

STEROID HORMONES IN SERUM AND IN PLASMA BY LC-MS/MS

REF LC72310

11-DEOXYCORTICOSTERONE, 11-DEOXYCORTISOL, 17-HYDROXY-PREGNENOLONE, 17-HYDROXY-PROGESTERONE, 21-DEOXYCORTISOL, ALDOSTERONE, ANDROSTENEDIONE, ANDROSTERONE, CORTICOSTERONE, CORTISOL, CORTISONE, DEHYDROEPIANDROSTERONE (DHEA), DEHYDROEPIANDROSTERONE SULFATE (DHEAS), DIHYDROTESTOSTERONE (DHT), β -ESTRADIOL, ESTRONE, PREGNENOLONE, PROGESTERONE, TESTOSTERONE

This product fulfills all the requirements of Directive 98/79/EC on in vitro diagnostic medical devices (IVD). The declaration of conformity is available upon request.



INSTRUCTIONS FOR USE

IVD

For *in vitro* diagnostic use

CE



EUREKA S.R.L. LAB DIVISION
Via M. D'Antona 28
60033 Chiaravalle (AN) - Italy
Tel +39 071 7450790
eureka-support@sentinel.it
www.eurekakit.com

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INTENDED USE

In vitro diagnostic device intended for the detection and quantitative determination of 11-Deoxycorticosterone, 11-Deoxycortisol, 17-OH-Pregnenolone, 17-OH-Progesterone, 21-Deoxycortisol, Aldosterone, Androstenedione, Androsterone, Corticosterone, Cortisol, Cortisone, DHEA, DHEAS, Dihydrotestosterone, β -Estradiol, Estrone, Pregnenolone, Progesterone, Testosterone in serum and in plasma as an aid for the diagnosis of numerous steroid-related endocrine diseases. Manual method for professional use.

KIT CONTENT FOR 100 TESTS

CONTENT	DESCRIPTION	PACKAGING	WARNING
Reagent A	Deproteinization Solution	4 x 25 ml	Store at +2 °C  +8 °C
Reagent B	Internal Standard Solution	2 x 500 μ l	Store at -25 °C  -15 °C
Reagent C	Diluting Solution	1 x 12 ml	Store at +2 °C  +8 °C
Multiparametric Calibrator in plasma		7 x 2 x 1 ml	(Packed separately – Code LC72316 -see data sheet)
Reagent M1	Mobile Phase M1	2 x 500 ml	Store at +2 °C  +8 °C
Reagent M2	Mobile Phase M2	3 x 500 ml	Store at +2 °C  +8 °C

ACCESSORIES AND CONSUMABLES AVAILABLE SEPARATELY

CODE	DESCRIPTION	PACKAGING
LC72316	Calibrator for Steroid Hormones in plasma	7 x 2 x 1 ml
LC72319	Control for Steroid Hormones in plasma-Levels 1, 2 and 3	3 x 5 x 1 ml
SK72310	Starter kit for Steroid Hormones in plasma	27 x 1 ml
LC72311	Mobile Phase M1	4 x 500 ml
LC72321	Mobile Phase M2	4 x 500 ml
LC72330	Labelled Internal Standard Mix Solution in plasma	2 x 500 µl
Z699675902	Analytical Column Poroshell 120- EC - C18 (50 x 2,1 mm - 1,9 µm)	1 Pc
S29057U	Standard glass vials of 2 ml with screw cap for Autosampler	1 x 100 Pcs
S24717	Glass Insert 100 µl for vials of 2 ml	1 x 100 Pcs
L-30-210	Eppendorf Test tubes by 1,5 ml with caps	1 x 1000 Pcs

INSTRUMENTS

DESCRIPTION	WARNING
Centrifugal evaporator	Required
LC/MS System with triple quadrupole ESI+/- according to molecules that you need to analyze	Required
Operational Computer	Required
Autosampler	Required

MATRIX - COLLECTION AND STORAGE PROCEDURE

MATRIX	PROCEDURE
Plasma	Dispense 3 ml of Whole Blood into a test tube with EDTA as anticoagulant. Centrifuge at 4000 rpm for 5 minutes. Collect the supernatant (plasma) and store it at  ^{-15 °C} for no longer than 1 month.
Serum	Dispense 3 ml of venous blood into a tube for serum with or without gel. Centrifuge at 4000 rpm for 5 minutes. Separate the serum and store it at  ^{-15 °C} for no longer than 1 month.

