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

CAT. NO. PS2683
SIZE: 3 x 1ml
GTIN: 05055273204902

LOT NO. 451LPC
EXPIRY: 2019-01-28

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.

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.

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Cat. No. PS2683 Lot No. 451LPC Size: 3 x 1 ml Expiry: 2019-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	33.3	28.3	38.3	Vitros (IFCC Cal.)
	g/dl	3.33	2.83	3.83	
	g/l	36.2	30.8	41.6	Bromocresol Green (IFCC Cal.)
	g/dl	3.62	3.08	4.16	
	g/l	35.8	30.4	41.2	Bromocresol Purple (IFCC Cal.)
	g/dl	3.58	3.04	4.12	
	g/l	35.8	30.4	41.2	Nephelometric (IFCC Cal.)
	g/dl	3.58	3.04	4.12	
	g/l	36.9	31.4	42.4	Bromocresol Green (Non IFCC Cal.)
	g/dl	3.69	3.14	4.24	
	g/l	35.0	29.8	40.3	Bromocresol Purple (Non IFCC Cal.)
	g/dl	3.50	2.98	4.02	
	g/l	34.7	29.5	39.9	Turbidimetric Assays (IFCC Cal.)
	g/dl	3.47	2.95	3.99	
	g/l	37.0	31.5	42.6	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	3.70	3.15	4.25	
Alpha-1-Acid Glycoprotein	g/l	0.883	0.706	1.06	Turbidimetric (IFCC Cal.)
	mg/dl	88.3	70.6	106	
	g/l	0.902	0.722	1.08	Nephelometric (IFCC Cal.)
	mg/dl	90.2	72.2	108	
	g/l	0.910	0.728	1.09	Turbidimetric (Non IFCC Cal.)
	mg/dl	91.0	72.8	109	
Alpha-1-Antitrypsin	g/l	1.53	1.22	1.84	Turbidimetric (IFCC Cal.)
	mg/dl	153	122	184	
	g/l	1.65	1.32	1.98	Nephelometric (IFCC Cal.)
	mg/dl	165	132	198	
	g/l	1.56	1.25	1.87	Nephelometric (Non IFCC Cal.)
	mg/dl	156	125	187	
	g/l	1.56	1.25	1.87	Turbidimetric (Non IFCC Cal.)
	mg/dl	156	125	187	
Alpha-2-Macroglobulin	g/l	2.19	1.75	2.63	Turbidimetric (IFCC Cal.)
	mg/dl	219	175	263	
	g/l	2.19	1.75	2.63	Nephelometric (IFCC Cal.)
	mg/dl	219	175	263	
	g/l	2.21	1.77	2.65	Nephelometric (Non IFCC Cal.)
	mg/dl	221	177	265	
	g/l	2.30	1.84	2.76	Turbidimetric (Non IFCC Cal.)
	mg/dl	230	184	276	
Alphafoetoprotein	KIU/l = IU/ml	31.7	25.4	38.0	Chemiluminescence (IFCC Cal.)
	ng/ml	38.4	30.7	46.1	
	KIU/l = IU/ml	34.0	27.2	40.8	Chemiluminescence (Non IFCC Cal.)
	ng/ml	41.1	32.9	49.3	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

