PRODUCT INFORMATION

663LPC

PS2684

Please note that while Antithrombin III is present in PS2684 - Liquid Assayed Specific Protein Control Level 3 - lot 663LPC, targets and ranges are not available for this analyte at this time and will be added in due course.

CCS INC127

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

CAT. NO.	PS2684	**LOT NO.**	663LPC
SIZE:	3 x 1 ml	**EXPIRY:**	2025-01-28
GTIN:	05055273204919		

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of serum on clinical chemistry and immunoassay systems. The Assayed Liquid Protein Controls are for the control of accuracy.

DEVICE DESCRIPTION
The Liquid Protein Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values table. Note: Free Lambda light chains are not for use in the U.S.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY
OPENED: Store refrigerated (+2°C to +8°C). Protein control material is stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

Note: Free Kappa Light Chains is present in the Liquid Assayed Specific Protein Control material but no claim is made for the expected value or stability of this analyte.

PREPARATION
The Liquid Protein Controls are supplied ready for use. Allow the control to come to room temperature before analysis.

MATERIALS PROVIDED
Liquid Protein Control - Level 3 3 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

LIMITATIONS
RF: Please note that the dilution of multi-controls on certain systems can result in the over recovery of R.F. compared to the undiluted control. This is due to complex Immunoglobulin interactions.

ASSIGNED VALUES
Each batch of Protein Control is submitted to approximately 100 laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch, a control range is provided for individual parameters and each parameter method.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: (+44 (0) 28 94451070 or email Technical.Services@randox.com.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 23 May '23 me

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 663LPC Size 3 x 1 ml Expiry 2025-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	57.6	49.0	66.2	Bromocresol Green (IFCC Cal.)
	g/dl	5.76	4.90	6.62	
	g/l	58.0	49.3	66.7	Bromocresol Purple (IFCC Cal.)
	g/dl	5.80	4.93	6.67	
	g/l	60.2	51.2	69.2	Nephelometric (IFCC Cal.)
	g/dl	6.02	5.12	6.92	
	g/l	59.2	50.3	68.1	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.92	5.03	6.81	
	g/l	57.7	49.0	66.4	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.77	4.90	6.64	
Alpha-1-Acid Glycoprotein	g/l	1.79	1.43	2.15	Turbidimetric (IFCC Cal.)
	mg/dl	179	143	215	
	g/l	1.88	1.50	2.26	Nephelometric (IFCC Cal.)
	mg/dl	188	150	226	
	g/l	1.73	1.38	2.08	Turbidimetric (Non IFCC Cal.)
	mg/dl	173	138	208	
Alpha-1-Antitrypsin	g/l	1.83	1.46	2.20	Turbidimetric (IFCC Cal.)
	mg/dl	183	146	220	
	g/l	2.09	1.67	2.51	Nephelometric (IFCC Cal.)
	mg/dl	209	167	251	
	g/l	1.83	1.46	2.20	Turbidimetric (Non IFCC Cal.)
	mg/dl	183	146	220	
Alpha-2-Macroglobulin	g/l	3.40	2.72	4.08	Nephelometric (IFCC Cal.)
	mg/dl	340	272	408	
Alphafoetoprotein	KIU/l = IU/ml	41.9	33.5	50.3	Chemiluminescence (IFCC Cal.)
	ng/ml	50.7	40.5	60.9	
	KIU/l = IU/ml	41.3	33.0	49.6	Chemiluminescence (Non IFCC Cal.)
	ng/ml	50.0	39.9	60.1	
Anti Streptolysin O	IU/ml	277	222	332	Turbidimetric (IFCC Cal.)
	IU/ml	291	233	349	Turbidimetric (Non IFCC Cal.)
	IU/ml	179	143	215	Neph. Beckman (IFCC Cal.)
	IU/ml	167	134	200	Neph. Beckman (Non IFCC Cal.)
	IU/ml	279	223	335	Siemens Nephelometric (IFCC Cal.)
	IU/ml	276	221	331	Siemens Nephelometric (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	4.99	3.99	5.99	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	4.93	3.94	5.92	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.87	4.70	7.04	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.58	4.46	6.70	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	56.0	44.8	67.2	Vitros (IFCC Cal.)
	mg/l	66.5	53.2	79.8	Turbidimetric (IFCC Cal.)
	mg/l	63.8	51.0	76.6	Nephelometric (IFCC Cal.)
	mg/l	72.5	58.0	87.0	Nephelometric (Non IFCC Cal.)

