

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

**CAT. NO.** PS2684                      **LOT NO.** 640LPC  
**SIZE** 3 x 1 ml                      **EXPIRY:** 2024-01-28  
**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](mailto:Technical.Services@randox.com).

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

Cat. No. PS2684 Lot. No. 640LPC Size 3 x 1ml Expiry 2024-01-28

		Range			
Analyte	unit	Target	low	high	methods
Albumin	g/l	62.1	52.8	71.4	Bromocresol Green (IFCC Cal.)
	g/dl	6.21	5.28	7.14	
	g/l	64.6	54.9	74.3	Bromocresol Purple (IFCC Cal.)
	g/dl	6.46	5.49	7.43	
	g/l	65.2	55.4	75.0	Nephelometric (IFCC Cal.)
	g/dl	6.52	5.54	7.50	
	g/l	64.6	54.9	74.3	Bromocresol Green (Non IFCC Cal.)
	g/dl	6.46	5.49	7.43	
g/l	64.0	54.4	73.6	Turbidimetric Assays (IFCC Cal.)	
g/dl	6.40	5.44	7.36		
Alpha-1-Acid Glycoprotein	g/l	1.61	1.29	1.93	Turbidimetric (IFCC Cal.)
	mg/dl	161	129	193	Nephelometric (IFCC Cal.)
	g/l	1.66	1.33	1.99	
	mg/dl	166	133	199	
Alpha-1-Antitrypsin	g/l	1.54	1.23	1.85	Turbidimetric (Non IFCC Cal.)
	mg/dl	154	123	185	
	g/l	1.77	1.42	2.12	Turbidimetric (IFCC Cal.)
	mg/dl	177	142	212	
Alpha-1-Antitrypsin	g/l	1.87	1.50	2.24	Nephelometric (IFCC Cal.)
	mg/dl	187	150	224	
	g/l	1.78	1.42	2.14	Turbidimetric (Non IFCC Cal.)
	mg/dl	178	142	214	
Alpha-2-Macroglobulin	g/l	2.88	2.30	3.46	Nephelometric (IFCC Cal.)
	mg/dl	288	230	346	
Alphafoetoprotein	KIU/l = IU/ml	44.3	35.4	53.2	Chemiluminescence (IFCC Cal.)
	ng/ml	53.6	42.8	64.4	
	KIU/l = IU/ml	47.1	37.7	56.5	Chemiluminescence (Non IFCC Cal.)
	ng/ml	57.0	45.6	68.4	
Anti Streptolysin O	IU/ml	270	216	324	Turbidimetric (IFCC Cal.)
	IU/ml	288	230	346	Turbidimetric (Non IFCC Cal.)
	IU/ml	161	129	193	Neph. Beckman (IFCC Cal.)
	IU/ml	152	122	182	Neph. Beckman (Non IFCC Cal.)
	IU/ml	270	216	324	Siemens Nephelometric (Non IFCC Cal.)
Antithrombin III	mg/l	364	273	455	Turbidimetric (Non IFCC Cal.)
	mg/dl	36.4	27.3	45.5	
Beta-2-microglobulin	µg/ml = mg/l	4.79	3.83	5.75	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	4.82	3.86	5.78	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.59	4.47	6.71	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.36	4.29	6.43	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	53.1	42.5	63.7	Vitros (IFCC Cal.)
	mg/l	65.0	52.0	78.0	Turbidimetric (IFCC Cal.)
	mg/l	66.4	53.1	79.7	Nephelometric (IFCC Cal.)

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

Cat. No. PS2684 Lot. No. 640LPC Size 3 x 1ml Expiry 2024-01-28

Analyte	unit	Target	Range		methods
			low	high	
C-Reactive Protein	mg/l	68.3	54.6	82.0	Nephelometric (Non IFCC Cal.)
	mg/l	65.9	52.7	79.1	Turbidimetric (Non IFCC Cal.)
	mg/l	66.3	53.0	79.6	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	65.9	52.7	79.1	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	66.0	52.8	79.2	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	67.5	54.0	81.0	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	71.9	57.5	86.3	Beckman Turb Latex (IFCC Cal)
	mg/l	67.2	53.8	80.6	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.570	0.399	0.741	Nephelometric (IFCC Cal.)
	mg/dl	57.0	39.9	74.1	
	g/l	0.495	0.347	0.643	Turbidimetric (IFCC Cal.)
	mg/dl	49.5	34.7	64.3	
	g/l	0.416	0.291	0.541	Turbidimetric (Non IFCC Cal.)
mg/dl	41.6	29.1	54.1		
	Complement C3	g/l	2.45	1.96	2.94
mg/dl		245	196	294	
g/l		2.36	1.89	2.83	Nephelometric (IFCC Cal.)
mg/dl		236	189	283	
g/l		2.36	1.89	2.83	Nephelometric (Non IFCC Cal.)
mg/dl		236	189	283	
g/l		2.52	2.02	3.02	Turbidimetric (Non IFCC Cal.)
mg/dl		252	202	302	
Complement C4	g/l	2.38	1.90	2.86	Vitros 5.1 FS microtip assay
	mg/dl	238	190	286	
	g/l	0.494	0.395	0.593	Turbidimetric (IFCC Cal.)
	mg/dl	49.4	39.5	59.3	
	g/l	0.498	0.398	0.598	Nephelometric (IFCC Cal.)
	mg/dl	49.8	39.8	59.8	
	g/l	0.494	0.395	0.593	Nephelometric (Non IFCC Cal.)
	mg/dl	49.4	39.5	59.3	
Ferritin	g/l	0.486	0.389	0.583	Turbidimetric (Non IFCC Cal.)
	mg/dl	48.6	38.9	58.3	
	g/l	0.481	0.385	0.577	Vitros 5.1 FS microtip assay
	mg/dl	48.1	38.5	57.7	
	ng/ml = µg/l	234	187	281	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	197	158	236	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	275	220	330	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	264	211	317	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	195	156	234	Nephelometric (IFCC Cal.)
Haptoglobin	mg/L	20.5	16.4	24.6	Nephelometric - Binding Site
	mg/L	18.2	14.6	21.8	Nephelometric - Siemens
	mg/L	19.3	15.4	23.2	Turbidimetric
Haptoglobin	g/l	1.33	1.06	1.60	Nephelometric (IFCC Cal.)
	mg/dl	133	106	160	
	g/l	1.34	1.07	1.61	Turbidimetric (IFCC Cal.)
mg/dl	134	107	161		