REFERENCE VALUES

Hormones	Normal Range (ng/ml)
11-Deoxycorticosterone	< 0,5
11-Deoxycortisol	< 0,9
17-OH-Pregnenolone	< 7,3
17-OH-Progesterone	< 1,7
21-Deoxycortisol	< 0,12
Aldosterone	0,025 – 0,229
Androstenedione	< 2,0
Androsterone	0,20 – 0,80
Corticosterone	1,2 – 20,5
Cortisol	46,0 – 207,0
Cortisone	7,1 – 27,9
DHEA	Male: 1,8 – 12,5 Female: 1,3 – 9,8
DHEAS	148,0 – 3.852,0
Dihydrotestosterone	Male: 0,25 – 0,75 Female: 0,05 – 0,30
β-Estradiol	Male: < 0,05 Female: 0,05 – 0,145 (follicular) 0,112 – 0,443 (ovulation) 0,05 – 0,241 (luteal) < 0,059 (postmenopause)
Estrone	Male: 0,01 – 0,06 Female: 0,017 – 0,20 (premenopause) 0,007 - 0,04 (postmenopause)
Pregnenolone	< 1,3
Progesterone	Male: < 0,13 Female: < 9,4
Testosterone	Male: 2,9 – 8,6 Female: < 1,7

Please, note: the values reported here refer to ADULTS subjects

References:

- Taylor et al. A 13-Steroid Serum Panel Based on LC-MS/MS: Use in Detection of Adrenocortical Carcinoma. Clinical Chemistry (2017), 63:12)
- Thomas L (Hrsg). Labor und Diagnose. 8. Aufl, Verlag TH Books Frankfurt/Main (2012).
- Shackleton C. Genetic disorders of steroid metabolism diagnosed by mass spectrometry. In: Blau N, Duran M, Gibson KM (eds). Laboratory guide to the methods in biochemical genetics (2008), pag. 549-606. Springer-Verlag, Berlin Heidelberg

ANALYTICAL PROCEDURE

STEP	DESCRIPTION																				
1	IMPORTANT: DO NOT USE GLASS TUBES OR VIALS DURING ANY STEP OF THE PREPARATION! Reconstitution of Deproteinization Solution. Add 250 µl of Reagent B to Reagent A (Stable for 3 months at  - 15 °C - 25 °C) Dispense into Eppendorf tubes in sequence: <table><tr><td></td><td>Calibrator (µl)</td><td>Sample (µl)</td><td>Controls (µl)</td></tr><tr><td>Calibrator</td><td>400</td><td></td><td></td></tr><tr><td>Sample</td><td></td><td>400</td><td></td></tr><tr><td>Controls</td><td></td><td></td><td>400</td></tr><tr><td>Reagent A (after reconstitution)</td><td>1000</td><td>1000</td><td>1000</td></tr></table> Deproteinize directly on Vortex for 10 sec.		Calibrator (µl)	Sample (µl)	Controls (µl)	Calibrator	400			Sample		400		Controls			400	Reagent A (after reconstitution)	1000	1000	1000
	Calibrator (µl)	Sample (µl)	Controls (µl)																		
Calibrator	400																				
Sample		400																			
Controls			400																		
Reagent A (after reconstitution)	1000	1000	1000																		
2	Centrifuge at 14.000 rpm for 10 minutes. Take the supernatant and dry with the evaporator (maximum temperature: 55 °C). (Stable for 1 month at  - 15 °C - 25 °C)																				
3	Add 100 µl of Reagent C to dry Eppendorf tubes. Vortex for 1 minute. Centrifuge at 14.000 rpm for 5 minutes. Transfer all the supernatant into vials with insert.																				
INJECTION	Inject 15 µl of the solution into the LC system																				

GRADIENT

Time (min)	% M1 (PUMP A)	% M2 (PUMP B)	Flow (µl/min)
0	65	35	400
0.5	65	35	400
2.0	55	45	400
7.8	29,5	70,5	400
7.9	2	98	400
9.9	2	98	400
10.0	65	35	400
12.0	65	35	400

PARAMETERS

Parameters set on triple quadrupole SCIEX 4500

	STEROID HORMONES PARAMETERS ESI POSITIVE	STEROID HORMONES PARAMETERS ESI NEGATIVE (to optimized DHEAS and/or Aldosterone in case of low sensitivity in ESI + mode)
CURTAIN GAS (CUR)	25	30
COLLISION GAS (CAD)	9	8
ION SPRAY VOLTAGE (IS)	5500 V	-4500 V
TEMPERATURE (TEM)	600°C	600°C
ION SOURCE GAS 1 (GS1)	50	50
ION SOURCE GAS 2 (GS2)	60	60

