

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

Cat. No. PS2684 **Lot No.** 455LPC
Size: 3 x 1 ml **Expiry:** 2018-02

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 Kappa and 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.

PREPARATION

The Liquid Protein Controls are supplied ready for use.

MATERIALS PROVIDED

Liquid Assayed Specific 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 Liquid 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.

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Cat. No. PS2684 Lot No. 455LPC Size: 3 x 1 ml Expiry: 2018-02

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	52.4	44.5	60.3	Bromocresol Green (IFCC Cal.)
	g/dl	5.24	4.45	6.03	
	g/l	53.7	45.6	61.8	Bromocresol Purple (IFCC Cal.)
	g/dl	5.37	4.56	6.18	
	g/l	53.7	45.6	61.8	Nephelometric (IFCC Cal.)
	g/dl	5.37	4.56	6.18	
	g/l	53.7	45.6	61.8	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.37	4.56	6.18	
	g/l	53.3	45.3	61.3	Bromocresol Purple (Non IFCC Cal.)
	g/dl	5.33	4.53	6.13	
	g/l	54.3	46.2	62.4	Nephelometric (Non IFCC Cal.)
	g/dl	5.43	4.62	6.24	
Alpha-1-Acid Glycoprotein	g/l	54.2	46.1	62.3	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.42	4.61	6.23	
	g/l	1.58	1.26	1.90	Turbidimetric (IFCC Cal.)
	mg/dl	158	126	190	
	g/l	1.65	1.32	1.98	Nephelometric (IFCC Cal.)
	mg/dl	165	132	198	
Alpha-1-Antitrypsin	g/l	1.73	1.38	2.08	Nephelometric (Non IFCC Cal.)
	mg/dl	173	138	208	
	g/l	1.53	1.22	1.84	Turbidimetric (Non IFCC Cal.)
	mg/dl	153	122	184	
	g/l	1.83	1.46	2.20	Turbidimetric (IFCC Cal.)
	mg/dl	183	146	220	
Alpha-1-Antitrypsin	g/l	1.96	1.57	2.35	Nephelometric (IFCC Cal.)
	mg/dl	196	157	235	
	g/l	2.12	1.70	2.54	Nephelometric (Non IFCC Cal.)
	mg/dl	212	170	254	
	g/l	1.80	1.44	2.16	Turbidimetric (Non IFCC Cal.)
	mg/dl	180	144	216	
Alpha-2-Macroglobulin	g/l	2.65	2.12	3.18	Turbidimetric (IFCC Cal.)
	mg/dl	265	212	318	
	g/l	2.60	2.08	3.12	Nephelometric (IFCC Cal.)
	mg/dl	260	208	312	
	g/l	2.80	2.24	3.36	Nephelometric (Non IFCC Cal.)
	mg/dl	280	224	336	
Alpha-2-Macroglobulin	g/l	2.83	2.26	3.40	Turbidimetric (Non IFCC Cal.)
	mg/dl	283	226	340	
Alphafoetoprotein	KIU/l = IU/ml	45.2	36.2	54.2	Chemiluminescence (IFCC Cal.)
	ng/ml	54.7	43.8	65.6	
	KIU/l = IU/ml	46.3	37.0	55.6	Chemiluminescence (Non IFCC Cal.)
	ng/ml	56.0	44.8	67.2	

