

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

**CAT. NO.** PS2683                      **LOT NO.** 634LPC  
**SIZE:** 3 x 1ml                      **EXPIRY:** 2023-09-28  
**GTIN:** 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.

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. 634LPC Size 3 x 1ml Expiry 2023-09-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	46.6	39.6	53.6	Bromocresol Green (IFCC Cal.)
	g/dl	4.66	3.96	5.36	
	g/l	46.9	39.9	53.9	Bromocresol Purple (IFCC Cal.)
	g/dl	4.69	3.99	5.39	
	g/l	46.8	39.8	53.8	Nephelometric (IFCC Cal.)
	g/dl	4.68	3.98	5.38	
	g/l	47.9	40.7	55.1	Bromocresol Green (Non IFCC Cal.)
	g/dl	4.79	4.07	5.51	
	g/l	47.8	40.6	55.0	Turbidimetric Assays (IFCC Cal.)
	g/dl	4.78	4.06	5.50	
g/l	47.8	40.6	55.0	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	4.78	4.06	5.50		
Alpha-1-Acid Glycoprotein	g/l	1.14	0.912	1.37	Turbidimetric (IFCC Cal.)
	mg/dl	114	91.2	137	Nephelometric (IFCC Cal.)
	g/l	1.17	0.936	1.40	
	mg/dl	117	93.6	140	
Alpha-1-Antitrypsin	g/l	1.10	0.880	1.32	Turbidimetric (Non IFCC Cal.)
	mg/dl	110	88.0	132	
	g/l	1.44	1.15	1.73	Turbidimetric (IFCC Cal.)
	mg/dl	144	115	173	
Alpha-1-Antitrypsin	g/l	1.50	1.20	1.80	Nephelometric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.42	1.14	1.70	Turbidimetric (Non IFCC Cal.)
	mg/dl	142	114	170	
Alpha-2-Macroglobulin	g/l	2.26	1.81	2.71	Nephelometric (IFCC Cal.)
	mg/dl	226	181	271	
Alphafoetoprotein	KIU/l = IU/ml	30.8	24.6	37.0	Chemiluminescence (IFCC Cal.)
	ng/ml	37.3	29.8	44.8	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	31.2	25.0	37.4	
Anti Streptolysin O	ng/ml	37.8	30.3	45.3	Turbidimetric (IFCC Cal.)
	IU/ml	237	190	284	
	IU/ml	248	198	298	
	IU/ml	140	112	168	
	IU/ml	238	190	286	
Anti-thrombin III	IU/ml	241	193	289	Siemens Nephelometric (Non IFCC Cal.)
	mg/l	306	230	383	Turbidimetric (Non IFCC Cal.)
Beta-2-microglobulin	mg/dl	30.6	23.0	38.3	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.24	2.59	3.89	
	µg/ml = mg/l	3.27	2.62	3.92	
	µg/ml = mg/l	3.76	3.01	4.51	
C-Reactive Protein	µg/ml = mg/l	3.73	2.98	4.48	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.73	2.98	4.48	Turbidimetric (Non IFCC Cal.)
	mg/l	36.5	29.2	43.8	Vitros (IFCC Cal.)

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

Cat. No. PS2683 Lot. No. 634LPC Size 3 x 1ml Expiry 2023-09-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	46.0	36.8	55.2	Turbidimetric (IFCC Cal.)
	mg/l	42.2	33.8	50.6	Nephelometric (IFCC Cal.)
	mg/l	46.2	37.0	55.4	Turbidimetric (Non IFCC Cal.)
	mg/l	45.8	36.6	55.0	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	45.3	36.2	54.4	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	45.5	36.4	54.6	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	46.3	37.0	55.6	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	47.5	38.0	57.0	Beckman Turb Latex (IFCC Cal)
	mg/l	46.2	37.0	55.4	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.447	0.335	0.559	Nephelometric (IFCC Cal.)
	mg/dl	44.7	33.5	55.9	
	g/l	0.395	0.296	0.494	Turbidimetric (IFCC Cal.)
	mg/dl	39.5	29.6	49.4	
	g/l	0.390	0.293	0.487	Nephelometric (Non IFCC Cal.)
	mg/dl	39.0	29.3	48.7	
	g/l	0.319	0.239	0.399	Turbidimetric (Non IFCC Cal.)
mg/dl	31.9	23.9	39.9		
Complement C3	g/l	2.07	1.66	2.48	Turbidimetric (IFCC Cal.)
	mg/dl	207	166	248	
	g/l	1.99	1.59	2.39	Nephelometric (IFCC Cal.)
	mg/dl	199	159	239	
	g/l	2.03	1.62	2.44	Nephelometric (Non IFCC Cal.)
	mg/dl	203	162	244	
	g/l	2.14	1.71	2.57	Turbidimetric (Non IFCC Cal.)
	mg/dl	214	171	257	
Complement C4	g/l	1.97	1.58	2.36	Vitros 5.1 FS microtip assay
	mg/dl	197	158	236	
	g/l	0.396	0.317	0.475	Turbidimetric (IFCC Cal.)
	mg/dl	39.6	31.7	47.5	
	g/l	0.395	0.316	0.474	Nephelometric (IFCC Cal.)
	mg/dl	39.5	31.6	47.4	
	g/l	0.361	0.289	0.433	Nephelometric (Non IFCC Cal.)
	mg/dl	36.1	28.9	43.3	
Ferritin	g/l	0.379	0.303	0.455	Turbidimetric (Non IFCC Cal.)
	mg/dl	37.9	30.3	45.5	
	g/l	0.390	0.312	0.468	Vitros 5.1 FS microtip assay
	mg/dl	39.0	31.2	46.8	
	ng/ml = µg/l	220	176	264	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	202	162	242	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	267	214	320	Chemiluminescence (IFCC Cal.)
ng/ml = µg/l	250	200	300	Chemiluminescence (Non IFCC Cal.)	
Free Lambda Light Chains	ng/ml = µg/l	198	158	238	Nephelometric (IFCC Cal.)
	mg/L	17.2	13.8	20.6	Nephelometric - Binding Site
	mg/L	15.4	12.3	18.5	Nephelometric - Siemens
Haptoglobin	mg/L	15.3	12.2	18.4	Turbidimetric
	g/l	1.08	0.864	1.30	Nephelometric (IFCC Cal.)
	mg/dl	108	86.4	130	

