

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

<b>CAT. NO.</b>	PS2683	<b>LOT NO.</b>	676LPC
<b>SIZE</b>	3 x 1ml	<b>EXPIRY:</b>	2025-06-28
<b>GTIN:</b>	05055273204902		

### 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 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 2 3 x 1 ml

**MATERIALS REQUIRED BUT NOT PROVIDED**

N/A

**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](mailto:Technical.Services@randox.com).

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## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 676LPC Size 3 x 1 ml Expiry 2025-06-28

Analyte	unit	Target	Range		methods	
			low	high		
Albumin	g/l	39.8	33.8	45.8	Bromocresol Green (IFCC Cal.)	
	g/dl	3.98	3.38	4.58		
	g/l	38.3	32.6	44.0	Bromocresol Purple (IFCC Cal.)	
	g/dl	3.83	3.26	4.40		
	g/l	39.8	33.8	45.8	Nephelometric (IFCC Cal.)	
	g/dl	3.98	3.38	4.58		
	g/l	40.8	34.7	46.9	Bromocresol Green (Non IFCC Cal.)	
	g/dl	4.08	3.47	4.69		
	g/l	38.8	33.0	44.6	Turbidimetric Assays (IFCC Cal.)	
	g/dl	3.88	3.30	4.46		
Alpha-1-Acid Glycoprotein	g/l	1.15	0.920	1.38	Turbidimetric (IFCC Cal.)	
	mg/dl	115	92.0	138	Nephelometric (IFCC Cal.)	
	g/l	1.18	0.944	1.42		
	mg/dl	118	94.4	142		
	g/l	1.15	0.920	1.38	Turbidimetric (Non IFCC Cal.)	
	mg/dl	115	92.0	138		
	Alpha-1-Antitrypsin	g/l	1.09	0.872	1.31	Turbidimetric (IFCC Cal.)
		mg/dl	109	87.2	131	Turbidimetric (Non IFCC Cal.)
g/l		1.10	0.880	1.32		
mg/dl	110	88.0	132			
Alpha-2-Macroglobulin	g/l	2.31	1.85	2.77	Nephelometric (IFCC Cal.)	
	mg/dl	231	185	277		
Alphafetoprotein	KIU/l = IU/ml	27.8	22.2	33.4	Chemiluminescence (IFCC Cal.)	
	ng/ml	33.6	26.9	40.3		
	KIU/l = IU/ml	28.1	22.5	33.7	Chemiluminescence (Non IFCC Cal.)	
	ng/ml	34.0	27.2	40.8		
Anti Streptolysin O	IU/ml	197	158	236	Turbidimetric (Non IFCC Cal.)	
	IU/ml	186	149	223	Neph. others (Non IFCC Cal.)	
	IU/ml	130	104	156	Neph. Beckman (IFCC Cal.)	
	IU/ml	124	99.2	149	Neph. Beckman (Non IFCC Cal.)	
Beta-2-microglobulin	µg/ml = mg/l	2.31	1.85	2.77	Nephelometric (IFCC Cal.)	
	µg/ml = mg/l	2.32	1.86	2.78	Nephelometric (Non IFCC Cal.)	
	µg/ml = mg/l	2.71	2.17	3.25	Turbidimetric (IFCC Cal.)	
	µg/ml = mg/l	2.68	2.14	3.22	Turbidimetric (Non IFCC Cal.)	
C-Reactive Protein	mg/l	44.8	35.8	53.8	Vitros (IFCC Cal.)	
	mg/l	48.7	39.0	58.4	Turbidimetric (IFCC Cal.)	
	mg/l	47.4	37.9	56.9	Nephelometric (IFCC Cal.)	
	mg/l	46.4	37.1	55.7	Vitros (Non IFCC Cal.)	
	mg/l	48.5	38.8	58.2	Nephelometric (Non IFCC Cal.)	
	mg/l	48.6	38.9	58.3	Turbidimetric (Non IFCC Cal.)	
	mg/l	49.2	39.4	59.0	Roche Turbidimetric Gen 3 (IFCC Cal.)	
	mg/l	48.4	38.7	58.1	Roche Turbidimetric Gen 3 (non-IFCC Cal.)	

