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

CAT. NO. PS2684 **LOT NO.** 452LPC
SIZE: 3 x 1 ml **EXPIRY:** 2019-01-31

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 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 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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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	52.8	44.9	60.7	Bromocresol Green (IFCC Cal.)
	g/dl	5.28	4.49	6.07	
	g/l	52.7	44.8	60.6	Bromocresol Purple (IFCC Cal.)
	g/dl	5.27	4.48	6.06	
	g/l	53.4	45.4	61.4	Nephelometric (IFCC Cal.)
	g/dl	5.34	4.54	6.14	
	g/l	53.3	45.3	61.3	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.33	4.53	6.13	
	g/l	51.5	43.8	59.2	Bromocresol Purple (Non IFCC Cal.)
	g/dl	5.15	4.38	5.92	
	g/l	52.6	44.7	60.5	Nephelometric (Non IFCC Cal.)
	g/dl	5.26	4.47	6.05	
	g/l	52.2	44.4	60.0	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.22	4.44	6.00	
	g/l	54.8	46.6	63.0	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	5.48	4.66	6.30	
Alpha-1-Acid Glycoprotein	g/l	1.30	1.04	1.56	Turbidimetric (IFCC Cal.)
	mg/dl	130	104	156	
	g/l	1.38	1.10	1.66	Nephelometric (IFCC Cal.)
	mg/dl	138	110	166	
	g/l	1.33	1.06	1.60	Nephelometric (Non IFCC Cal.)
	mg/dl	133	106	160	
	g/l	1.32	1.06	1.58	Turbidimetric (Non IFCC Cal.)
	mg/dl	132	106	158	
Alpha-1-Antitrypsin	g/l	2.29	1.83	2.75	Turbidimetric (IFCC Cal.)
	mg/dl	229	183	275	
	g/l	2.58	2.06	3.10	Nephelometric (IFCC Cal.)
	mg/dl	258	206	310	
	g/l	2.69	2.15	3.23	Nephelometric (Non IFCC Cal.)
	mg/dl	269	215	323	
	g/l	2.32	1.86	2.78	Turbidimetric (Non IFCC Cal.)
	mg/dl	232	186	278	
Alpha-2-Macroglobulin	g/l	3.35	2.68	4.02	Turbidimetric (IFCC Cal.)
	mg/dl	335	268	402	
	g/l	3.31	2.65	3.97	Nephelometric (IFCC Cal.)
	mg/dl	331	265	397	
	g/l	3.39	2.71	4.07	Nephelometric (Non IFCC Cal.)
	mg/dl	339	271	407	
	g/l	3.43	2.74	4.12	Turbidimetric (Non IFCC Cal.)
	mg/dl	343	274	412	
Alphafoetoprotein	KIU/l = IU/ml	47.4	37.9	56.9	Chemiluminescence (IFCC Cal.)
	ng/ml	57.4	45.9	68.9	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	49.9	39.9	59.9	Chemiluminescence (Non IFCC Cal.)
	ng/ml	60.4	48.3	72.5	
Anti Streptolysin O	IU/ml	363	290	436	Turbidimetric (IFCC Cal.)
	IU/ml	367	294	440	Turbidimetric (Non IFCC Cal.)
	IU/ml	251	201	301	Neph. Beckman (IFCC Cal.)
	IU/ml	253	202	304	Neph. Beckman (Non IFCC Cal.)
	IU/ml	398	318	478	Neph. Behring (IFCC Cal.)
	IU/ml	401	321	481	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	445	334	556	Turbidimetric (IFCC Cal.)
	mg/dl	44.5	33.4	55.6	
	mg/l	422	317	528	Turbidimetric (Non IFCC Cal.)
	mg/dl	42.2	31.7	52.8	
Beta-2-microglobulin	µg/ml = mg/l	5.19	4.15	6.23	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	5.37	4.30	6.44	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	5.45	4.36	6.54	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	5.60	4.48	6.72	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.86	4.69	7.03	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	6.01	4.81	7.21	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	5.99	4.79	7.19	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	56.6	45.3	67.9	Vitros (IFCC Cal.)
	mg/l	68.9	55.1	82.7	Turbidimetric (IFCC Cal.)
