

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

CAT. NO. PS2683

LOT NO. 517LPC

SIZE: 3 x 1ml

EXPIRY: 2021-11-28

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.

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.

Rev. 11 Jun '18 ne

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Cat. No. PS2683 Lot No. 517LPC Size: 3 x 1 ml Expiry: 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	38.0	32.3	43.7	Bromocresol Green (IFCC Cal.)
	g/dl	3.80	3.23	4.37	
	g/l	37.6	32.0	43.2	Bromocresol Purple (IFCC Cal.)
	g/dl	3.76	3.20	4.32	
	g/l	37.8	32.1	43.5	Nephelometric (IFCC Cal.)
	g/dl	3.78	3.21	4.35	
	g/l	38.7	32.9	44.5	Bromocresol Green (Non IFCC Cal.)
	g/dl	3.87	3.29	4.45	
	g/l	36.8	31.3	42.3	Bromocresol Purple (Non IFCC Cal.)
	g/dl	3.68	3.13	4.23	
Alpha-1-Acid Glycoprotein	g/l	0.764	0.611	0.917	Turbidimetric (IFCC Cal.)
	mg/dl	76.4	61.1	91.7	
	g/l	0.823	0.658	0.988	Nephelometric (IFCC Cal.)
	mg/dl	82.3	65.8	98.8	
Alpha-1-Antitrypsin	g/l	0.756	0.605	0.907	Turbidimetric (Non IFCC Cal.)
	mg/dl	75.6	60.5	90.7	
	g/l	1.43	1.14	1.72	Turbidimetric (IFCC Cal.)
	mg/dl	143	114	172	
Alpha-1-Antitrypsin	g/l	1.63	1.30	1.96	Nephelometric (IFCC Cal.)
	mg/dl	163	130	196	
	g/l	1.67	1.34	2.00	Nephelometric (Non IFCC Cal.)
	mg/dl	167	134	200	
Alpha-1-Antitrypsin	g/l	1.46	1.17	1.75	Turbidimetric (Non IFCC Cal.)
	mg/dl	146	117	175	
	g/l	2.14	1.71	2.57	Turbidimetric (IFCC Cal.)
	mg/dl	214	171	257	
Alpha-2-Macroglobulin	g/l	2.13	1.70	2.56	Nephelometric (IFCC Cal.)
	mg/dl	213	170	256	
	g/l	2.17	1.74	2.60	Nephelometric (Non IFCC Cal.)
	mg/dl	217	174	260	
Alpha-2-Macroglobulin	g/l	2.16	1.73	2.59	Turbidimetric (Non IFCC Cal.)
	mg/dl	216	173	259	
	KIU/l = IU/ml	36.4	29.1	43.7	Chemiluminescence (IFCC Cal.)
	ng/ml	44.0	35.2	52.8	
Alphafoetoprotein	KIU/l = IU/ml	36.6	29.3	43.9	Chemiluminescence (Non IFCC Cal.)
	ng/ml	44.3	35.5	53.1	
Anti Streptolysin O	IU/ml	248	198	298	Turbidimetric (IFCC Cal.)
	IU/ml	251	201	301	Turbidimetric (Non IFCC Cal.)

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Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	263	210	316	Neph. others (IFCC Cal.)
	IU/ml	264	211	317	Neph. others (Non IFCC Cal.)
	IU/ml	163	130	196	Neph. Beckman (IFCC Cal.)
	IU/ml	154	123	185	Neph. Beckman (Non IFCC Cal.)
Antithrombin III	mg/l	276	207	345	Turbidimetric (IFCC Cal.)
	mg/dl	27.6	20.7	34.5	
Beta-2-microglobulin	µg/ml = mg/l	3.80	3.04	4.56	Enzyme Immunoassay (IFCC Cal.)
	µg/ml = mg/l	3.69	2.95	4.43	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.81	3.05	4.57	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	3.93	3.14	4.72	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.84	3.07	4.61	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	3.73	2.98	4.48	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	46.1	36.9	55.3	Vitros (IFCC Cal.)
	mg/l	44.9	35.9	53.9	Turbidimetric (IFCC Cal.)
	mg/l	42.3	33.8	50.8	Nephelometric (IFCC Cal.)
	mg/l	43.1	34.5	51.7	Nephelometric (Non IFCC Cal.)
	mg/l	44.5	35.6	53.4	Turbidimetric (Non IFCC Cal.)
	mg/l	46.2	37.0	55.4	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.433	0.325	0.541	Nephelometric (IFCC Cal.)
	mg/dl	43.3	32.5	54.1	
	g/l	0.376	0.278	0.474	Turbidimetric (IFCC Cal.)
	mg/dl	37.6	27.8	47.4	
	g/l	0.421	0.316	0.526	Nephelometric (Non IFCC Cal.)
	mg/dl	42.1	31.6	52.6	
	g/l	0.355	0.266	0.444	Turbidimetric (Non IFCC Cal.)
	mg/dl	35.5	26.6	44.4	
	g/l	0.323	0.242	0.404	Neph. Beckman (IFCC Cal.)
	mg/dl	32.3	24.2	40.4	
	g/l	0.419	0.314	0.524	Randox Immunoturbidimetric
	mg/dl	41.9	31.4	52.4	
Complement C3	g/l	1.50	1.20	1.80	Turbidimetric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.47	1.18	1.76	Nephelometric (IFCC Cal.)
	mg/dl	147	118	176	
	g/l	1.52	1.22	1.82	Nephelometric (Non IFCC Cal.)
	mg/dl	152	122	182	
	g/l	1.51	1.21	1.81	Turbidimetric (Non IFCC Cal.)
	mg/dl	151	121	181	
Complement C4	g/l	0.324	0.259	0.389	Turbidimetric (IFCC Cal.)
	mg/dl	32.4	25.9	38.9	
	g/l	0.344	0.275	0.413	Nephelometric (IFCC Cal.)
	mg/dl	34.4	27.5	41.3	
	g/l	0.350	0.280	0.420	Nephelometric (Non IFCC Cal.)
	mg/dl	35.0	28.0	42.0	
	g/l	1.51	1.21	1.81	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	151	121	181	