FRAGMENTATION OF ANALYTES AND LABELLED INTERNAL STANDARDS (IS)

ANALYTES	RT (min)	FRAGMENTATION		LABELLED IS USED FOR CALIBRATION	RT (min)	FRAGMENTATION	
		PAREN T ION (Q1)	FRAGM ENT ION (Q3)			PAREN ION (Q1)	FRAGMENT ION (Q3)
11-Deoxycorticosterone -1	5.01	331.1	97.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
11-Deoxycorticosterone -2	5.01	331.1	109.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
11-Deoxycortisol - 1	4.06	347.1	97.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
11-Deoxycortisol - 2	4.06	347.1	109.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
17-OH-Pregnenolone - 1	5.57	297.2	105.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
17-OH-Pregnenolone - 2	5.57	297.2	145.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
17-OH-Progesterone - 1	5.53	331.0	97.0	<i>17-OH-Progesterone-¹³C3</i>	5.53	334.1	112.1
17-OH-Progesterone - 2	5.53	331.0	109	<i>17-OH-Progesterone-¹³C3</i>	5.53	334.1	112.1
21-Deoxycortisol - 1	3.64	347.2	311.1	<i>Cortisol-D4</i>	2.96	367.1	121.0
21-Deoxycortisol - 2	3.64	347.2	269.2	<i>Cortisol-D4</i>	2.96	367.1	121.0
Aldosterone - 1 -	2.25	359.1	188.9	<i>Aldosterone-D7 -</i>	2.25	366.0	194.1
Aldosterone - 1 +	2.25	361.2	315.1	<i>Aldosterone-D7 +</i>	2.25	368.2	322.1
Androstenedione - 1	4.63	287.1	109.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
Androstenedione - 2	4.63	287.1	97.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
Androsterone - 1	7.20	273.1	159.2	<i>Testosterone-D3</i>	5.05	292.2	97.1
Androsterone - 2	7.20	273.1	147.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
Corticosterone - 1	3.87	347.1	121.1	<i>Testosterone-D3</i>	5.05	292.2	97.1
Corticosterone - 2	3.87	347.1	107.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
Cortisol - 1	2.96	363.1	121.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
Cortisol - 2	2.96	363.1	115.1	<i>Cortisol-D4</i>	2.96	367.1	121.0
Cortisone - 1	2.66	361.2	163.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
Cortisone - 2	2.66	361.2	121.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
DHEA - 1	5.43	289.1	213.1	<i>DHEA-D6</i>	5.43	277.2	259.2
DHEA - 2	5.43	289.1	253.0	<i>DHEA-D6</i>	5.43	277.2	259.2
DHEAS - 1 -	3.75	367.0	133.0	<i>DHEAS-D5 -</i>	3.74	374.0	100.0
DHEAS - 1 +	3.75	271.2	133.0	<i>DHEAS-D5 +</i>	3.74	276.2	138.0
DHEAS - 2 +	3.75	271.2	157.0	<i>DHEAS-D5 +</i>	3.74	276.2	138.0
DHT - 1	6.54	291.1	255.2	<i>Testosterone-D3</i>	5.05	292.2	97.1
DHT - 2	6.54	291.1	159.2	<i>Testosterone-D3</i>	5.05	292.2	97.1
β-Estradiol - 1	4.60	255.1	159.1	<i>β-Estradiol-D5</i>	5.39	260.2	161.0

β -Estradiol - 2	4.60	255.1	144.0	<i>β-Estradiol-D5</i>	5.39	260.2	161.0
Estrone - 1	4.62	271.2	133.0	<i>DHEA-D6</i>	5.43	277.2	259.2
Estrone - 2	4.62	271.2	157.0	<i>DHEA-D6</i>	5.43	277.2	259.2
Pregnenolone - 1	7.58	299.1	159.2	<i>Pregnenolone-D4</i>	7.58	303.2	285.2
Pregnenolone - 2	7.58	299.1	131.1	<i>Pregnenolone-D4</i>	7.58	303.2	285.2
Progesterone - 1	6.86	315.1	97.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
Progesterone - 2	6.86	315.1	109.0	<i>Cortisol-D4</i>	2.96	367.1	121.0
Testosterone - 1	5.05	289.1	97.0	<i>Testosterone-D3</i>	5.05	292.2	97.1
Testosterone - 2	5.05	289.1	109.0	<i>Testosterone-D3</i>	5.05	292.2	97.1

TECHNICAL FEATURES - PART I

ABBREVIATION	MEANING
C LLOQ	Concentration at low limit of quantification
C1	Low concentration
C2	Medium concentration
C3	High concentration
Max C	The highest concentration