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

Cat. No. PS2684 Lot No. 455LPC Size: 3 x 1 ml Expiry: 2018-02

Range					
Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	297	238	356	Turbidimetric (IFCC Cal.)
	IU/ml	303	242	364	Turbidimetric (Non IFCC Cal.)
	IU/ml	182	146	218	Neph. Beckman (IFCC Cal.)
	IU/ml	177	142	212	Neph. Beckman (Non IFCC Cal.)
	IU/ml	308	246	370	Neph. Behring (IFCC Cal.)
	IU/ml	305	244	366	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	304	228	380	Turbidimetric (IFCC Cal.)
	mg/dl	30.4	22.8	38.0	
Beta-2-microglobulin	µg/ml = mg/l	4.69	3.75	5.63	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	5.09	4.07	6.11	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	5.17	4.14	6.20	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	5.39	4.31	6.47	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.48	4.38	6.58	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.51	4.41	6.61	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	4.92	3.94	5.90	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	45.8	36.6	55.0	Vitros (IFCC Cal.)
	mg/l	70.3	56.2	84.4	Turbidimetric (IFCC Cal.)
	mg/l	72.1	57.7	86.5	Nephelometric (IFCC Cal.)
	mg/l	44.8	35.8	53.8	Vitros (Non IFCC Cal.)
	mg/l	65.1	52.1	78.1	Nephelometric (Non IFCC Cal.)
	mg/l	69.2	55.4	83.0	Turbidimetric (Non IFCC Cal.)
Caeruloplasmin	g/l	0.515	0.412	0.618	Nephelometric (IFCC Cal.)
	mg/dl	51.5	41.2	61.8	
	g/l	0.518	0.414	0.622	Turbidimetric (IFCC Cal.)
	mg/dl	51.8	41.4	62.2	
	g/l	0.500	0.400	0.600	Nephelometric (Non IFCC Cal.)
	mg/dl	50.0	40.0	60.0	
	g/l	0.546	0.437	0.655	Turbidimetric (Non IFCC Cal.)
	mg/dl	54.6	43.7	65.5	
	g/l	0.476	0.420	0.630	Neph. Beckman (IFCC Cal.)
	mg/dl	47.6	42.0	53.2	
Complement C3	g/l	0.591	0.473	0.709	Randox Immunoturbidimetric
	mg/dl	59.1	47.3	70.9	
	g/l	2.27	1.82	2.72	Turbidimetric (IFCC Cal.)
	mg/dl	227	182	272	
	g/l	2.32	1.86	2.78	Nephelometric (IFCC Cal.)
	mg/dl	232	186	278	
	g/l	2.30	1.84	2.76	Nephelometric (Non IFCC Cal.)
	mg/dl	230	184	276	
	g/l	2.27	1.82	2.72	Turbidimetric (Non IFCC Cal.)
	mg/dl	227	182	272	
Complement C4	g/l	2.16	1.73	2.59	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	216	173	259	
	g/l	0.475	0.380	0.570	Turbidimetric (IFCC Cal.)
	mg/dl	47.5	38.0	57.0	
	g/l	0.527	0.422	0.632	Nephelometric (IFCC Cal.)
	mg/dl	52.7	42.2	63.2	