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Cat. No. PS2683 Lot No. 451LPC Size: 3 x 1 ml Expiry: 2019-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Anti Streptolysin O	IU/ml	245	196	294	Turbidimetric (IFCC Cal.)
	IU/ml	247	198	296	Turbidimetric (Non IFCC Cal.)
	IU/ml	166	133	199	Neph. Beckman (IFCC Cal.)
	IU/ml	158	126	190	Neph. Beckman (Non IFCC Cal.)
	IU/ml	277	222	332	Neph. Behring (IFCC Cal.)
	IU/ml	272	218	326	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	282	212	353	Turbidimetric (IFCC Cal.)
	mg/dl	28.2	21.2	35.3	
Beta-2-microglobulin	µg/ml = mg/l	3.65	2.92	4.38	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	3.61	2.89	4.33	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	3.78	3.02	4.54	Enzyme Immunoassay (IFCC Cal.)
	µg/ml = mg/l	3.69	2.95	4.43	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.69	2.95	4.43	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	3.96	3.17	4.75	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.96	3.17	4.75	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	3.69	2.95	4.43	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	47.9	38.3	57.5	Vitros (IFCC Cal.)
	mg/l	46.1	36.9	55.3	Turbidimetric (IFCC Cal.)
	mg/l	43.4	34.7	52.1	Nephelometric (IFCC Cal.)
	mg/l	48.8	39.0	58.6	Vitros (Non IFCC Cal.)
	mg/l	41.4	33.1	49.7	Nephelometric (Non IFCC Cal.)
	mg/l	45.3	36.2	54.4	Turbidimetric (Non IFCC Cal.)
	mg/l	47.9	38.3	57.5	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.272	0.218	0.326	Nephelometric (IFCC Cal.)
	mg/dl	27.2	21.8	32.6	
	g/l	0.382	0.267	0.497	Turbidimetric (IFCC Cal.)
	mg/dl	38.2	26.7	49.7	
	g/l	0.272	0.218	0.326	Nephelometric (Non IFCC Cal.)
	mg/dl	27.2	21.8	32.6	
	g/l	0.399	0.279	0.519	Turbidimetric (Non IFCC Cal.)
	mg/dl	39.9	27.9	51.9	
	g/l	0.236	0.189	0.283	Neph. Beckman (IFCC Cal.)
	mg/dl	23.6	18.9	28.3	
	g/l	0.309	0.247	0.371	Randox Immunoturbidimetric
	mg/dl	30.9	24.7	37.1	
Complement C3	g/l	1.44	1.15	1.73	Turbidimetric (IFCC Cal.)
	mg/dl	144	115	173	
	g/l	1.45	1.16	1.74	Nephelometric (IFCC Cal.)
	mg/dl	145	116	174	
	g/l	1.48	1.18	1.78	Nephelometric (Non IFCC Cal.)
	mg/dl	148	118	178	
	g/l	1.43	1.14	1.72	Turbidimetric (Non IFCC Cal.)
	mg/dl	143	114	172	
	g/l	1.32	1.06	1.58	Vitros 5.1 FS microtip assay
	mg/dl	132	106	158	
	g/l	1.34	1.07	1.61	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	134	107	161	

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Cat. No. PS2683 Lot No. 451LPC Size: 3 x 1 ml Expiry: 2019-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Complement C4	g/l	0.319	0.255	0.383	Turbidimetric (IFCC Cal.)
	mg/dl	31.9	25.5	38.3	
	g/l	0.354	0.283	0.425	Nephelometric (IFCC Cal.)
	mg/dl	35.4	28.3	42.5	
	g/l	0.359	0.287	0.431	Nephelometric (Non IFCC Cal.)
	mg/dl	35.9	28.7	43.1	
	g/l	0.306	0.245	0.367	Turbidimetric (Non IFCC Cal.)
	mg/dl	30.6	24.5	36.7	
	g/l	0.308	0.246	0.370	Vitros 5.1 FS microtip assay
	mg/dl	30.8	24.6	37.0	
	g/l	0.304	0.243	0.365	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	30.4	24.3	36.5	
Ferritin	ng/ml = µg/l	216	173	259	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	222	178	266	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	223	178	268	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	233	186	280	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	216	173	259	Enzyme Immunoassay (IFCC Cal.)
	ng/ml = µg/l	206	165	247	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	32.1	25.7	38.5	Nephelometric - Beckman
	mg/L	28.6	22.9	34.3	Nephelometric - Binding Site
	mg/L	21.9	17.5	26.3	Nephelometric - Siemens
	mg/L	27.6	22.1	33.1	Turbidimetric
Haptoglobin	g/l	1.34	1.07	1.61	Nephelometric (IFCC Cal.)
	mg/dl	134	107	161	
	g/l	1.35	1.08	1.62	Turbidimetric (IFCC Cal.)
	mg/dl	135	108	162	
	g/l	1.33	1.06	1.60	Nephelometric (Non IFCC Cal.)
	mg/dl	133	106	160	
	g/l	1.36	1.09	1.63	Turbidimetric (Non IFCC Cal.)
	mg/dl	136	109	163	
Immunoglobulin A	g/l	2.39	1.79	2.99	Turbidimetric (IFCC Cal.)
	mg/dl	239	179	299	
	g/l	2.53	1.90	3.16	Nephelometric (IFCC Cal.)
	mg/dl	253	190	316	
	g/l	2.59	1.94	3.24	Nephelometric (Non IFCC Cal.)
	mg/dl	259	194	324	
	g/l	2.34	1.76	2.93	Turbidimetric (Non IFCC Cal.)
	mg/dl	234	176	292	
	g/l	2.46	1.85	3.08	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	246	185	307	
	g/l	2.45	1.84	3.06	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	245	184	306	