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Analyte	unit	Target	Range		methods
			low	high	
Haptoglobin	g/l	1.08	0.864	1.30	Turbidimetric (IFCC Cal.)
	mg/dl	108	86.4	130	
	g/l	1.07	0.856	1.28	Turbidimetric (Non IFCC Cal.)
	mg/dl	107	85.6	128	
Immunoglobulin A	g/l	3.98	2.99	4.98	Turbidimetric (IFCC Cal.)
	mg/dl	398	299	497	
	g/l	4.18	3.14	5.23	Nephelometric (IFCC Cal.)
	mg/dl	418	314	522	
	g/l	4.09	3.07	5.11	Nephelometric (Non IFCC Cal.)
	mg/dl	409	307	511	
	g/l	4.03	3.02	5.04	Turbidimetric (Non IFCC Cal.)
	mg/dl	403	302	504	
Immunoglobulin E	g/l	4.26	3.20	5.33	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	426	320	532	
Immunoglobulin E	KIU/l = IU/ml	172	138	206	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	161	129	193	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	145	116	174	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	18.7	15.3	22.1	Turbidimetric (IFCC Cal.)
	mg/dl	1870	1530	2210	
	g/l	18.4	15.1	21.7	Nephelometric (IFCC Cal.)
	mg/dl	1840	1510	2170	
	g/l	18.1	14.8	21.4	Nephelometric (Non IFCC Cal.)
	mg/dl	1810	1480	2140	
	g/l	18.7	15.3	22.1	Turbidimetric (Non IFCC Cal.)
	mg/dl	1870	1530	2210	
Immunoglobulin G	g/l	20.0	16.4	23.6	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2000	1640	2360	
Immunoglobulin M	g/l	1.45	1.16	1.74	Turbidimetric (IFCC Cal.)
	mg/dl	145	116	174	
	g/l	1.49	1.19	1.79	Nephelometric (IFCC Cal.)
	mg/dl	149	119	179	
	g/l	1.45	1.16	1.74	Nephelometric (Non IFCC Cal.)
	mg/dl	145	116	174	
	g/l	1.44	1.15	1.73	Turbidimetric (Non IFCC Cal.)
	mg/dl	144	115	173	
Immunoglobulin M	g/l	1.49	1.19	1.79	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	149	119	179	
Kappa Light Chain	g/l	14.8	11.8	17.8	Nephelometric - Beckman
	mg/dl	1480	1180	1780	
	g/l	4.35	3.48	5.22	Nephelometric - Siemens
	mg/dl	435	348	522	
Kappa Light Chain	g/l	4.67	3.74	5.60	Turbidimetric
	mg/dl	467	374	560	
Lambda Light Chain	g/l	8.33	6.66	10.0	Nephelometric - Beckman
	mg/dl	833	666	1000	

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Range					
Analyte	unit	Target	low	high	methods
Lambda Light Chain	g/l	2.46	1.97	2.95	Nephelometric - Siemens
	mg/dl	246	197	295	
	g/l	2.67	2.14	3.20	Turbidimetric
	mg/dl	267	214	320	
Prealbumin	g/l	0.294	0.235	0.353	Nephelometric (IFCC Cal.)
	mg/dl	29.4	23.5	35.3	
	g/l	0.279	0.223	0.335	Turbidimetric (IFCC Cal.)
	mg/dl	27.9	22.3	33.5	
	g/l	0.288	0.230	0.346	Turbidimetric (Non IFCC Cal.)
	mg/dl	28.8	23.0	34.6	
Protein Total	g/l	79.0	63.2	94.8	Biuret reaction end point
	g/dl	7.90	6.32	9.48	
Retinol Binding Protein	mg/l	49.0	39.2	58.8	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	34.8	26.1	43.5	Turbidimetric (Non IFCC Cal.)
	U/ml	30.3	22.7	37.9	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	3.41	2.73	4.09	Turbidimetric (IFCC Cal.)
	mg/dl	341	273	409	
	g/l	3.47	2.78	4.16	Turbidimetric (Non IFCC Cal.)
	mg/dl	347	278	416	
	g/l	3.37	2.70	4.04	Nephelometric (IFCC Cal.)
mg/dl	337	270	404		