

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

**CAT. NO.** PS2682                      **LOT NO.** 638LPC  
**SIZE:** 3 x 1 ml                      **EXPIRY:** 2024-01-28  
**GTIN:** 05055273204896

### 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 I 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](mailto:Technical.Services@randox.com).



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

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## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 638LPC Size 3 x 1 ml Expiry 2024-01-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	24.4	20.7	28.1	Bromocresol Green (IFCC Cal.)
	g/dl	2.44	2.07	2.81	
	g/l	23.8	20.2	27.4	Bromocresol Purple (IFCC Cal.)
	g/dl	2.38	2.02	2.74	
	g/l	24.2	20.6	27.8	Nephelometric (IFCC Cal.)
	g/dl	2.42	2.06	2.78	
	g/l	24.6	20.9	28.3	Bromocresol Green (Non IFCC Cal.)
	g/dl	2.46	2.09	2.83	
	g/l	23.8	20.2	27.4	Turbidimetric Assays (IFCC Cal.)
	g/dl	2.38	2.02	2.74	
g/l	24.1	20.5	27.7	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	2.41	2.05	2.77		
Alpha-1-Acid Glycoprotein	g/l	0.545	0.436	0.654	Turbidimetric (IFCC Cal.)
	mg/dl	54.5	43.6	65.4	
	g/l	0.564	0.451	0.677	Nephelometric (IFCC Cal.)
	mg/dl	56.4	45.1	67.7	
	g/l	0.537	0.430	0.644	Turbidimetric (Non IFCC Cal.)
	mg/dl	53.7	43.0	64.4	
Alpha-1-Antitrypsin	g/l	0.737	0.590	0.884	Turbidimetric (IFCC Cal.)
	mg/dl	73.7	59.0	88.4	
	g/l	0.777	0.622	0.932	Nephelometric (IFCC Cal.)
	mg/dl	77.7	62.2	93.2	
	g/l	0.736	0.589	0.883	Turbidimetric (Non IFCC Cal.)
	mg/dl	73.6	58.9	88.3	
Alpha-2-Macroglobulin	g/l	1.08	0.864	1.30	Nephelometric (IFCC Cal.)
	mg/dl	108	86.4	130	
Alphafoetoprotein	KIU/l = IU/ml	15.3	12.2	18.4	Chemiluminescence (IFCC Cal.)
	ng/ml	18.5	14.8	22.2	
	KIU/l = IU/ml	15.4	12.3	18.5	Chemiluminescence (Non IFCC Cal.)
	ng/ml	18.6	14.9	22.3	
Anti Streptolysin O	IU/ml	117	93.6	140	Turbidimetric (IFCC Cal.)
	IU/ml	124	99.0	149	Turbidimetric (Non IFCC Cal.)
	IU/ml	72.6	58.1	87.1	Neph. Beckman (Non IFCC Cal.)
	IU/ml	125	100	150	Siemens Nephelometric (IFCC Cal.)
	IU/ml	129	103	155	Siemens Nephelometric (Non IFCC Cal.)
Antithrombin III	mg/l	157	118	196	Turbidimetric (Non IFCC Cal.)
	mg/dl	15.7	11.8	19.6	
Beta-2-microglobulin	µg/ml = mg/l	1.66	1.33	1.99	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.66	1.33	1.99	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.91	1.53	2.29	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.98	1.58	2.38	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	21.6	17.3	25.9	Vitros (IFCC Cal.)

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Analyte	unit	Target	Range		methods
			low	high	
C-Reactive Protein	mg/l	23.9	19.1	28.7	Turbidimetric (IFCC Cal.)
	mg/l	21.6	17.3	25.9	Nephelometric (IFCC Cal.)
	mg/l	22.6	18.1	27.1	Nephelometric (Non IFCC Cal.)
	mg/l	23.4	18.7	28.1	Turbidimetric (Non IFCC Cal.)
	mg/l	22.5	18.0	27.0	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	22.1	17.7	26.5	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	22.3	17.8	26.8	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	22.7	18.2	27.2	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	20.8	16.6	25.0	Beckman Turb Latex (IFCC Cal.)
	mg/l	22.5	18.0	27.0	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.212	0.159	0.265	Nephelometric (IFCC Cal.)
	mg/dl	21.2	15.9	26.5	
	g/l	0.196	0.147	0.245	Nephelometric (Non IFCC Cal.)
	mg/dl	19.6	14.7	24.5	
	g/l	0.153	0.115	0.191	Turbidimetric (Non IFCC Cal.)
mg/dl	15.3	11.5	19.1		
Complement C3	g/l	1.04	0.832	1.25	Turbidimetric (IFCC Cal.)
	mg/dl	104	83.2	125	
	g/l	1.00	0.800	1.20	Nephelometric (IFCC Cal.)
	mg/dl	100	80.0	120	
	g/l	1.00	0.800	1.20	Nephelometric (Non IFCC Cal.)
	mg/dl	100	80.0	120	
Complement C4	g/l	1.08	0.864	1.30	Turbidimetric (Non IFCC Cal.)
	mg/dl	108	86.4	130	
	g/l	0.198	0.158	0.238	Turbidimetric (IFCC Cal.)
	mg/dl	19.8	15.8	23.8	
	g/l	0.196	0.157	0.235	Nephelometric (IFCC Cal.)
	mg/dl	19.6	15.7	23.5	
Complement C4	g/l	0.188	0.150	0.226	Nephelometric (Non IFCC Cal.)
	mg/dl	18.8	15.0	22.6	
	g/l	0.185	0.148	0.222	Turbidimetric (Non IFCC Cal.)
	mg/dl	18.5	14.8	22.2	
	g/l	0.204	0.163	0.245	Vitros 5.1 FS microtip assay
	mg/dl	20.4	16.3	24.5	
Ferritin	ng/ml = µg/l	115	92.0	138	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	102	81.6	122	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	139	111	167	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	129	103	155	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	104	83.2	125	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	9.71	7.77	11.7	Nephelometric - Binding Site
	mg/L	8.48	6.78	10.2	Nephelometric - Siemens
	mg/L	8.17	6.54	9.80	Turbidimetric
Haptoglobin	g/l	0.526	0.421	0.631	Nephelometric (IFCC Cal.)
	mg/dl	52.6	42.1	63.1	
	g/l	0.544	0.435	0.653	Turbidimetric (IFCC Cal.)
	mg/dl	54.4	43.5	65.3	

