

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

CAT. NO.	PS2682	LOT NO.	661LPC
SIZE	3 x 1 ml	EXPIRY:	2025-01-28
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 I, 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 9445 1070 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 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 661LPC Size 3 x 1 ml Expiry 2025-01-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	21.2	18.0	24.4	Bromocresol Green (IFCC Cal.)
	g/dl	2.12	1.80	2.44	
	g/l	19.5	16.6	22.4	Bromocresol Purple (IFCC Cal.)
	g/dl	1.95	1.66	2.24	
	g/l	20.4	17.3	23.5	Nephelometric (IFCC Cal.)
	g/dl	2.04	1.73	2.35	
	g/l	21.3	18.1	24.5	Bromocresol Green (Non IFCC Cal.)
	g/dl	2.13	1.81	2.45	
Alpha-1-Acid Glycoprotein	g/l	20.1	17.1	23.1	Turbidimetric Assays (IFCC Cal.)
	g/dl	2.01	1.71	2.31	
	g/l	0.551	0.441	0.661	Turbidimetric (IFCC Cal.)
	mg/dl	55.1	44.1	66.1	
	g/l	0.609	0.487	0.731	Nephelometric (IFCC Cal.)
	mg/dl	60.9	48.7	73.1	
	g/l	0.556	0.445	0.667	Turbidimetric (Non IFCC Cal.)
	mg/dl	55.6	44.5	66.7	
Alpha-1-Antitrypsin	g/l	0.620	0.496	0.744	Nephelometric (IFCC Cal.)
	mg/dl	62.0	49.6	74.4	
	g/l	0.580	0.464	0.696	Turbidimetric (Non IFCC Cal.)
	mg/dl	58.0	46.4	69.6	
Alpha-2-Macroglobulin	g/l	1.13	0.904	1.36	Nephelometric (IFCC Cal.)
	mg/dl	113	90.4	136	
Alphafoetoprotein	KIU/l = IU/ml	14.5	11.6	17.4	Chemiluminescence (IFCC Cal.)
	ng/ml	17.5	14.0	21.0	
	KIU/l = IU/ml	15.0	12.0	18.0	Chemiluminescence (Non IFCC Cal.)
	ng/ml	18.2	14.5	21.9	
Anti Streptolysin O	IU/ml	91.4	68.6	114	Turbidimetric (IFCC Cal.)
	IU/ml	94.6	71.0	118	Turbidimetric (Non IFCC Cal.)
	IU/ml	63.8	47.9	79.8	Neph. Beckman (IFCC Cal.)
	IU/ml	62.6	47.0	78.3	Neph. Beckman (Non IFCC Cal.)
	IU/ml	101	75.8	126	Siemens Nephelometric (IFCC Cal.)
	IU/ml	96.9	72.7	121	Siemens Nephelometric (Non IFCC Cal.)
Antithrombin III	mg/l	144	108	180	Turbidimetric (Non IFCC Cal.)
	mg/dl	14.4	10.8	18.0	
Beta-2-microglobulin	µg/ml = mg/l	1.65	1.32	1.98	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.66	1.33	1.99	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.86	1.49	2.23	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.93	1.54	2.32	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	26.2	21.0	31.4	Vitros (IFCC Cal.)
	mg/l	23.3	18.6	28.0	Turbidimetric (IFCC Cal.)
	mg/l	20.8	16.6	25.0	Nephelometric (IFCC Cal.)
	mg/l	21.3	17.0	25.6	Nephelometric (Non IFCC Cal.)

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

Cat. No. PS2682 Lot. No. 661LPC Size 3 x 1 ml Expiry 2025-01-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	23.3	18.6	28.0	Turbidimetric (Non IFCC Cal.)
	mg/l	20.8	16.6	25.0	Beckman Turb Latex (IFCC Cal)
	mg/l	21.9	17.5	26.3	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.230	0.180	0.280	Nephelometric (IFCC Cal.)
	mg/dl	23.0	18.0	28.0	
	g/l	0.172	0.140	0.210	Turbidimetric (Non IFCC Cal.)
	mg/dl	17.2	14.0	20.4	
Complement C3	g/l	0.993	0.794	1.19	Turbidimetric (IFCC Cal.)
	mg/dl	99.3	79.4	119	
	g/l	0.961	0.769	1.15	Nephelometric (IFCC Cal.)
	mg/dl	96.1	76.9	115	
	g/l	0.953	0.762	1.14	Nephelometric (Non IFCC Cal.)
	mg/dl	95.3	76.2	114	
	g/l	1.03	0.824	1.24	Turbidimetric (Non IFCC Cal.)
	mg/dl	103	82.4	124	
Complement C4	g/l	0.993	0.794	1.19	Vitros 5.1 FS microtip assay
	mg/dl	99.3	79.4	119	
	g/l	0.184	0.147	0.221	Turbidimetric (IFCC Cal.)
	mg/dl	18.4	14.7	22.1	
	g/l	0.196	0.157	0.235	Nephelometric (IFCC Cal.)
	mg/dl	19.6	15.7	23.5	
	g/l	0.198	0.158	0.238	Nephelometric (Non IFCC Cal.)
	mg/dl	19.8	15.8	23.8	
Ferritin	g/l	0.177	0.142	0.212	Turbidimetric (Non IFCC Cal.)
	mg/dl	17.7	14.2	21.2	
	g/l	0.198	0.158	0.238	Vitros 5.1 FS microtip assay
	mg/dl	19.8	15.8	23.8	
Free Lambda Light Chains	ng/ml = µg/l	101	80.8	121	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	81.0	64.8	97.2	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	114	91.2	137	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	83.4	66.7	100	Nephelometric (IFCC Cal.)
Haptoglobin	mg/L	7.44	5.95	8.93	Turbidimetric
	mg/L	8.89	7.11	10.7	Nephelometric - Binding Site
	mg/L	7.26	5.81	8.71	Nephelometric - Siemens
Immunoglobulin A	g/l	0.632	0.506	0.758	Nephelometric (IFCC Cal.)
	mg/dl	63.2	50.6	75.8	
	g/l	0.674	0.539	0.809	Turbidimetric (IFCC Cal.)
	mg/dl	67.4	53.9	80.9	
Immunoglobulin A	g/l	0.677	0.542	0.812	Turbidimetric (Non IFCC Cal.)
	mg/dl	67.7	54.2	81.2	
	g/l	1.73	1.30	2.16	Turbidimetric (IFCC Cal.)
	mg/dl	173	130	216	
Immunoglobulin A	g/l	1.81	1.36	2.26	Nephelometric (IFCC Cal.)
	mg/dl	181	136	226	
	g/l	1.82	1.37	2.28	Nephelometric (Non IFCC Cal.)
	mg/dl	182	137	227	

