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

CAT. NO. PS2684 **LOT NO.** 667LPC
SIZE: 3 x 1 ml **EXPIRY:** 2024-06-28

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. 29 Nov '22 me

RANDOX

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

Cat. No. PS2684 Lot. No. 667LPC Size 3 x 1ml Expiry 2024-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	64.4	54.7	74.1	Bromocresol Green (IFCC Cal.)
	g/dl	6.44	5.47	7.41	
	g/l	63.7	54.1	73.3	Bromocresol Purple (IFCC Cal.)
	g/dl	6.37	5.41	7.33	
	g/l	65.9	56.0	75.8	Nephelometric (IFCC Cal.)
	g/dl	6.59	5.60	7.58	
	g/l	66.7	56.7	76.7	Bromocresol Green (Non IFCC Cal.)
	g/dl	6.67	5.67	7.67	
	g/l	64.4	54.7	74.1	Turbidimetric Assays (IFCC Cal.)
	g/dl	6.44	5.47	7.41	
	g/l	65.4	55.6	75.2	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	6.54	5.56	7.52	
Alpha-1-Acid Glycoprotein	g/l	1.83	1.46	2.20	Turbidimetric (IFCC Cal.)
	mg/dl	183	146	220	
	g/l	1.91	1.53	2.29	Nephelometric (IFCC Cal.)
	mg/dl	191	153	229	
	g/l	1.82	1.46	2.18	Turbidimetric (Non IFCC Cal.)
	mg/dl	182	146	218	
Alpha-1-Antitrypsin	g/l	1.51	1.21	1.81	Turbidimetric (IFCC Cal.)
	mg/dl	151	121	181	
	g/l	1.81	1.45	2.17	Nephelometric (IFCC Cal.)
	mg/dl	181	145	217	
	g/l	1.47	1.18	1.76	Turbidimetric (Non IFCC Cal.)
	mg/dl	147	118	176	
Alpha-2-Macroglobulin	g/l	3.48	2.78	4.18	Nephelometric (IFCC Cal.)
	mg/dl	348	278	418	
Alphafoetoprotein	KIU/l = IU/ml	43.1	34.5	51.7	Chemiluminescence (IFCC Cal.)
	ng/ml	52.2	41.7	62.7	
	KIU/l = IU/ml	44.1	35.3	52.9	Chemiluminescence (Non IFCC Cal.)
	ng/ml	53.4	42.7	64.1	
Anti Streptolysin O	IU/ml	288	230	346	Turbidimetric (IFCC Cal.)
	IU/ml	296	237	355	Turbidimetric (Non IFCC Cal.)
	IU/ml	171	137	205	Neph. Beckman (IFCC Cal.)
	IU/ml	172	138	206	Neph. Beckman (Non IFCC Cal.)
	IU/ml	281	225	337	Siemens Nephelometric (IFCC Cal.)
	IU/ml	281	225	337	Siemens Nephelometric (Non IFCC Cal.)
Antithrombin III	mg/l	309	232	386	Turbidimetric (IFCC Cal.)
	mg/dl	30.9	23.2	38.6	
	mg/l	350	263	438	Colorimetric
	mg/dl	35.0	26.3	43.8	
Beta-2-microglobulin	µg/ml = mg/l	4.41	3.53	5.29	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	4.34	3.47	5.21	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. 667LPC Size 3 x 1ml Expiry 2024-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Beta-2-microglobulin	µg/ml = mg/l	4.98	3.98	5.98	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	4.88	3.90	5.86	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	45.3	36.2	54.4	Vitros (IFCC Cal.)
	mg/l	71.2	57.0	85.4	Turbidimetric (IFCC Cal.)
	mg/l	70.9	56.7	85.1	Nephelometric (IFCC Cal.)
	mg/l	71.7	57.4	86.0	Turbidimetric (Non IFCC Cal.)
	mg/l	71.6	57.3	85.9	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	70.8	56.6	85.0	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	72.2	57.8	86.6	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	72.9	58.3	87.5	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	78.0	62.4	93.6	Beckman Turb Latex (IFCC Cal)
	mg/l	72.3	57.8	86.8	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.683	0.512	0.854	Nephelometric (IFCC Cal.)
	mg/dl	68.3	51.2	85.4	
	g/l	0.569	0.427	0.711	Turbidimetric (IFCC Cal.)
	mg/dl	56.9	42.7	71.1	
	g/l	0.614	0.461	0.767	Nephelometric (Non IFCC Cal.)
	mg/dl	61.4	46.1	76.7	
	g/l	0.502	0.377	0.627	Turbidimetric (Non IFCC Cal.)
	mg/dl	50.2	37.7	62.7	
Complement C3	g/l	2.86	2.29	3.43	Turbidimetric (IFCC Cal.)
	mg/dl	286	229	343	
	g/l	2.76	2.21	3.31	Nephelometric (IFCC Cal.)
	mg/dl	276	221	331	
	g/l	2.79	2.23	3.35	Nephelometric (Non IFCC Cal.)
	mg/dl	279	223	335	
	g/l	2.96	2.37	3.55	Turbidimetric (Non IFCC Cal.)
	mg/dl	296	237	355	
	g/l	2.77	2.22	3.32	Vitros 5.1 FS microtip assay
	mg/dl	277	222	332	
Complement C4	g/l	0.544	0.435	0.653	Turbidimetric (IFCC Cal.)
	mg/dl	54.4	43.5	65.3	
	g/l	0.566	0.453	0.679	Nephelometric (IFCC Cal.)
	mg/dl	56.6	45.3	67.9	
	g/l	0.553	0.442	0.664	Nephelometric (Non IFCC Cal.)
	mg/dl	55.3	44.2	66.4	
	g/l	0.525	0.420	0.630	Turbidimetric (Non IFCC Cal.)
	mg/dl	52.5	42.0	63.0	
	g/l	0.535	0.428	0.642	Vitros 5.1 FS microtip assay
	mg/dl	53.5	42.8	64.2	
Ferritin	ng/ml = µg/l	247	198	296	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	228	182	274	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	303	242	364	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	283	226	340	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	210	168	252	Nephelometric (IFCC Cal.)
Free Lambda Light	mg/L	21.6	17.3	25.9	Nephelometric - Binding Site

