

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

CAT. NO.	PS2683	LOT NO.	662LPC
SIZE	3 x 1ml	EXPIRY:	2025-01-28
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.

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

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

Cat. No. PS2683 Lot. No. 662LPC Size 3 x 1ml Expiry 2025-01-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	41.3	35.1	47.5	Bromocresol Green (IFCC Cal.)
	g/dl	4.13	3.51	4.75	
	g/l	39.1	33.2	45.0	Bromocresol Purple (IFCC Cal.)
	g/dl	3.91	3.32	4.50	
	g/l	40.0	34.0	46.0	Nephelometric (IFCC Cal.)
	g/dl	4.00	3.40	4.60	
	g/l	41.7	35.4	48.0	Bromocresol Green (Non IFCC Cal.)
	g/dl	4.17	3.54	4.80	
	g/l	39.3	33.4	45.2	Turbidimetric Assays (IFCC Cal.)
	g/dl	3.93	3.34	4.52	
	g/l	40.3	34.3	46.3	Turbidimetric (Non IFCC Cal.)
	g/dl	4.03	3.43	4.63	
Alpha-1-Acid Glycoprotein	g/l	1.18	0.944	1.42	Turbidimetric (IFCC Cal.)
	mg/dl	118	94.4	142	Nephelometric (IFCC Cal.)
	g/l	1.23	0.984	1.48	
	mg/dl	123	98.4	148	Turbidimetric (Non IFCC Cal.)
	g/l	1.16	0.928	1.39	
	mg/dl	116	92.8	139	
Alpha-1-Antitrypsin	g/l	1.23	0.984	1.48	Turbidimetric (IFCC Cal.)
	mg/dl	123	98.4	148	Nephelometric (IFCC Cal.)
	g/l	1.35	1.08	1.62	
	mg/dl	135	108	162	Turbidimetric (Non IFCC Cal.)
	g/l	1.24	0.992	1.49	
	mg/dl	124	99.2	149	
Alpha-2-Macroglobulin	g/l	2.27	1.82	2.72	Nephelometric (IFCC Cal.)
	mg/dl	227	182	272	
Alphafoetoprotein	KIU/l = IU/ml	27.9	22.3	33.5	Chemiluminescence (IFCC Cal.)
	ng/ml	33.8	27.0	40.6	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	28.9	23.1	34.7	
	ng/ml	35.0	28.0	42.0	
Anti Streptolysin O	IU/ml	190	152	228	Turbidimetric (IFCC Cal.)
	IU/ml	193	154	232	Turbidimetric (Non IFCC Cal.)
	IU/ml	110	88.0	132	Neph. Beckman (Non IFCC Cal.)
	IU/ml	184	147	221	Siemens Nephelometric (Non IFCC Cal.)
Antithrombin III	mg/l	312	234	390	Turbidimetric (Non IFCC Cal.)
	mg/dl	31.2	23.4	39.0	
Beta-2-microglobulin	µg/ml = mg/l	3.25	2.60	3.90	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.12	2.50	3.74	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	3.79	3.03	4.55	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.73	2.98	4.48	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	44.2	35.4	53.0	Vitros (IFCC Cal.)
	mg/l	45.4	36.3	54.5	Turbidimetric (IFCC Cal.)

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Cat. No. PS2683 Lot. No. 662LPC Size 3 x 1ml Expiry 2025-01-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	43.8	35.0	52.6	Nephelometric (IFCC Cal.)
	mg/l	45.3	36.2	54.4	Turbidimetric (Non IFCC Cal.)
	mg/l	48.3	38.6	58.0	Beckman Turb Latex (IFCC Cal.)
	mg/l	45.4	36.3	54.5	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.483	0.362	0.604	Nephelometric (IFCC Cal.)
	mg/dl	48.3	36.2	60.4	
	g/l	0.417	0.313	0.521	Turbidimetric (IFCC Cal.)
	mg/dl	41.7	31.3	52.1	
	g/l	0.409	0.307	0.511	Nephelometric (Non IFCC Cal.)
	mg/dl	40.9	30.7	51.1	
Complement C3	g/l	0.360	0.270	0.450	Turbidimetric (Non IFCC Cal.)
	mg/dl	36.0	27.0	45.0	
	g/l	2.00	1.60	2.40	Turbidimetric (IFCC Cal.)
	mg/dl	200	160	240	
	g/l	1.98	1.58	2.38	Nephelometric (IFCC Cal.)
	mg/dl	198	158	238	
Complement C4	g/l	1.94	1.55	2.33	Nephelometric (Non IFCC Cal.)
	mg/dl	194	155	233	
	g/l	2.06	1.65	2.47	Turbidimetric (Non IFCC Cal.)
	mg/dl	206	165	247	
	g/l	1.93	1.54	2.32	Vitros 5.1 FS microtip assay
	mg/dl	193	154	232	
Complement C4	g/l	0.379	0.303	0.455	Turbidimetric (IFCC Cal.)
	mg/dl	37.9	30.3	45.5	
	g/l	0.396	0.317	0.475	Nephelometric (IFCC Cal.)
	mg/dl	39.6	31.7	47.5	
	g/l	0.387	0.310	0.464	Nephelometric (Non IFCC Cal.)
	mg/dl	38.7	31.0	46.4	
Ferritin	g/l	0.365	0.292	0.438	Turbidimetric (Non IFCC Cal.)
	mg/dl	36.5	29.2	43.8	
	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	196	157	235	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	160	128	192	Turbidimetric (Non IFCC Cal.)
Free Lambda Light Chains	ng/ml = µg/l	253	202	304	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	221	177	265	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	164	131	197	Nephelometric (IFCC Cal.)
	mg/L	12.4	9.92	14.9	Nephelometric - Siemens
Haptoglobin	mg/L	15.7	12.6	18.8	Nephelometric - Binding Site
	mg/L	14.8	11.8	17.8	Turbidimetric
	g/l	1.32	1.06	1.58	Nephelometric (IFCC Cal.)
Haptoglobin	mg/dl	132	106	158	
	g/l	1.35	1.08	1.62	Turbidimetric (IFCC Cal.)
	mg/dl	135	108	162	
	g/l	1.35	1.08	1.62	Turbidimetric (Non IFCC Cal.)
Haptoglobin	mg/dl	135	108	162	