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Cat. No. PS2683 Lot No. 451LPC Size: 3 x 1 ml Expiry: 2019-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin E	KIU/l = IU/ml	122	97.6	146	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	110	88.0	132	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	107	85.6	128	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	107	85.6	128	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	122	97.6	146	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	13.8	11.3	16.3	Turbidimetric (IFCC Cal.)
	mg/dl	1380	1130	1630	
	g/l	14.2	11.6	16.8	Nephelometric (IFCC Cal.)
	mg/dl	1420	1160	1680	
	g/l	14.0	11.5	16.5	Nephelometric (Non IFCC Cal.)
	mg/dl	1400	1150	1650	
	g/l	13.7	11.2	16.2	Turbidimetric (Non IFCC Cal.)
	mg/dl	1370	1120	1620	
	g/l	14.7	12.1	17.3	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1470	1210	1730	
	g/l	14.4	11.8	17.0	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	1440	1180	1700	
Immunoglobulin M	g/l	1.84	1.47	2.21	Turbidimetric (IFCC Cal.)
	mg/dl	184	147	221	
	g/l	1.94	1.55	2.33	Nephelometric (IFCC Cal.)
	mg/dl	194	155	233	
	g/l	1.93	1.54	2.32	Nephelometric (Non IFCC Cal.)
	mg/dl	193	154	232	
	g/l	1.90	1.52	2.28	Turbidimetric (Non IFCC Cal.)
	mg/dl	190	152	228	
	g/l	1.85	1.48	2.22	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	185	148	222	
	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	11.7	9.36	14.0	Nephelometric - Beckman
	mg/dl	1170	936	1400	
	g/l	3.64	2.91	4.37	Nephelometric - Siemens
	mg/dl	364	291	437	
	g/l	3.62	2.90	4.34	Turbidimetric
	mg/dl	362	290	434	
Lambda Light Chain	g/l	5.94	4.75	7.13	Nephelometric - Beckman
	mg/dl	594	475	713	
	g/l	1.89	1.51	2.27	Nephelometric - Siemens
	mg/dl	189	151	227	
	g/l	1.86	1.49	2.23	Turbidimetric
	mg/dl	186	149	223	
Prealbumin	g/l	0.327	0.262	0.392	Nephelometric (IFCC Cal.)
	mg/dl	32.7	26.2	39.2	
	g/l	0.304	0.243	0.365	Turbidimetric (IFCC Cal.)
	mg/dl	30.4	24.3	36.5	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prealbumin	g/l	0.309	0.247	0.371	Nephelometric (Non IFCC Cal.)
	mg/dl	30.9	24.7	37.1	
	g/l	0.305	0.244	0.366	Turbidimetric (Non IFCC Cal.)
	mg/dl	30.5	24.4	36.6	
Protein Total	g/l	65.1	52.1	78.1	Biuret reaction end point
	g/dl	6.51	5.21	7.81	
Retinol Binding Protein	mg/l	47.5	38.0	57.0	Nephelometric (IFCC Cal.)
	mg/l	48.3	38.6	58.0	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	54.5	43.6	65.4	Turbidimetric (Non IFCC Cal.)
	U/ml	53.2	42.6	63.8	Neph. Beckman (Non IFCC Cal.)
	U/ml	40.2	32.2	48.2	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	2.56	2.05	3.07	Turbidimetric (IFCC Cal.)
	mg/dl	256	205	307	
	g/l	2.60	2.08	3.12	Turbidimetric (Non IFCC Cal.)
	mg/dl	260	208	312	
	g/l	2.52	2.02	3.02	Nephelometric (IFCC Cal.)
	mg/dl	252	202	302	
	g/l	2.55	2.04	3.06	Nephelometric (Non IFCC Cal.)
	mg/dl	255	204	306	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
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