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 676LPC Size 3 x 1 ml Expiry 2025-06-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	48.8	39.0	58.6	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	49.3	39.4	59.2	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	49.0	39.2	58.8	Beckman Turb Latex (IFCC Cal.)
	mg/l	48.4	38.7	58.1	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.495	0.371	0.619	Nephelometric (IFCC Cal.)
	mg/dl	49.5	37.1	61.9	
	g/l	0.430	0.323	0.538	Nephelometric (Non IFCC Cal.)
	mg/dl	43.0	32.3	53.8	
	g/l	0.338	0.254	0.423	Turbidimetric (Non IFCC Cal.)
mg/dl	33.8	25.4	42.3		
Complement C3	g/l	2.06	1.65	2.47	Turbidimetric (IFCC Cal.)
	mg/dl	206	165	247	
	g/l	2.03	1.62	2.44	Nephelometric (IFCC Cal.)
	mg/dl	203	162	244	
	g/l	2.01	1.61	2.41	Nephelometric (Non IFCC Cal.)
	mg/dl	201	161	241	
	g/l	2.11	1.69	2.53	Turbidimetric (Non IFCC Cal.)
	mg/dl	211	169	253	
Complement C4	g/l	1.98	1.58	2.38	Vitros 5.1 FS microtip assay
	mg/dl	198	158	238	
	g/l	0.380	0.304	0.456	Turbidimetric (IFCC Cal.)
	mg/dl	38.0	30.4	45.6	
	g/l	0.395	0.316	0.474	Nephelometric (IFCC Cal.)
	mg/dl	39.5	31.6	47.4	
	g/l	0.399	0.319	0.479	Nephelometric (Non IFCC Cal.)
	mg/dl	39.9	31.9	47.9	
Ferritin	g/l	0.365	0.292	0.438	Turbidimetric (Non IFCC Cal.)
	mg/dl	36.5	29.2	43.8	
	g/l	0.364	0.291	0.437	Vitros 5.1 FS microtip assay
	mg/dl	36.4	29.1	43.7	
	ng/ml = µg/l	165	132	198	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	143	114	172	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	192	154	230	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	136	109	163	Nephelometric (IFCC Cal.)
	mg/L	15.7	12.6	18.8	Nephelometric - Binding Site
	mg/L	15.0	12.0	18.0	Nephelometric - Siemens
Haptoglobin	mg/L	14.4	11.5	17.3	Turbidimetric
	g/l	1.27	1.02	1.52	Nephelometric (IFCC Cal.)
	mg/dl	127	102	152	
	g/l	1.27	1.02	1.52	Turbidimetric (IFCC Cal.)
	mg/dl	127	102	152	
Immunoglobulin A	g/l	1.29	1.03	1.55	Turbidimetric (Non IFCC Cal.)
	mg/dl	129	103	155	
	g/l	3.42	2.57	4.28	Turbidimetric (IFCC Cal.)
	mg/dl	342	257	427	
Immunoglobulin A	g/l	3.67	2.75	4.59	Nephelometric (IFCC Cal.)
	mg/dl	367	275	459	

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Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin A	g/l	3.67	2.75	4.59	Nephelometric (Non IFCC Cal.)
	mg/dl	367	275	459	
	g/l	3.43	2.57	4.29	Turbidimetric (Non IFCC Cal.)
	mg/dl	343	257	429	
	g/l	3.57	2.68	4.46	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	357	268	446	
Immunoglobulin E	KIU/l = IU/ml	165	132	198	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	139	111	167	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	130	104	156	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	17.6	14.4	20.8	Turbidimetric (IFCC Cal.)
	mg/dl	1760	1440	2080	
	g/l	17.5	14.4	20.7	Nephelometric (IFCC Cal.)
	mg/dl	1750	1440	2060	
	g/l	17.2	14.1	20.3	Nephelometric (Non IFCC Cal.)
	mg/dl	1720	1410	2030	
	g/l	17.7	14.5	20.9	Turbidimetric (Non IFCC Cal.)
	mg/dl	1770	1450	2090	
	g/l	18.5	15.2	21.8	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1850	1520	2180	
Immunoglobulin M	g/l	1.48	1.18	1.78	Turbidimetric (IFCC Cal.)
	mg/dl	148	118	178	
	g/l	1.59	1.27	1.91	Nephelometric (IFCC Cal.)
	mg/dl	159	127	191	
	g/l	1.61	1.29	1.93	Nephelometric (Non IFCC Cal.)
	mg/dl	161	129	193	
	g/l	1.46	1.17	1.75	Turbidimetric (Non IFCC Cal.)
	mg/dl	146	117	175	
Kappa Light Chain	g/l	4.14	3.31	4.97	Nephelometric - Siemens
	mg/dl	414	331	497	
	g/l	4.20	3.36	5.04	Turbidimetric
	mg/dl	420	336	504	
Lambda Light Chain	g/l	2.30	1.84	2.76	Turbidimetric
	mg/dl	230	184	276	
	g/l	2.26	1.81	2.71	Nephelometric - Siemens
	mg/dl	226	181	271	
Prealbumin	g/l	0.210	0.168	0.252	Nephelometric (IFCC Cal.)
	mg/dl	21.0	16.8	25.2	
	g/l	0.200	0.160	0.240	Turbidimetric (IFCC Cal.)
	mg/dl	20.0	16.0	24.0	
	g/l	0.210	0.168	0.252	Turbidimetric (Non IFCC Cal.)
	mg/dl	21.0	16.8	25.2	

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot. No. 676LPC Size 3 x 1 ml Expiry 2025-06-28

Range					
Analyte	unit	Target	low	high	methods
Protein Total	g/l	69.5	55.6	83.4	Biuret reaction end point
	g/dl	6.95	5.56	8.34	
Retinol Binding Protein	mg/l	41.8	33.4	50.2	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	31.8	23.9	39.8	Turbidimetric (Non IFCC Cal.)
	U/ml	26.6	20.0	33.3	Nephelometric (Non IFCC Cal.)
	U/ml	32.7	24.5	40.9	Latex (Non-IFCC Cal.)
Transferrin	g/l	2.53	2.02	3.04	Turbidimetric (IFCC Cal.)
	mg/dl	253	202	304	
	g/l	2.56	2.05	3.07	Turbidimetric (Non IFCC Cal.)
	mg/dl	256	205	307	
	g/l	2.50	2.00	3.00	Nephelometric (IFCC Cal.)
mg/dl	250	200	300		