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 638LPC Size 3 x 1 ml Expiry 2024-01-28

Analyte	unit	Target	Range		methods	
			low	high		
Haptoglobin	g/l	0.557	0.446	0.668	Turbidimetric (Non IFCC Cal.)	
	mg/dl	55.7	44.6	66.8		
Immunoglobulin A	g/l	2.04	1.53	2.55	Turbidimetric (IFCC Cal.)	
	mg/dl	204	153	255		
	g/l	2.12	1.59	2.65	Nephelometric (IFCC Cal.)	
	mg/dl	212	159	265		
	g/l	2.07	1.55	2.59	Nephelometric (Non IFCC Cal.)	
	mg/dl	207	155	259		
	g/l	2.06	1.55	2.58	Turbidimetric (Non IFCC Cal.)	
	mg/dl	206	155	257		
Immunoglobulin E	g/l	2.16	1.62	2.70	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	216	162	270		
	KIU/l = IU/ml	87.5	70.0	105	Chemiluminescence (Non IFCC Cal.)	
Immunoglobulin E	KIU/l = IU/ml	82.8	66.2	99.0	Nephelometric (Non IFCC Cal.)	
	KIU/l = IU/ml	77.5	62.0	93.0	Turbidimetric (Non IFCC Cal.)	
	Immunoglobulin G	g/l	9.49	7.78	11.2	Turbidimetric (IFCC Cal.)
mg/dl		949	778	1120		
g/l		9.61	7.88	11.3	Nephelometric (IFCC Cal.)	
mg/dl		961	788	1134		
g/l		9.58	7.86	11.3	Nephelometric (Non IFCC Cal.)	
mg/dl		958	786	1130		
g/l		9.49	7.78	11.2	Turbidimetric (Non IFCC Cal.)	
mg/dl		949	778	1120		
Immunoglobulin G	g/l	10.0	8.20	11.8	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	1000	820	1180		
	Immunoglobulin M	g/l	0.730	0.584	0.876	Turbidimetric (IFCC Cal.)
		mg/dl	73.0	58.4	87.6	
	Immunoglobulin M	g/l	0.744	0.595	0.893	Nephelometric (IFCC Cal.)
		mg/dl	74.4	59.5	89.3	
	Immunoglobulin M	g/l	0.733	0.586	0.880	Nephelometric (Non IFCC Cal.)
		mg/dl	73.3	58.6	88.0	
Immunoglobulin M	g/l	0.729	0.583	0.875	Turbidimetric (Non IFCC Cal.)	
	mg/dl	72.9	58.3	87.5		
Immunoglobulin M	g/l	0.758	0.606	0.910	Vitros 5.1 FS Microtip (IFCC)	
	mg/dl	75.8	60.6	91.0		
Kappa Light Chain	g/l	2.21	1.77	2.65	Nephelometric - Siemens	
	mg/dl	221	177	265		
	g/l	2.41	1.93	2.89	Turbidimetric	
	mg/dl	241	193	289		
Lambda Light Chain	g/l	4.11	3.29	4.93	Nephelometric - Beckman	
	mg/dl	411	329	493		
	g/l	1.31	1.05	1.57	Nephelometric - Siemens	
	mg/dl	131	105	157		
Prealbumin	g/l	1.29	1.03	1.55	Turbidimetric	
	mg/dl	129	103	155		
Prealbumin	g/l	0.139	0.111	0.167	Nephelometric (IFCC Cal.)	
	mg/dl	13.9	11.1	16.7		

## LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 638LPC Size 3 x 1 ml Expiry 2024-01-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.139	0.111	0.167	Turbidimetric (IFCC Cal.)
	mg/dl	13.9	11.1	16.7	
	g/l	0.147	0.118	0.176	Turbidimetric (Non IFCC Cal.)
	mg/dl	14.7	11.8	17.6	
Protein Total	g/l	44.5	35.6	53.4	Biuret reaction end point
	g/dl	4.45	3.56	5.34	
Retinol Binding Protein	mg/l	22.8	18.2	27.4	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	15.9	11.9	19.9	Turbidimetric (Non IFCC Cal.)
	U/ml	15.9	11.9	19.9	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	1.72	1.38	2.06	Turbidimetric (IFCC Cal.)
	mg/dl	172	138	206	
	g/l	1.72	1.38	2.06	Turbidimetric (Non IFCC Cal.)
	mg/dl	172	138	206	
	g/l	1.66	1.33	1.99	Nephelometric (IFCC Cal.)
	mg/dl	166	133	199	