	mg/l	69.1	55.3	82.9	Nephelometric (IFCC Cal.)
	mg/l	61.7	49.4	74.0	Vitros (Non IFCC Cal.)
	mg/l	63.5	50.8	76.2	Nephelometric (Non IFCC Cal.)
	mg/l	68.1	54.5	81.7	Turbidimetric (Non IFCC Cal.)
	mg/l	72.8	58.2	87.4	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.487	0.390	0.584	Nephelometric (IFCC Cal.)
	mg/dl	48.7	39.0	58.4	
	g/l	0.619	0.433	0.805	Turbidimetric (IFCC Cal.)
	mg/dl	61.9	43.3	80.5	
	g/l	0.456	0.365	0.547	Nephelometric (Non IFCC Cal.)
	mg/dl	45.6	36.5	54.7	
	g/l	0.673	0.471	0.875	Turbidimetric (Non IFCC Cal.)
	mg/dl	67.3	47.1	87.5	
	g/l	0.349	0.279	0.419	Neph. Beckman (IFCC Cal.)
	mg/dl	34.9	27.9	41.9	
	g/l	0.483	0.386	0.580	Randox Immunoturbidimetric
	mg/dl	48.3	38.6	58.0	
Complement C3	g/l	2.17	1.74	2.60	Turbidimetric (IFCC Cal.)
	mg/dl	217	174	260	
	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	2.17	1.74	2.60	Turbidimetric (Non IFCC Cal.)
	mg/dl	217	174	260	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Complement C3	g/l	2.05	1.64	2.46	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	205	164	246	
Complement C4	g/l	0.485	0.388	0.582	Turbidimetric (IFCC Cal.)
	mg/dl	48.5	38.8	58.2	
	g/l	0.553	0.442	0.664	Nephelometric (IFCC Cal.)
	mg/dl	55.3	44.2	66.4	
	g/l	0.557	0.446	0.668	Nephelometric (Non IFCC Cal.)
	mg/dl	55.7	44.6	66.8	
	g/l	0.475	0.380	0.570	Turbidimetric (Non IFCC Cal.)
	mg/dl	47.5	38.0	57.0	
	g/l	0.470	0.376	0.564	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	47.0	37.6	56.4	
Ferritin	ng/ml = µg/l	321	257	385	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	325	260	390	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	335	268	402	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	341	273	409	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	307	246	368	Enzyme Immunoassay (IFCC Cal.)
	ng/ml = µg/l	346	277	415	Enzyme Immunoassay (Non IFCC Cal.)
	ng/ml = µg/l	303	242	364	Nephelometric (IFCC Cal.)
	ng/ml = µg/l	302	242	362	Nephelometric (Non IFCC Cal.)
Free Kappa Light Chains	mg/L	33.6	26.9	40.3	Nephelometric - Beckman
	mg/L	29.4	23.5	35.3	Nephelometric - Binding Site
	mg/L	15.5	12.4	18.6	Nephelometric - Siemens
	mg/L	30.7	24.6	36.8	Turbidimetric
Free Lambda Light Chains	mg/L	47.0	37.6	56.4	Nephelometric - Beckman
	mg/L	41.2	33.0	49.4	Nephelometric - Binding Site
	mg/L	23.8	19.0	28.6	Nephelometric - Siemens
	mg/L	38.6	30.9	46.3	Turbidimetric
Haptoglobin	g/l	2.07	1.66	2.48	Nephelometric (IFCC Cal.)
	mg/dl	207	166	248	
	g/l	2.03	1.62	2.44	Turbidimetric (IFCC Cal.)
	mg/dl	203	162	244	
	g/l	2.01	1.61	2.41	Nephelometric (Non IFCC Cal.)
	mg/dl	201	161	241	
	g/l	2.04	1.63	2.45	Turbidimetric (Non IFCC Cal.)
	mg/dl	204	163	245	
Immunoglobulin A	g/l	3.59	2.69	4.49	Turbidimetric (IFCC Cal.)
	mg/dl	359	269	449	
	g/l	3.85	2.89	4.81	Nephelometric (IFCC Cal.)
	mg/dl	385	289	481	
	g/l	3.96	2.97	4.95	Nephelometric (Non IFCC Cal.)
	mg/dl	396	297	495	
	g/l	3.56	2.67	4.45	Turbidimetric (Non IFCC Cal.)
	mg/dl	356	267	445	
	g/l	3.67	2.75	4.59	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	367	275	459	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin A	g/l	3.68	2.76	4.60	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	368	276	460	
Immunoglobulin E	KIU/l = IU/ml	166	133	199	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	164	131	197	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	159	127	191	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	159	127	191	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	177	142	212	Turbidimetric (Non IFCC Cal.)