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

Cat. No. PS2684 Lot. No. 640LPC Size 3 x 1ml Expiry 2024-01-28

Analyte	unit	Target	Range		methods
			low	high	
Haptoglobin	g/l	1.33	1.06	1.60	Turbidimetric (Non IFCC Cal.)
	mg/dl	133	106	160	
Immunoglobulin A	g/l	4.49	3.37	5.61	Turbidimetric (IFCC Cal.)
	mg/dl	449	337	561	
	g/l	4.77	3.58	5.96	Nephelometric (IFCC Cal.)
	mg/dl	477	358	596	
	g/l	4.82	3.62	6.03	Nephelometric (Non IFCC Cal.)
	mg/dl	482	362	602	
	g/l	4.53	3.40	5.66	Turbidimetric (Non IFCC Cal.)
	mg/dl	453	340	566	
g/l	4.93	3.70	6.16	Vitros 5.1 FS Microtip (IFCC)	
mg/dl	493	370	616		
Immunoglobulin E	KIU/l = IU/ml	236	189	283	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	212	170	254	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	205	164	246	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	22.6	18.5	26.7	Turbidimetric (IFCC Cal.)
	mg/dl	2260	1850	2670	
	g/l	21.9	18.0	25.8	Nephelometric (IFCC Cal.)
	mg/dl	2190	1800	2580	
	g/l	22.1	18.1	26.1	Nephelometric (Non IFCC Cal.)
	mg/dl	2210	1810	2610	
	g/l	22.8	18.7	26.9	Turbidimetric (Non IFCC Cal.)
	mg/dl	2280	1870	2690	
g/l	25.5	20.9	30.1	Vitros 5.1 FS Microtip (IFCC)	
mg/dl	2550	2090	3010		
Immunoglobulin M	g/l	1.82	1.46	2.18	Turbidimetric (IFCC Cal.)
	mg/dl	182	146	218	
	g/l	1.90	1.52	2.28	Nephelometric (IFCC Cal.)
	mg/dl	190	152	228	
	g/l	1.87	1.50	2.24	Nephelometric (Non IFCC Cal.)
	mg/dl	187	150	224	
	g/l	1.81	1.45	2.17	Turbidimetric (Non IFCC Cal.)
	mg/dl	181	145	217	
g/l	1.93	1.54	2.32	Vitros 5.1 FS Microtip (IFCC)	
mg/dl	193	154	232		
Kappa Light Chain	g/l	19.1	15.3	22.9	Nephelometric - Beckman
	mg/dl	1910	1530	2290	
	g/l	5.23	4.18	6.28	Nephelometric - Siemens
	mg/dl	523	418	628	
	g/l	5.68	4.54	6.82	Turbidimetric
mg/dl	568	454	682		
Lambda Light Chain	g/l	10.5	8.40	12.6	Nephelometric - Beckman
	mg/dl	1050	840	1260	
	g/l	2.96	2.37	3.55	Nephelometric - Siemens
	mg/dl	296	237	355	
	g/l	3.15	2.52	3.78	Turbidimetric
mg/dl	315	252	378		

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

Cat. No. PS2684 Lot. No. 640LPC Size 3 x 1ml Expiry 2024-01-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.404	0.323	0.485	Nephelometric (IFCC Cal.)
	mg/dl	40.4	32.3	48.5	
	g/l	0.363	0.290	0.436	Turbidimetric (IFCC Cal.)
	mg/dl	36.3	29.0	43.6	
	g/l	0.364	0.291	0.437	Turbidimetric (Non IFCC Cal.)
mg/dl	36.4	29.1	43.7		
Protein Total	g/l	103	82.4	124	Biuret reaction end point
	g/dl	10.3	8.24	12.4	
Retinol Binding Protein	mg/l	66.3	53.0	79.6	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	51.0	38.3	63.8	Turbidimetric (Non IFCC Cal.)
	U/ml	35.0	26.3	43.8	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	4.40	3.52	5.28	Turbidimetric (IFCC Cal.)
	mg/dl	440	352	528	
	g/l	4.51	3.61	5.41	Turbidimetric (Non IFCC Cal.)
	mg/dl	451	361	541	
	g/l	4.36	3.49	5.23	Nephelometric (IFCC Cal.)
mg/dl	436	349	523		