ANALYTES	CONCENTRATIONS USED TO CALCULATE REPRODUCIBILITY AND ACCURACY (ng/ml)				
	C LLOQ	C1	C2	C3	MAX C
11-Deoxycorticosterone	0,01	0,49	1,5	4,4	22
11-Deoxycortisol	0,02	0,17	0,5	1,5	7,5
17-OH-Pregnenolone	0,06	1,1	1,8	2,2	11
17-OH-Progesterone	0,03	0,12	0,37	1,1	5,5
21-Deoxycortisol	0,01	0,05	0,13	0,40	2,0
Aldosterone	0,03	0,06	0,17	0,5	2,5
Androstenedione	0,02	0,18	0,53	1,6	8,0
Androsterone	0,13	0,44	1,3	4,0	20
Corticosterone	0,04	0,44	1,3	4,0	20
Cortisol	0,02	9,0	27	81	103
Cortisone	0,27	9,0	27	81	403
DHEA	0,1	0,9	2,7	8,1	40
DHEAS	15	136	408	1225	6123
DHT	0,07	0,14	0,42	1,2	6,2
β-Estradiol	0,03	0,07	0,13	0,4	2,0
Estrone	0,01	0,02	0,07	0,2	1
Pregnenolone	0,06	1,1	1,8	2,2	11
Progesterone	0,005	0,82	2,4	7,3	37
Testosterone	0,006	0,27	0,80	2,4	12

ANALYTES	ACCURACY INTRA SERIE (RELATIVE ERROR %)		ACCURACY INTER SERIE (RELATIVE ERROR %)	
	C1 (%)	C3 (%)	C1 (%)	C3 (%)
11-Deoxycorticosterone	4,2	5,1	5,5	6,5
11-Deoxycortisol	3,2	4,5	5,1	10,1
17-OH-Pregnenolone	8,1	5,9	6,4	6,2
17-OH-Progesterone	4,6	1,5	4,9	3,0
21-Deoxycortisol	2,2	4,6	5,4	7,9
Aldosterone	5,5	9,9	8,1	10,9
Androstenedione	1,3	4,5	4,1	6,9
Androsterone	0,8	4,2	2,7	5,6
Corticosterone	4,7	1,5	6,6	2,9
Cortisol	1,2	1,3	2,5	3,6
Cortisone	2,4	0,2	3,7	3,7
DHEA	4,7	8,3	5,7	5,3
DHEAS	3,4	2,2	4,2	3,9
DHT	3,1	2,6	3,9	6,2
β-Estradiol	2,2	5,3	4,4	6,0
Estrone	6,1	9,2	6,1	5,4
Pregnenolone	5,1	6,4	5,4	6,6
Progesterone	3,8	2,2	4,6	7,2
Testosterone	5,4	3,3	8,9	5,3

TECHNICAL FEATURES - PART II

ANALYTES	REPRODUCIBILITY INTRA SERIE (COEFFICIENT OF VARIATION %)			REPRODUCIBILITY INTER SERIE (COEFFICIENT OF VARIATION %)		
	C LLOQ %	C2 %	Max C %	C LLOQ %	C2 %	Max C %
11-Deoxycorticosterone	12,3	2,0	4,0	11,8	8,6	9,0
11-Deoxycortisol	3,5	2,0	2,4	13,6	10,2	6,5
17-OH-Pregnenolone	7,9	4,9	4,8	8,9	9,6	9,6
17-OH-Progesterone	3,2	2,3	1,3	8,4	5,8	2,7
21-Deoxycortisol	5,8	1,6	1,5	10,0	3,5	2,4
Aldosterone	5,4	7,5	2,8	15,5	9,0	3,8
Androstenedione	3,8	4,2	2,5	12,1	9,1	8,2
Androsterone	4,8	3,3	4,0	10,3	4,1	6,8
Corticosterone	6,7	3,1	2,5	8,3	10,8	10,4
Cortisol	1,2	1,0	1,3	3,8	3,7	7,5
Cortisone	2,4	2,9	2,1	7,0	3,6	3,9
DHEA	3,0	6,1	4,2	10,0	10,7	7,1
DHEAS	2,5	2,1	1,2	6,2	2,9	3,3
DHT	4,6	3,9	4,2	9,1	10,5	8,6
β-Estradiol	8,9	7,3	4,7	15,8	14,8	7,2
Estrone	4,1	10,5	4,2	11,0	12,5	10,4
Pregnenolone	8,5	4,7	5,8	9,1	5,9	12,1
Progesterone	3,8	4,5	5,2	7,5	5,2	6,1
Testosterone	5,2	2,2	3,3	6,9	8,9	6,2

