,30	2,90	4,00	4,00
17-Hydroxyprogesterone	7,10	6,80	5,50	5,40	4,10	3,10
21-Hydroxyprogesterone	6,90	6,10	5,60	4,30	3,50	3,80

## Ordering Information

Product Code	Product
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<b>7150022</b>	<b>NeoMass CAH Kit</b> For 200 analyses
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Kit Contents	Mobile Phase A, 700 ml Mobile Phase B, 700 ml Rinsing Solution, 300 ml Extraction Solution with Internal Standard, 33 ml Reconstitution Solution, 20 ml Sample Preparation Tubes, 2 x 200 pcs Instruction for use
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### Components available separately

#### Start Accessories:

3467707/H	CAH-Analytical Column/HPLC, equilibrated, with original test chromatogram, 1 pc.
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3467707/U	CAH-Analytical Column/U(H)PLC, equilibrated, with original test chromatogram, 1 pc.
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3467708	Tuning Mixture CAH (lyophilized), Mixture of analytes and labelled internal standards for MS optimization, 2 ml.
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3467709	System Suitability Mixture CAH (lyophilized), 2 ml.
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3467700	NeoMass CAH Multilevel Calibrators, Dried Blood Spot Calibrators Level 0-7, 1 x 8 spots.
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3467701	NeoMass CAH Multilevel Controls, Dried Blood Spot Controls Level 1-3, 2 x 3 spots.
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2205	Sample Preparation Plates, U-bottomed, 2 x 3 plates.
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2605	Sample Analysis Plates, V-bottomed, 1 x 3 plates.
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1541891	Extraction Plate Cover, 1 x 6 covers.
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1541850	Analysis Plate Cover, 1 x 3 covers.
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### Kit Components available separately

3467702	Extraction Solution with Internal Standard, 33 ml
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3467703	Reconstitution Solution, 20 ml
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3467704	Mobile Phase A, 700 ml
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3467705	Mobile Phase B, 700 ml
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3467706	Rinsing Solution, 300 ml
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3467710	Sample Preparation Tubes, 2 x 200 pcs
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