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

Cat. No. PS2684 Lot No. 455LPC Size: 3 x 1 ml Expiry: 2018-02

Range					
Analyte	unit	Target	low	high	methods
Complement C4	g/l	0.522	0.418	0.626	Nephelometric (Non IFCC Cal.)
	mg/dl	52.2	41.8	62.6	
	g/l	0.471	0.377	0.565	Turbidimetric (Non IFCC Cal.)
	mg/dl	47.1	37.7	56.5	
	g/l	0.468	0.374	0.562	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	46.8	37.4	56.2	
Ferritin	ng/ml = µg/l	276	221	331	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	279	223	335	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	322	258	386	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	290	232	348	Nephelometric (IFCC Cal.)
	ng/ml = µg/l	285	228	342	Nephelometric (Non IFCC Cal.)
Free Kappa Light Chains	mg/L	16.6	13.3	19.9	Turbidimetric
	mg/L	19.4	15.5	23.3	Nephelometric - Beckman
	mg/L	17.5	14.0	21.0	Nephelometric - Binding Site
	mg/L	8.57	6.86	10.3	Nephelometric - Siemens
Free Lambda Light Chains	mg/L	16.1	12.9	19.3	Turbidimetric
	mg/L	20.1	16.1	24.1	Nephelometric - Beckman
	mg/L	19.3	15.4	23.2	Nephelometric - Binding Site
	mg/L	16.6	13.3	19.9	Nephelometric - Siemens
Haptoglobin	g/l	1.55	1.24	1.86	Nephelometric (IFCC Cal.)
	mg/dl	155	124	186	
	g/l	1.50	1.20	1.80	Turbidimetric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.53	1.22	1.84	Nephelometric (Non IFCC Cal.)
	mg/dl	153	122	184	
Immunoglobulin A	g/l	1.49	1.19	1.79	Turbidimetric (Non IFCC Cal.)
	mg/dl	149	119	179	
	g/l	4.31	3.23	5.39	Turbidimetric (IFCC Cal.)
	mg/dl	431	323	539	
	g/l	4.72	3.54	5.90	Nephelometric (IFCC Cal.)
	mg/dl	472	354	590	
	g/l	4.63	3.47	5.79	Nephelometric (Non IFCC Cal.)
	mg/dl	463	347	579	
Immunoglobulin E	g/l	4.29	3.22	5.36	Turbidimetric (Non IFCC Cal.)
	mg/dl	429	322	536	
	g/l	4.60	3.45	5.75	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	460	345	575	
	g/l	4.56	3.42	5.70	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	456	342	570	
	KIU/l = IU/ml	194	155	233	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	198	158	238	Chemiluminescence (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	190	152	228	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	199	159	239	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	199	159	239	Turbidimetric (Non IFCC Cal.)
	g/l	21.7	17.8	25.6	Turbidimetric (IFCC Cal.)
	mg/dl	2170	1780	2560	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin G	g/l	22.3	18.3	26.3	Nephelometric (IFCC Cal.)
	mg/dl	2230	1830	2630	
	g/l	21.8	17.9	25.7	Nephelometric (Non IFCC Cal.)
	mg/dl	2180	1790	2570	
	g/l	21.8	17.9	25.7	Turbidimetric (Non IFCC Cal.)
	mg/dl	2180	1790	2570	
	g/l	24.1	19.8	28.4	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	2410	1980	2840	
Immunoglobulin M	g/l	1.75	1.40	2.10	Turbidimetric (IFCC Cal.)
	mg/dl	175	140	210	
	g/l	1.90	1.52	2.28	Nephelometric (IFCC Cal.)
	mg/dl	190	152	228	
	g/l	1.92	1.54	2.30	Nephelometric (Non IFCC Cal.)
	mg/dl	192	154	230	
	g/l	1.80	1.44	2.16	Turbidimetric (Non IFCC Cal.)
	mg/dl	180	144	216	
	g/l	1.86	1.49	2.23	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	186	149	223	
	g/l	1.81	1.45	2.17	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	181	145	217	
Kappa Light Chain	g/l	5.59	4.47	6.71	Turbidimetric
	mg/dl	559	447	671	
	g/l	19.3	15.4	23.2	Nephelometric - Beckman
	mg/dl	1930	1540	2320	
	g/l	5.19	4.15	6.23	Nephelometric - Siemens
	mg/dl	519	415	623	
Lambda Light Chain	g/l	3.24	2.59	3.89	Turbidimetric
	mg/dl	324	259	389	
	g/l	10.7	8.56	12.8	Nephelometric - Beckman
	mg/dl	1070	856	1280	
	g/l	3.01	2.41	3.61	Nephelometric - Siemens
	mg/dl	301	241	361	
Prealbumin	g/l	0.324	0.259	0.389	Nephelometric (IFCC Cal.)
	mg/dl	32.4	25.9	38.9	
	g/l	0.302	0.242	0.362	Turbidimetric (IFCC Cal.)
	mg/dl	30.2	24.2	36.2	
	g/l	0.310	0.248	0.372	Nephelometric (Non IFCC Cal.)
	mg/dl	31.0	24.8	37.2	
	g/l	0.310	0.248	0.372	Turbidimetric (Non IFCC Cal.)
	mg/dl	31.0	24.8	37.2	
Protein Total	g/l	91.4	73.1	110	Biuret reaction end point
	g/dl	9.14	7.31	11.0	
Retinol Binding Protein	mg/l	55.3	44.2	66.4	Nephelometric (IFCC Cal.)
	mg/l	56.1	44.9	67.3	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	66.1	52.9	79.3	Turbidimetric (Non IFCC Cal.)

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

Cat. No. PS2684 Lot No. 455LPC Size: 3 x 1 ml Expiry: 2018-02

Range					
Analyte	unit	Target	low	high	methods
Rheumatoid Factor	U/ml	82.7	66.2	99.2	Neph. Beckman (Non IFCC Cal.)
	U/ml	50.3	40.2	60.4	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	4.49	3.59	5.39	Turbidimetric (IFCC Cal.)
	mg/dl	449	359	539	
	g/l	4.57	3.66	5.48	Turbidimetric (Non IFCC Cal.)
	mg/dl	457	366	548	
	g/l	4.52	3.62	5.42	Nephelometric (IFCC Cal.)
	mg/dl	452	362	542	
	g/l	4.44	3.55	5.33	Nephelometric (Non IFCC Cal.)
	mg/dl	444	355	533	