TECHNICAL FEATURES - PART III

ANALYTES	LLOD (ng/ml)	LINEARITY ng/ml	COEFFICIENT OF CORRELATION R2 + STD DEV
11-Deoxycorticosterone	0,006	0,01 – 22	0,9978 $\pm$ 0,0016
11-Deoxycortisol	0,006	0,02 – 6.000	0,9989 $\pm$ 0,0009
17-OH-Pregnenolone	0,02	0,06 – 250	0,9956 $\pm$ 0,0036
17-OH-Progesterone	0,006	0,03 – 570	0,9991 $\pm$ 0,0012
21-Deoxycortisol	0,003	0,01 – 4,5	0,9995 $\pm$ 0,0003
Aldosterone	0,009	0,03 – 560	0,9991 $\pm$ 0,0004
Androstenedione	0,005	0,02 – 1.060	0,9991 $\pm$ 0,0006
Androsterone	0,04	0,13 – 2.200	0,9992 $\pm$ 0,0005
Corticosterone	0,012	0,04 – 3.020	0,9990 $\pm$ 0,0011
Cortisol	0,005	0,02 – 3.020	0,9997 $\pm$ 0,0003
Cortisone	0,08	0,27 – 896	0,9996 $\pm$ 0,0004
DHEA	0,03	0,1 – 500	0,9988 $\pm$ 0,0013
DHEAS	5,0	15 – 852.900	0,9982 $\pm$ 0,0025
DHT	0,02	0,07 – 1.630	0,9991 $\pm$ 0,0007
β -Estradiol	0,01	0,03 – 510	0,9990 $\pm$ 0,0006
Estrone	0,003	0,01 – 510	0,9993 $\pm$ 0,0004
Pregnenolone	0,02	0,06 – 64	0,9983 $\pm$ 0,0013
Progesterone	0,001	0,005 – 4.000	0,9985 $\pm$ 0,0017
Testosterone	0,002	0,006 - 260	0,9991 $\pm$ 0,0009