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

Cat. No. PS2683 Lot. No. 662LPC Size 3 x 1ml Expiry 2025-01-28

Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin A	g/l	3.40	2.55	4.25	Turbidimetric (IFCC Cal.)
	mg/dl	340	255	425	
	g/l	3.58	2.69	4.48	Nephelometric (IFCC Cal.)
	mg/dl	358	269	447	
	g/l	3.54	2.66	4.43	Nephelometric (Non IFCC Cal.)
	mg/dl	354	266	442	
	g/l	3.40	2.55	4.25	Turbidimetric (Non IFCC Cal.)
	mg/dl	340	255	425	
Immunoglobulin E	g/l	3.63	2.72	4.54	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	363	272	454	
	g/l	3.63	2.72	4.54	Vitros 5.1 FS Microtip (IFCC)
Immunoglobulin E	KIU/l = IU/ml	155	124	186	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	136	109	163	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	124	99.0	149	Turbidimetric (Non IFCC Cal.)
	g/l	17.3	14.2	20.4	Turbidimetric (IFCC Cal.)
	mg/dl	1730	1420	2040	
	g/l	17.2	14.1	20.3	Nephelometric (IFCC Cal.)
	mg/dl	1720	1410	2030	
	g/l	17.0	13.9	20.1	Nephelometric (Non IFCC Cal.)
Immunoglobulin G	mg/dl	1700	1390	2010	
	g/l	17.4	14.3	20.5	Turbidimetric (Non IFCC Cal.)
	mg/dl	1740	1430	2050	
	g/l	18.2	14.9	21.5	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1820	1490	2150	
	g/l	1.50	1.20	1.80	Turbidimetric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.58	1.26	1.90	Nephelometric (IFCC Cal.)
Immunoglobulin M	mg/dl	158	126	190	
	g/l	1.56	1.25	1.87	Nephelometric (Non IFCC Cal.)
	mg/dl	156	125	187	
	g/l	1.50	1.20	1.80	Turbidimetric (Non IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.53	1.22	1.84	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	153	122	184	
	g/l	14.6	11.7	17.5	Nephelometric - Beckman
Kappa Light Chain	mg/dl	1460	1170	1750	
	g/l	4.07	3.26	4.88	Nephelometric - Siemens
	mg/dl	407	326	488	
	g/l	4.24	3.39	5.09	Turbidimetric
Lambda Light Chain	mg/dl	424	339	509	
	g/l	7.87	6.30	9.44	Nephelometric - Beckman
	mg/dl	787	630	944	
	g/l	2.22	1.78	2.66	Nephelometric - Siemens
Prealbumin	mg/dl	222	178	266	
	g/l	2.32	1.86	2.78	Turbidimetric
	mg/dl	232	186	278	
Prealbumin	g/l	0.232	0.186	0.278	Nephelometric (IFCC Cal.)
	mg/dl	23.2	18.6	27.8	

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Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.226	0.181	0.271	Turbidimetric (IFCC Cal.)
	mg/dl	22.6	18.1	27.1	
	g/l	0.226	0.181	0.271	Turbidimetric (Non IFCC Cal.)
	mg/dl	22.6	18.1	27.1	
Protein Total	g/l	70.1	56.1	84.1	Biuret reaction end point
	g/dl	7.01	5.61	8.41	
Retinol Binding Protein	mg/l	46.8	37.4	56.2	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	43.3	32.5	54.1	Turbidimetric (Non IFCC Cal.)
	U/ml	46.8	35.1	58.5	Latex (Non-IFCC Cal.)
	U/ml	42.1	31.6	52.6	Neph. Beckman (Non IFCC Cal.)
Transferrin	g/l	2.76	2.21	3.31	Turbidimetric (IFCC Cal.)
	mg/dl	276	221	331	
	g/l	2.79	2.23	3.35	Turbidimetric (Non IFCC Cal.)
	mg/dl	279	223	335	
	g/l	2.74	2.19	3.29	Nephelometric (IFCC Cal.)
	mg/dl	274	219	329	