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 663LPC Size 3 x 1 ml Expiry 2025-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
C-Reactive Protein	mg/l	67.2	53.8	80.6	Turbidimetric (Non IFCC Cal.)
	mg/l	67.3	53.8	80.8	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	66.4	53.1	79.7	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	66.5	53.2	79.8	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	68.5	54.8	82.2	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	74.5	59.6	89.4	Beckman Turb Latex (IFCC Cal)
	mg/l	67.5	54.0	81.0	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.698	0.558	0.838	Nephelometric (IFCC Cal.)
	mg/dl	69.8	55.8	83.8	
	g/l	0.614	0.491	0.737	Turbidimetric (IFCC Cal.)
	mg/dl	61.4	49.1	73.7	
	g/l	0.646	0.517	0.775	Nephelometric (Non IFCC Cal.)
	mg/dl	64.6	51.7	77.5	
	g/l	0.558	0.446	0.775	Turbidimetric (Non IFCC Cal.)
	mg/dl	55.8	44.6	67.0	
Complement C3	g/l	2.99	2.39	3.59	Turbidimetric (IFCC Cal.)
	mg/dl	299	239	359	
	g/l	2.95	2.36	3.54	Nephelometric (IFCC Cal.)
	mg/dl	295	236	354	
	g/l	2.96	2.37	3.55	Nephelometric (Non IFCC Cal.)
	mg/dl	296	237	355	
	g/l	3.16	2.53	3.79	Turbidimetric (Non IFCC Cal.)
	mg/dl	316	253	379	
	g/l	2.89	2.31	3.47	Vitros 5.1 FS microtip assay
	mg/dl	289	231	347	
Complement C4	g/l	0.556	0.445	0.667	Turbidimetric (IFCC Cal.)
	mg/dl	55.6	44.5	66.7	
	g/l	0.611	0.489	0.733	Nephelometric (IFCC Cal.)
	mg/dl	61.1	48.9	73.3	
	g/l	0.596	0.477	0.715	Nephelometric (Non IFCC Cal.)
	mg/dl	59.6	47.7	71.5	
	g/l	0.542	0.434	0.650	Turbidimetric (Non IFCC Cal.)
	mg/dl	54.2	43.4	65.0	
	g/l	0.561	0.449	0.673	Vitros 5.1 FS microtip assay
	mg/dl	56.1	44.9	67.3	
Ferritin	ng/ml = µg/l	287	230	344	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	251	201	301	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	328	262	394	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	246	197	295	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	20.4	16.3	24.5	Turbidimetric
	mg/L	15.4	12.3	18.5	Nephelometric - Siemens
	mg/L	21.7	17.4	26.0	Nephelometric - Binding Site
Haptoglobin	g/l	2.01	1.61	2.41	Nephelometric (IFCC Cal.)
	mg/dl	201	161	241	
	g/l	2.00	1.60	2.40	Turbidimetric (IFCC Cal.)
	mg/dl	200	160	240	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 663LPC Size 3 x 1 ml Expiry 2025-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Haptoglobin	g/l	2.01	1.61	2.41	Turbidimetric (Non IFCC Cal.)
	mg/dl	201	161	241	
Immunoglobulin A	g/l	5.05	3.79	6.31	Turbidimetric (IFCC Cal.)
	mg/dl	505	379	631	
	g/l	5.38	4.04	6.73	Nephelometric (IFCC Cal.)
	mg/dl	538	404	672	
	g/l	5.58	4.19	6.98	Nephelometric (Non IFCC Cal.)
	mg/dl	558	419	697	
	g/l	5.07	3.80	6.34	Turbidimetric (Non IFCC Cal.)
	mg/dl	507	380	634	
	g/l	5.18	3.89	6.48	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	518	389	647	
Immunoglobulin E	KIU/l = IU/ml	239	191	287	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	195	156	234	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	188	150	226	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	26.0	21.3	30.7	Turbidimetric (IFCC Cal.)
	mg/dl	2600	2130	3070	
	g/l	24.9	20.4	29.4	Nephelometric (IFCC Cal.)
	mg/dl	2490	2040	2940	
	g/l	25.7	21.1	30.3	Nephelometric (Non IFCC Cal.)
	mg/dl	2570	2110	3030	
	g/l	26.4	21.6	31.2	Turbidimetric (Non IFCC Cal.)
	mg/dl	2640	2160	3120	
	g/l	27.6	22.6	32.6	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2760	2260	3260	
Immunoglobulin M	g/l	2.25	1.80	2.70	Turbidimetric (IFCC Cal.)
	mg/dl	225	180	270	
	g/l	2.35	1.88	2.82	Nephelometric (IFCC Cal.)
	mg/dl	235	188	282	
	g/l	2.37	1.90	2.84	Nephelometric (Non IFCC Cal.)
	mg/dl	237	190	284	
	g/l	2.23	1.78	2.68	Turbidimetric (Non IFCC Cal.)
	mg/dl	223	178	268	
	g/l	2.28	1.82	2.74	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	228	182	274	
Kappa Light Chain	g/l	6.24	4.99	7.49	Turbidimetric
	mg/dl	624	499	749	
	g/l	5.97	4.78	7.16	Nephelometric - Siemens
	mg/dl	597	478	716	
Lambda Light Chain	g/l	3.43	2.74	4.12	Turbidimetric
	mg/dl	343	274	412	
	g/l	3.25	2.60	3.90	Nephelometric - Siemens
	mg/dl	325	260	390	
Prealbumin	g/l	0.380	0.304	0.456	Nephelometric (IFCC Cal.)
	mg/dl	38.0	30.4	45.6	
	g/l	0.331	0.265	0.397	Turbidimetric (IFCC Cal.)
	mg/dl	33.1	26.5	39.7	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 663LPC Size 3 x 1 ml Expiry 2025-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prealbumin	g/l	0.336	0.269	0.403	Turbidimetric (Non IFCC Cal.)
	mg/dl	33.6	26.9	40.3	
Protein Total	g/l	101	80.8	121	Biuret reaction end point
	g/dl	10.1	8.08	12.1	
Retinol Binding Protein	mg/l	73.8	59.0	88.6	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	63.7	47.8	79.6	Turbidimetric (Non IFCC Cal.)
	U/ml	61.9	46.4	77.4	Nephelometric (Non IFCC Cal.)
	U/ml	70.0	52.5	87.5	Latex (Non-IFCC Cal.)
	U/ml	69.8	52.4	87.3	Neph. Beckman (Non IFCC Cal.)
	U/ml	54.3	40.7	67.9	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	4.10	3.28	4.92	Turbidimetric (IFCC Cal.)
	mg/dl	410	328	492	
	g/l	4.21	3.37	5.05	Turbidimetric (Non IFCC Cal.)
	mg/dl	421	337	505	
	g/l	4.08	3.26	4.90	Nephelometric (IFCC Cal.)
	mg/dl	408	326	490	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com