REFERENCE CHROMATOGRAMS

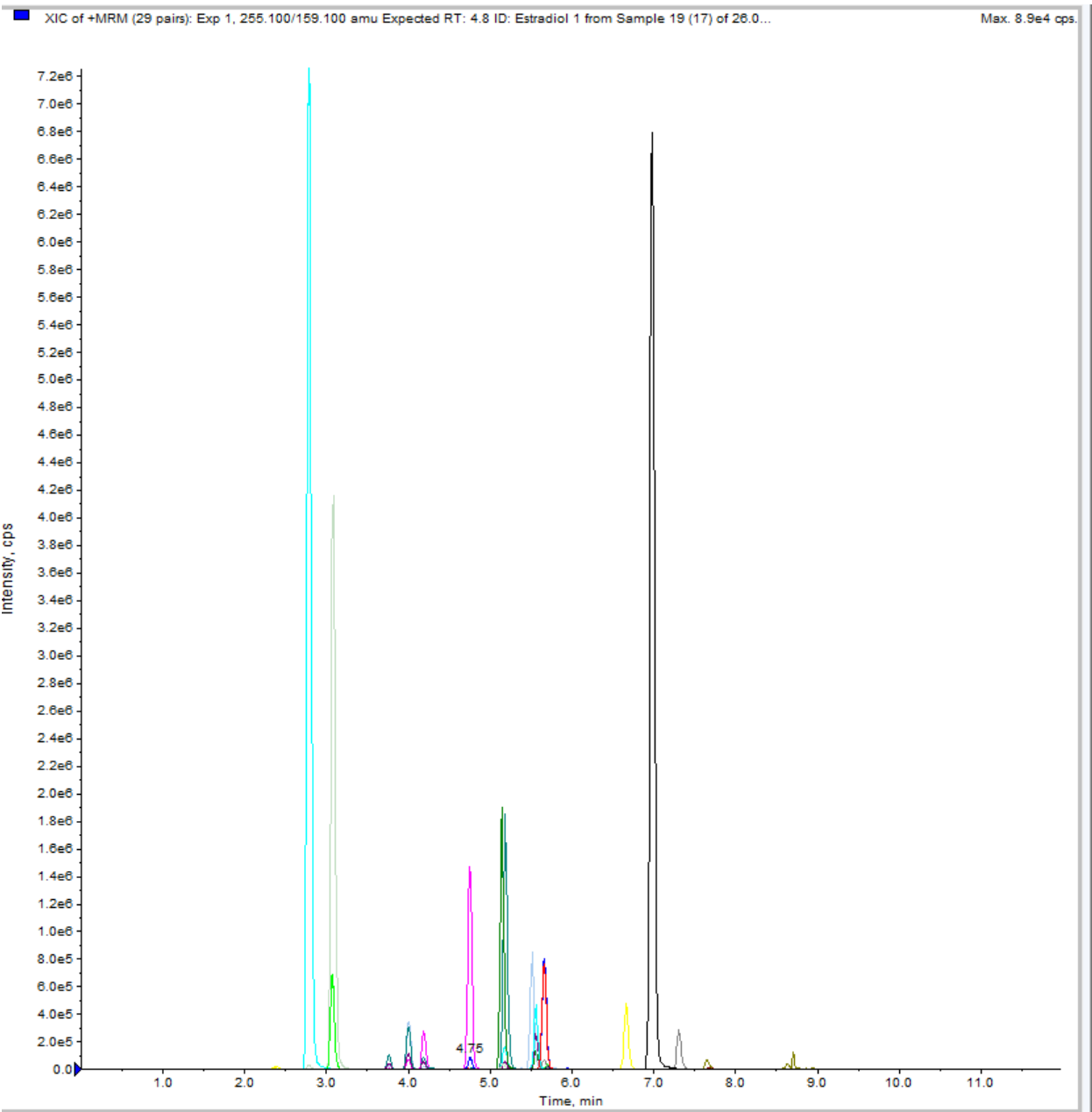


Fig.1 Calibrator level 5 for Steroid Hormones

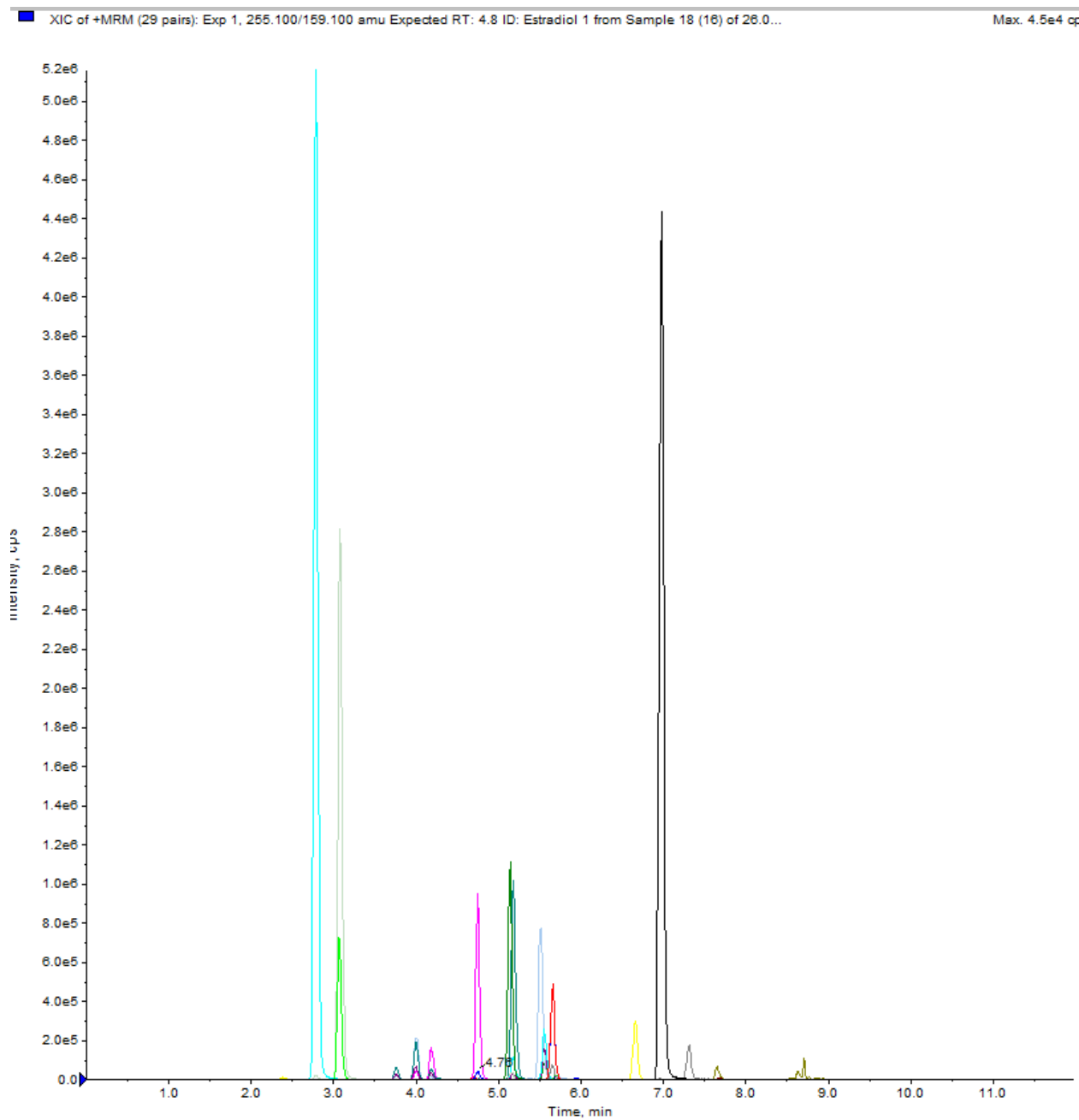


Fig.2 Control level 2 for Steroid Hormones

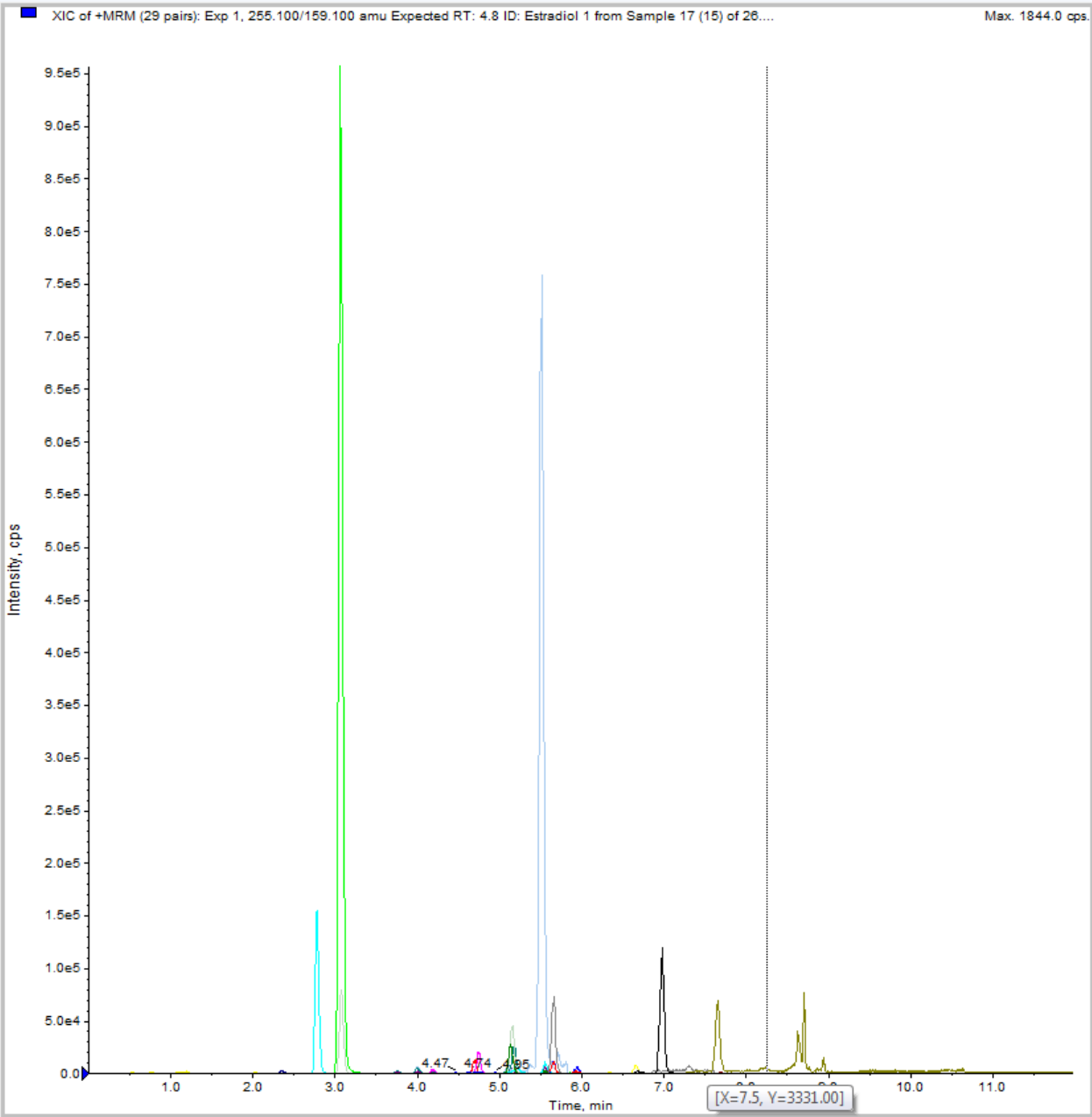


Fig.3 Real Sample treated for the dosage of Steroid Hormones

GENERAL WARNINGS**1. STORAGE AND SHELF LIFE**

All the components are ready-to-use. They are stable for 3 years at $+2^{\circ}\text{C}$  except from

