TRIMARIS

# **CAH**-Steroid profiling by LC-MS/MS

Kit for Quantitative Determination of 17-hydroxyprogesterone, Androstenedione, Cortisol, 11-deoxycortisol and 21-deoxycortisol in DRIED BLOOD SPOT Samples

Second-tier test

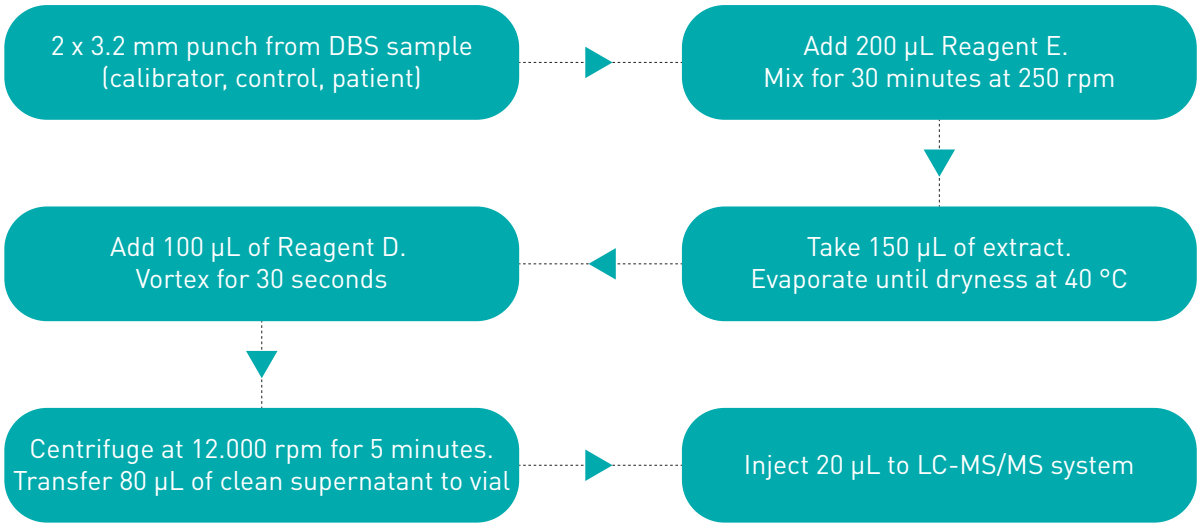
Congenital Adrenal Hyperplasia in newborns

## Introduction

Congenital adrenal hyperplasia (CAH) refers to a group of autosomal recessive disorders that impair steroid biosynthesis. CAH represents a continuous phenotypic spectrum with over 90% of all cases caused by 21-hydroxylase deficiency. CAH is the most common cause of genital ambiguity in the newborn and is present in about 1 in 15,000 live births worldwide.

CAH kit allows for the simultaneous specific determination of 17-OHP and other steroids related to CAH such as androstenedione, cortisol, 11-deoxycortisol, and 21-deoxycortisol in dried blood samples using LC-MS/MS. Application of this technology to the determination of the above mentioned specific 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.

## Sample Preparation




## Performance Data

### Linearity

Between LLOQ and highest value measured

| Analyte | Linearity Range |
|---|---|
| 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 |

### Recovery

Calculated by using certified reference materials

| Analyte | Recovery Rate |
|---|---|
| 17-OHP | %105.11 |
| Cortisol | %93.76 |
| Androstenedione | %95.05 |
| 11-deoxycortisol | %101.18 |
| 21-deoxycortisol | %101.45 |

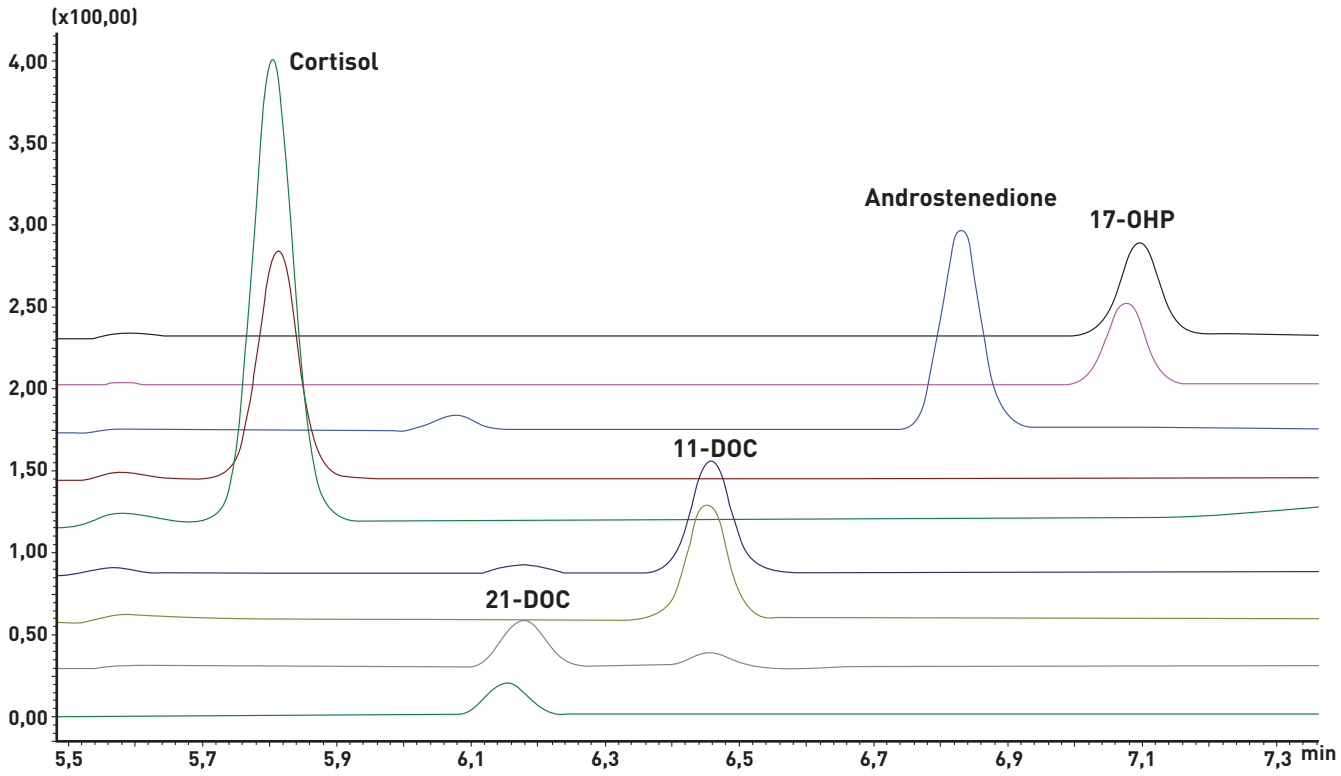
## Reproducibility

| Analyte | *Intra-assay precision (%CV) | **Inter-assay precision (%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 | Requires LC-MS/MS with sufficient sensitivity |
| Ionization | ESI positive |
| Flow | 0.4 mL/min, gradient |
| Column Oven | 40 °C |
| Injection Volume | 20 µL |
| Run Time | 12 minutes |

## Sample Chromatogram




## Ordering Information

| Product Code | Product Name | Tests |
|---|---|---|
| BR130022 | CAH Kit | 100 Tests |
| BR130023 | CAH Kit | 500 Tests |
| BR130023C1 | CAH Kit Analytical Column | |

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