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

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin A	g/l	1.72	1.29	2.15	Turbidimetric (Non IFCC Cal.)
	mg/dl	172	129	215	
	g/l	1.74	1.31	2.18	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	174	131	217	
Immunoglobulin E	KIU/l = IU/ml	80.9	64.7	97.1	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	70.7	56.6	84.8	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	66.7	53.4	80.0	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	8.68	7.12	10.2	Turbidimetric (IFCC Cal.)
	mg/dl	868	712	1024	Nephelometric (IFCC Cal.)
	g/l	8.90	7.30	10.5	
	mg/dl	890	730	1050	Nephelometric (Non IFCC Cal.)
	g/l	8.68	7.12	10.2	
	mg/dl	868	712	1024	Turbidimetric (Non IFCC Cal.)
	g/l	8.76	7.18	10.3	
	mg/dl	876	718	1034	Vitros 5.1 FS Microtip (IFCC)
	g/l	9.27	7.60	10.9	
	mg/dl	927	760	1094	
Immunoglobulin M	g/l	0.758	0.606	0.910	Turbidimetric (IFCC Cal.)
	mg/dl	75.8	60.6	91.0	Nephelometric (IFCC Cal.)
	g/l	0.796	0.637	0.955	
	mg/dl	79.6	63.7	95.5	Nephelometric (Non IFCC Cal.)
	g/l	0.809	0.647	0.971	
	mg/dl	80.9	64.7	97.1	Turbidimetric (Non IFCC Cal.)
	g/l	0.760	0.608	0.912	
	mg/dl	76.0	60.8	91.2	Vitros 5.1 FS Microtip (IFCC)
	g/l	0.760	0.608	0.912	
	mg/dl	76.0	60.8	91.2	
Kappa Light Chain	g/l	2.12	1.70	2.54	Turbidimetric
	mg/dl	212	170	254	Nephelometric - Siemens
	g/l	2.14	1.71	2.57	
	mg/dl	214	171	257	
Lambda Light Chain	g/l	1.19	0.950	1.43	Nephelometric - Siemens
	mg/dl	119	95.0	143	Turbidimetric
	g/l	1.13	0.900	1.36	
	mg/dl	113	90.0	136	
Prealbumin	g/l	0.113	0.079	0.147	Nephelometric (IFCC Cal.)
	mg/dl	11.3	7.90	14.7	Turbidimetric (IFCC Cal.)
	g/l	0.109	0.076	0.142	
	mg/dl	10.9	7.60	14.2	Turbidimetric (Non IFCC Cal.)
	g/l	0.111	0.078	0.144	
	mg/dl	11.1	7.80	14.4	
Protein Total	g/l	39.1	31.3	46.9	Biuret reaction end point
	g/dl	3.91	3.13	4.69	
Retinol Binding Protein	mg/l	19.5	15.6	23.4	Nephelometric (IFCC Cal.)
Rheumatoid Factor	U/ml	22.8	17.1	28.5	Turbidimetric (Non IFCC Cal.)
	U/ml	21.4	16.1	26.8	Nephelometric (Non IFCC Cal.)

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Range					
Analyte	unit	Target	low	high	methods
Rheumatoid Factor	U/ml	23.6	17.7	29.5	Latex (Non-IFCC Cal.)
Transferrin	g/l	1.39	1.11	1.67	Turbidimetric (IFCC Cal.)
	mg/dl	139	111	167	
	g/l	1.39	1.11	1.67	Turbidimetric (Non IFCC Cal.)
	mg/dl	139	111	167	
	g/l	1.37	1.10	1.64	Nephelometric (IFCC Cal.)
	mg/dl	137	110	164	