

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

**CAT. NO.** PS2684                      **LOT NO.** 677LPC  
**SIZE** 3 x 1 ml                      **EXPIRY:** 2025-06-28  
**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.

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

#### Pictogram



#### Warning

#### Hazard statement(s)

H317 May cause an allergic skin reaction.

#### Precautionary statement(s)

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

#### Supplemental Hazard Information (EU)

P302+P352 If on skin: Wash with plenty of water.  
P321 Specific treatment (see on this label).  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

The presence of a bar in the margin indicates a technical update from the previous revision.

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Dungloe, Donegal,  
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## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 3 (SP CONTROL 3)

Cat. No. PS2684 Lot. No. 677LPC

Size 3 x 1 ml Expiry 2025-06-28

Analyte	unit	Target	Range		methods	
			low	high		
Albumin	g/l	57.3	48.7	65.9	Bromocresol Green (IFCC Cal.)	
	g/dl	5.73	4.87	6.59		
	g/l	57.4	48.8	66.0	Bromocresol Purple (IFCC Cal.)	
	g/dl	5.74	4.88	6.60		
	g/l	58.1	49.4	66.8	Nephelometric (IFCC Cal.)	
	g/dl	5.81	4.94	6.68		
	g/l	58.9	50.1	67.7	Bromocresol Green (Non IFCC Cal.)	
	g/dl	5.89	5.01	6.77		
Alpha-1-Acid Glycoprotein	g/l	1.76	1.41	2.11	Turbidimetric (IFCC Cal.)	
	mg/dl	176	141	211		
	g/l	1.83	1.46	2.20	Nephelometric (IFCC Cal.)	
	mg/dl	183	146	220		
	g/l	1.72	1.38	2.06	Turbidimetric (Non IFCC Cal.)	
	mg/dl	172	138	206		
	Alpha-1-Antitrypsin	g/l	1.67	1.34	2.00	Turbidimetric (IFCC Cal.)
		mg/dl	167	134	200	
g/l		1.65	1.32	1.98	Turbidimetric (Non IFCC Cal.)	
Alpha-2-Macroglobulin	g/l	3.56	2.85	4.27	Nephelometric (IFCC Cal.)	
	mg/dl	356	285	427		
Alphafetoprotein	KIU/l = IU/ml	41.6	33.3	49.9	Chemiluminescence (IFCC Cal.)	
	ng/ml	50.3	40.3	60.3		
	KIU/l = IU/ml	41.1	32.9	49.3	Chemiluminescence (Non IFCC Cal.)	
	ng/ml	49.7	39.8	59.6		
Anti Streptolysin O	IU/ml	296	252	340	Turbidimetric (Non IFCC Cal.)	
	IU/ml	272	218	326	Neph. others (Non IFCC Cal.)	
	IU/ml	174	139	209	Neph. Beckman (IFCC Cal.)	
	IU/ml	190	152	228	Neph. Beckman (Non IFCC Cal.)	
Beta-2-microglobulin	µg/ml = mg/l	3.46	2.77	4.15	Nephelometric (IFCC Cal.)	
	µg/ml = mg/l	3.56	2.85	4.27	Nephelometric (Non IFCC Cal.)	
	µg/ml = mg/l	4.16	3.33	4.99	Turbidimetric (IFCC Cal.)	
	µg/ml = mg/l	3.95	3.16	4.74	Turbidimetric (Non IFCC Cal.)	
C-Reactive Protein	mg/l	51.6	41.3	61.9	Vitros (IFCC Cal.)	
	mg/l	72.2	57.8	86.6	Turbidimetric (IFCC Cal.)	
	mg/l	70.4	56.3	84.5	Nephelometric (IFCC Cal.)	
	mg/l	74.6	59.7	89.5	Nephelometric (Non IFCC Cal.)	
	mg/l	72.2	57.8	86.6	Turbidimetric (Non IFCC Cal.)	
	mg/l	73.7	59.0	88.4	Roche Turbidimetric Gen 3 (IFCC Cal.)	
	mg/l	71.8	57.4	86.2	Roche Turbidimetric Gen 3 (non-IFCC Cal.)	
	mg/l	72.1	57.7	86.5	Roche Turbidimetric Latex (IFCC Cal.)	