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. 667LPC Size 3 x 1ml Expiry 2024-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Free Lambda Light Chains	mg/L	23.7	19.0	28.4	Nephelometric - Siemens
	mg/L	19.7	15.8	23.6	Turbidimetric
Haptoglobin	g/l	1.73	1.38	2.08	Nephelometric (IFCC Cal.)
	mg/dl	173	138	208	
	g/l	1.71	1.37	2.05	Turbidimetric (IFCC Cal.)
	mg/dl	171	137	205	
	g/l	1.72	1.38	2.06	Turbidimetric (Non IFCC Cal.)
	mg/dl	172	138	206	
Immunoglobulin A	g/l	4.73	3.55	5.91	Turbidimetric (IFCC Cal.)
	mg/dl	473	355	591	
	g/l	4.95	3.71	6.19	Nephelometric (IFCC Cal.)
	mg/dl	495	371	619	
	g/l	4.96	3.72	6.20	Nephelometric (Non IFCC Cal.)
	mg/dl	496	372	620	
	g/l	4.77	3.58	5.96	Turbidimetric (Non IFCC Cal.)
	mg/dl	477	358	596	
	g/l	4.88	3.66	6.10	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	488	366	610	
Immunoglobulin E	KIU/l = IU/ml	246	197	295	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	202	162	242	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	199	159	239	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	25.7	21.1	30.3	Turbidimetric (IFCC Cal.)
	mg/dl	2570	2110	3030	
	g/l	24.2	19.8	28.6	Nephelometric (IFCC Cal.)
	mg/dl	2420	1980	2860	
	g/l	24.8	20.3	29.3	Nephelometric (Non IFCC Cal.)
	mg/dl	2480	2030	2930	
	g/l	26.0	21.3	30.7	Turbidimetric (Non IFCC Cal.)
	mg/dl	2600	2130	3070	
	g/l	26.5	21.7	31.3	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2650	2170	3130	
Immunoglobulin M	g/l	1.98	1.58	2.38	Turbidimetric (IFCC Cal.)
	mg/dl	198	158	238	
	g/l	2.05	1.64	2.46	Nephelometric (IFCC Cal.)
	mg/dl	205	164	246	
	g/l	2.03	1.62	2.44	Nephelometric (Non IFCC Cal.)
	mg/dl	203	162	244	
	g/l	1.97	1.58	2.36	Turbidimetric (Non IFCC Cal.)
	mg/dl	197	158	236	
	g/l	2.05	1.64	2.46	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	205	164	246	
Kappa Light Chain	g/l	21.3	17.0	25.6	Nephelometric - Beckman
	mg/dl	2130	1700	2560	
	g/l	5.91	4.73	7.09	Nephelometric - Siemens
	mg/dl	591	473	709	
	g/l	6.28	5.02	7.54	Turbidimetric
	mg/dl	628	502	754	

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. 667LPC Size 3 x 1ml Expiry 2024-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Lambda Light Chain	g/l	12.2	9.76	14.6	Nephelometric - Beckman
	mg/dl	1220	976	1460	
	g/l	3.09	2.47	3.71	Nephelometric - Siemens
	mg/dl	309	247	371	
	g/l	3.44	2.75	4.13	Turbidimetric
	mg/dl	344	275	413	
Prealbumin	g/l	0.296	0.237	0.355	Nephelometric (IFCC Cal.)
	mg/dl	29.6	23.7	35.5	
	g/l	0.277	0.222	0.332	Turbidimetric (IFCC Cal.)
	mg/dl	27.7	22.2	33.2	
	g/l	0.283	0.226	0.340	Turbidimetric (Non IFCC Cal.)
	mg/dl	28.3	22.6	34.0	
Protein Total	g/l	105	84.0	126	Biuret reaction end point
	g/dl	10.5	8.40	12.6	
Retinol Binding Protein	mg/l	70.5	56.4	84.6	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	48.0	36.0	60.0	Turbidimetric (Non IFCC Cal.)
	U/ml	42.6	32.0	53.3	Nephelometric (Non IFCC Cal.)
Transferrin	g/l	4.39	3.51	5.27	Turbidimetric (IFCC Cal.)
	mg/dl	439	351	527	
	g/l	4.52	3.62	5.42	Turbidimetric (Non IFCC Cal.)
	mg/dl	452	362	542	
	g/l	4.36	3.49	5.23	Nephelometric (IFCC Cal.)
	mg/dl	436	349	523	

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