Reagent B (Internal Standard Solution) that must be stored at -25°C .

After opening the shelf life of our internal standards is 6 months if stored at -25°C .

2. NEW COLUMN TREATMENT

Install a new analytical column Poroshell 120 EC C18 (50 x 2,1 mm -1,9 μm), thermostated at 55°C . Disconnect the detector and flux a solution of Mobile Phase M1: Mobile Phase M2 (20: 80 v/v) set flow at 400 μl / minute for 10 minutes. **Don't recycle the washing solutions.**

3. COLUMN CONDITIONING

Condition further the analytical column Poroshell 120 EC C18 (50 x 2,1 mm -1,9 μm), with a solution of Mobile Phase M1 : Mobile Phase M2 (20 : 80 v/v) at flow of 400 μl / minute for 10 minutes. Then, flux Mobile Phase M1: Mobile Phase M2 (80 : 20 v/v) set flow at 400 μl / min, for 5 minutes. And, flux Mobile Phase M1: Mobile Phase M2 (65 : 35 v/v) set flow at 400 μl / min, for 10 minutes. **Three injections of HPLC grade water before proceeding with the analytical series. It's NOT possible to make analysis at recycling phase.** If room temperature is $> 20^{\circ}\text{C}$, store

the Mobile Phase at $+2^{\circ}\text{C}$  between an analytical session and another.

4. COLUMN CLEANING

Disconnect the detector. Flux a solution of Mobile Phase M1: Mobile Phase M2 (80: 20 v/v) set flow at 400 μl / minute for 5 minutes discharge it, then flux Mobile Phase M1: Mobile Phase M2 (10: 90 v/v) set flow at 400 μl / minute, for 15 minutes. The column must be stored in a solution of Mobile Phase M1: Mobile Phase M2 (10: 90 v/v).

5. AUTOSAMPLER SYRINGE WASHING

Wash the syringe with $\text{H}_2\text{O}:\text{ACN}:\text{IPA}$ 33:33:33 + 0,1% Formic Acid before use.

ABBREVIATIONS

ABBREVIATIONS	MEANING
e.g. 5 x 1 x 1 ml	N° of levels x N° of vials x volume
e.g packaging of the starter kit 27 x 1 ml	N° of vials x volume Note: each vial contains one molecule (analyte or labelled IS)
17-OH-Pregnenolone	17-Hydroxy-pregnenolone
17-OH-Progesterone	17-Hydroxy-progesterone
DHEA	Dehydroepiandrosterone
DHEAS	Dehydroepiandrosterone Sulfate
DHT	Dihydrotestosterone
IS	Internal Standard
pc/pcs	Piece/pieces
RT	Retention Time
STD DEV	Standard Deviation

BIBLIOGRAPHY

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Steven J. Soldin and Offie P. Soldin Clin Chem 55:1061-1066, 2009
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R. Draisci, L. Palleschi, E. Ferretti, L. Lucentini, P. Cammarata Journal of Chromatography A, 870 (2000) 511–522
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REFERENCE STANDARDS

Quality Assurance System compliant with regulations:

UNI CEI EN ISO 13485:2016,

UNI EN ISO 9001:2015

Any modification made to the Medical Device unless authorized by Eureka S.r.l. - Lab Division makes this declaration invalid.

We declare that the devices comply with the following **Technical Standards**:

UNI CEI EN ISO 14971:2012

UNI CEI EN ISO 15223-1:2017

UNI EN ISO 18113-2:2012

We declare that the device is sold in a non-sterile package.

IVD SYMBOLS

NUMBER	SYMBOL	DESCRIPTION
1		Manufacturer
2		Product Model Number / Designation or Part Number
3		Caution, consult accompanying documents
4		Product Lot Number
5		Use By (Expiry)
6		Consult Operating Instructions
7		Date of manufacture
8		Temperature limitation
9		For <i>in vitro</i> diagnostic use
10		European Union conformity
11		Packaging