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

Cat. No. PS2684 Lot. No. 677LPC Size 3 x 1 ml Expiry 2025-06-28

Analyte	unit	Target	Range		methods
			low	high	
C-Reactive Protein	mg/l	72.9	58.3	87.5	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	79.0	63.2	94.8	Beckman Turb Latex (IFCC Cal.)
	mg/l	141	113	169	Immunofluorescence (Non IFCC Cal.)
	mg/l	73.0	58.4	87.6	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.726	0.545	0.908	Nephelometric (IFCC Cal.)
	mg/dl	72.6	54.5	90.8	
	g/l	0.606	0.454	0.758	Turbidimetric (IFCC Cal.)
	mg/dl	60.6	45.4	75.8	
	g/l	0.678	0.509	0.848	Nephelometric (Non IFCC Cal.)
	mg/dl	67.8	50.9	84.8	
Complement C3	g/l	3.07	2.61	3.53	Turbidimetric (IFCC Cal.)
	mg/dl	307	261	353	
	g/l	3.02	2.57	3.47	Nephelometric (IFCC Cal.)
	mg/dl	302	257	347	
	g/l	3.10	2.64	3.57	Nephelometric (Non IFCC Cal.)
	mg/dl	310	264	357	
	g/l	3.18	2.70	3.66	Turbidimetric (Non IFCC Cal.)
	mg/dl	318	270	366	
Complement C4	g/l	2.91	2.47	3.35	Vitros 5.1 FS microtip assay
	mg/dl	291	247	335	
	g/l	0.570	0.485	0.656	Turbidimetric (IFCC Cal.)
	mg/dl	57.0	48.5	65.6	
	g/l	0.600	0.510	0.690	Nephelometric (IFCC Cal.)
	mg/dl	60.0	51.0	69.0	
	g/l	0.590	0.502	0.679	Nephelometric (Non IFCC Cal.)
	mg/dl	59.0	50.2	67.9	
Ferritin	g/l	0.550	0.468	0.633	Turbidimetric (Non IFCC Cal.)
	mg/dl	55.0	46.8	63.3	
	g/l	0.550	0.468	0.633	Vitros 5.1 FS microtip assay
	mg/dl	55.0	46.8	63.3	
	ng/ml = µg/l	238	202	274	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	210	179	242	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	277	235	319	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	281	239	323	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	191	162	220	Nephelometric (IFCC Cal.)
	mg/L	22.2	17.8	26.6	Nephelometric - Binding Site
	mg/L	18.3	14.6	22.0	Nephelometric - Siemens
Haptoglobin	mg/L	20.2	16.2	24.2	Turbidimetric
	g/l	1.94	1.55	2.33	Nephelometric (IFCC Cal.)
	mg/dl	194	155	233	
	g/l	1.93	1.54	2.32	Turbidimetric (IFCC Cal.)
Haptoglobin	mg/dl	193	154	232	
	g/l	1.92	1.54	2.30	Turbidimetric (Non IFCC Cal.)
	mg/dl	192	154	230	
	g/l	1.92	1.54	2.30	Turbidimetric (Non IFCC Cal.)

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

Cat. No. PS2684 Lot. No. 677LPC Size 3 x 1 ml Expiry 2025-06-28

Analyte	unit	Target	Range		methods	
			low	high		
Immunoglobulin A	g/l	5.10	3.83	6.38	Turbidimetric (IFCC Cal.)	
	mg/dl	510	383	637		
	g/l	5.61	4.21	7.01	Nephelometric (IFCC Cal.)	
	mg/dl	561	421	701		
	g/l	5.62	4.22	7.03	Nephelometric (Non IFCC Cal.)	
	mg/dl	562	422	702		
	g/l	5.12	3.84	6.40	Turbidimetric (Non IFCC Cal.)	
	mg/dl	512	384	640		
Immunoglobulin E	g/l	5.17	3.88	6.46	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	517	388	646		
	KIU/l = IU/ml	246	197	295	Chemiluminescence (Non IFCC Cal.)	
Immunoglobulin E	KIU/l = IU/ml	197	158	236	Nephelometric (Non IFCC Cal.)	
	KIU/l = IU/ml	190	152	228	Turbidimetric (Non IFCC Cal.)	
	Immunoglobulin G	g/l	26.6	21.8	31.4	Turbidimetric (IFCC Cal.)
mg/dl		2660	2180	3140		
g/l		25.8	21.2	30.4	Nephelometric (IFCC Cal.)	
mg/dl		2580	2120	3040		
g/l		26.8	22.0	31.6	Nephelometric (Non IFCC Cal.)	
mg/dl		2680	2200	3160		
g/l		26.7	21.9	31.5	Turbidimetric (Non IFCC Cal.)	
mg/dl		2670	2190	3150		
Immunoglobulin G	g/l	28.3	23.2	33.4	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	2830	2320	3340		
	Immunoglobulin M	g/l	2.18	1.74	2.62	Turbidimetric (IFCC Cal.)
		mg/dl	218	174	262	
		g/l	2.37	1.90	2.84	Nephelometric (IFCC Cal.)
		mg/dl	237	190	284	
		g/l	2.38	1.90	2.86	Nephelometric (Non IFCC Cal.)
		mg/dl	238	190	286	
g/l		2.18	1.74	2.62	Turbidimetric (Non IFCC Cal.)	
mg/dl		218	174	262		
Kappa Light Chain	g/l	2.17	1.74	2.60	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	217	174	260		
	g/l	6.32	5.06	7.58	Nephelometric - Siemens	
	mg/dl	632	506	758		
Kappa Light Chain	g/l	6.48	5.18	7.78	Turbidimetric	
	mg/dl	648	518	778		
	Lambda Light Chain	g/l	3.42	2.74	4.10	Turbidimetric
		mg/dl	342	274	410	
g/l		3.28	2.62	3.94	Nephelometric - Siemens	
mg/dl		328	262	394		
Prealbumin	g/l	0.350	0.280	0.420	Nephelometric (IFCC Cal.)	
	mg/dl	35.0	28.0	42.0		
	g/l	0.310	0.248	0.372	Turbidimetric (IFCC Cal.)	
	mg/dl	31.0	24.8	37.2		
Prealbumin	g/l	0.310	0.248	0.372	Turbidimetric (Non IFCC Cal.)	
	mg/dl	31.0	24.8	37.2		

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

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Size 3 x 1 ml Expiry 2025-06-28

Range					
Analyte	unit	Target	low	high	methods
Protein Total	g/l	100	80.0	120	Biuret reaction end point
	g/dl	10.0	8.00	12.0	
Retinol Binding Protein	mg/l	64.4	51.5	77.3	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	48.0	36.0	60.0	Turbidimetric (Non IFCC Cal.)
	U/ml	41.3	31.0	51.6	Nephelometric (Non IFCC Cal.)
	U/ml	51.0	38.3	63.8	Latex (Non-IFCC Cal.)
Transferrin	g/l	3.78	3.02	4.54	Turbidimetric (IFCC Cal.)
	mg/dl	378	302	454	
	g/l	3.83	3.06	4.60	Turbidimetric (Non IFCC Cal.)
	mg/dl	383	306	460	
	g/l	3.71	2.97	4.45	
mg/dl	371	297	445		