

RANDOX

CERTIFICATE OF ANALYSIS

This is to certify that the following kit was tested by a
Randox Testing Laboratory and approved by the QC Department.

DATE OF MANUFACTURE: September 2017
KIT DESCRIPTION: IMMUNOASSAY PREMIUM PLUS TRI-LEVEL
CATALOGUE NO: IA3112
LOT NUMBERS: 430312 (1714EC, 1716EC, 1719EC)
EXPIRY DATE: 2020-04-28
SYSTEM OF ANALYSIS: Siemens Immulite 2000

TEST CONTROLS OR VIALS

ANALYTE	LOT NUMBER	RANGE	TARGET	RESULT	PRECISION (if applicable)
AFP (U/ml)	1714EC	7.50-11.2	9.37	9.20	N/A
				9.00	
CEA (ng/ml)	1714EC	4.15-6.23	5.19	5.60	
				5.50	
FPSA (ug/L)	1714EC	0.705-1.18	0.940	0.917	
				1.000	
AFP (U/ml)	1716EC	37.8-56.8	47.3	44.4	
				41.9	
CEA (ng/ml)	1716EC	30.2-45.2	37.7	35.4	
				36.9	
FPSA (ug/L)	1716EC	5.06-8.44	6.75	6.52	
				6.75	
AFP (U/ml)	1719EC	144-216	180	160	
				169	
CEA (ng/ml)	1719EC	65.9-98.9	82.4	82.1	
				82.2	
FPSA (ug/L)	1719EC	11.3-18.9	15.1	15.5	
				16.5	

QC TESTED BY: Davina Graham
DATE: 21 Sep 2017
RESULT (PASS/FAIL): Pass
QC APPROVED BY: *Adèle Martin*

Randox Laboratories Limited, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
T +44 (0) 28 9442 2413 F +44 (0) 28 9445 2912 E marketing@randox.com I www.randox.com

Directors: Dr S P Fitzgerald BSc PhD DSc (Hons) FRAE Man. R J Fitzgerald, W Fitzgerald OBE, R F Kelly BSc FCA.
Randox Laboratories Limited is a company registered in Northern Ireland, Company Number NI15738, VAT Number GB 353 0304 00.

FORM NO. 6521-QC
REVISION (4)
14 April 2016

RANDOX

Randox Laboratories Limited, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
T +44 (0) 28 9442 2413 **F** +44 (0) 28 9445 2912 **E** marketing@randox.com **I** www.randox.com

Directors: Dr S P Fitzgerald BSc PhD DSc (Hons) FIAE Man. R J Fitzgerald, W Fitzgerald OBE, R P Kelly BSc FCA.
Randox Laboratories Limited is a company registered in Northern Ireland. Company Number NI115738. VAT Number GB 353 0304 00.

FORM NO. 6521-QC
REVISION (4)
14 April 2016