	KIU/l = IU/ml	177	142	212	Randox Immunoturbidimetric
Immunoglobulin G	g/l	20.7	17.0	24.4	Turbidimetric (IFCC Cal.)
	mg/dl	2070	1700	2440	
	g/l	20.9	17.1	24.7	Nephelometric (IFCC Cal.)
	mg/dl	2090	1710	2470	
	g/l	20.8	17.1	24.5	Nephelometric (Non IFCC Cal.)
	mg/dl	2080	1710	2450	
	g/l	20.6	16.9	24.3	Turbidimetric (Non IFCC Cal.)
	mg/dl	2060	1690	2430	
	g/l	20.1	16.5	23.7	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2010	1650	2370	
	g/l	21.4	17.5	25.3	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	2140	1750	2530	
Immunoglobulin M	g/l	2.78	2.22	3.34	Turbidimetric (IFCC Cal.)
	mg/dl	278	222	334	
	g/l	2.91	2.33	3.49	Nephelometric (IFCC Cal.)
	mg/dl	291	233	349	
	g/l	2.89	2.31	3.47	Nephelometric (Non IFCC Cal.)
	mg/dl	289	231	347	
	g/l	2.87	2.30	3.44	Turbidimetric (Non IFCC Cal.)
	mg/dl	287	230	344	
	g/l	2.74	2.19	3.29	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	274	219	329	
	g/l	2.74	2.19	3.29	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	274	219	329	
Kappa Light Chain	g/l	17.9	14.3	21.5	Nephelometric - Beckman
	mg/dl	1790	1430	2150	
	g/l	5.26	4.21	6.31	Nephelometric - Siemens
	mg/dl	526	421	631	
	g/l	5.81	4.65	6.97	Turbidimetric
	mg/dl	581	465	697	
Lambda Light Chain	g/l	8.95	7.16	10.7	Nephelometric - Beckman
	mg/dl	895	716	1070	
	g/l	2.78	2.22	3.34	Nephelometric - Siemens
	mg/dl	278	222	334	
	g/l	2.88	2.30	3.46	Turbidimetric
	mg/dl	288	230	346	
Prealbumin	g/l	0.499	0.399	0.599	Nephelometric (IFCC Cal.)
	mg/dl	49.9	39.9	59.9	

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Prealbumin	g/l	0.451	0.361	0.541	Turbidimetric (IFCC Cal.)
	mg/dl	45.1	36.1	54.1	
	g/l	0.503	0.402	0.604	Nephelometric (Non IFCC Cal.)
	mg/dl	50.3	40.2	60.4	
	g/l	0.457	0.366	0.548	Turbidimetric (Non IFCC Cal.)
	mg/dl	45.7	36.6	54.8	
Protein Total	g/l	93.5	74.8	112	Biuret reaction end point
	g/dl	9.35	7.48	11.2	
Retinol Binding Protein	mg/l	70.3	56.2	84.4	Nephelometric (IFCC Cal.)
	mg/l	71.6	57.3	85.9	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	78.9	63.1	94.7	Turbidimetric (Non IFCC Cal.)
	U/ml	99.1	79.3	119	Neph. Beckman (Non IFCC Cal.)
	U/ml	56.1	44.9	67.3	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	3.83	3.06	4.60	Turbidimetric (IFCC Cal.)
	mg/dl	383	306	460	
	g/l	3.90	3.12	4.68	Turbidimetric (Non IFCC Cal.)
	mg/dl	390	312	468	
	g/l	3.71	2.97	4.45	Nephelometric (IFCC Cal.)
	mg/dl	371	297	445	
	g/l	3.83	3.06	4.60	Nephelometric (Non IFCC Cal.)
	mg/dl	383	306	460	

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