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Analyte	unit	Target	low	high	methods
Complement C4	g/l	0.306	0.245	0.367	Turbidimetric (Non IFCC Cal.)
	mg/dl	30.6	24.5	36.7	
	g/l	0.315	0.252	0.378	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	31.5	25.2	37.8	
Ferritin	ng/ml = µg/l	197	158	236	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	199	159	239	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	198	158	238	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	220	176	264	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	202	162	242	Enzyme Immunoassay (IFCC Cal.)
Free Lambda Light Chains	mg/L	19.6	15.7	23.5	Turbidimetric
	mg/L	26.4	21.1	31.7	Nephelometric - Beckman
	mg/L	20.2	16.2	24.2	Nephelometric - Binding Site
	mg/L	15.7	12.6	18.8	Nephelometric - Siemens
Haptoglobin	g/l	1.30	1.04	1.56	Nephelometric (IFCC Cal.)
	mg/dl	130	104	156	
	g/l	1.31	1.05	1.57	Turbidimetric (IFCC Cal.)
	mg/dl	131	105	157	
	g/l	1.27	1.02	1.52	Nephelometric (Non IFCC Cal.)
	mg/dl	127	102	152	
Immunoglobulin A	g/l	2.23	1.67	2.79	Turbidimetric (IFCC Cal.)
	mg/dl	223	167	279	
	g/l	2.36	1.77	2.95	Nephelometric (IFCC Cal.)
	mg/dl	236	177	295	
	g/l	2.50	1.88	3.13	Nephelometric (Non IFCC Cal.)
	mg/dl	250	188	312	
Immunoglobulin E	g/l	2.18	1.64	2.73	Turbidimetric (Non IFCC Cal.)
	mg/dl	218	164	272	
	g/l	2.30	1.73	2.88	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	230	173	287	
	KIU/l = IU/ml	143	114	172	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	134	107	161	Chemiluminescence (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	133	106	160	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	128	102	154	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	132	106	158	Turbidimetric (Non IFCC Cal.)
	g/l	12.4	10.2	14.6	Turbidimetric (IFCC Cal.)
	mg/dl	1240	1020	1460	
Immunoglobulin G	g/l	12.8	10.5	15.1	Nephelometric (IFCC Cal.)
	mg/dl	1280	1050	1510	
	g/l	13.0	10.7	15.3	Nephelometric (Non IFCC Cal.)
	mg/dl	1300	1070	1530	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin G	g/l	12.0	9.84	14.2	Turbidimetric (Non IFCC Cal.)
	mg/dl	1200	984	1416	
	g/l	12.9	10.6	15.2	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	1290	1060	1520	
Immunoglobulin M	g/l	1.74	1.39	2.09	Turbidimetric (IFCC Cal.)
	mg/dl	174	139	209	
	g/l	1.83	1.46	2.20	Nephelometric (IFCC Cal.)
	mg/dl	183	146	220	
	g/l	1.89	1.51	2.27	Nephelometric (Non IFCC Cal.)
	mg/dl	189	151	227	
	g/l	1.76	1.41	2.11	Turbidimetric (Non IFCC Cal.)
	mg/dl	176	141	211	
Kappa Light Chain	g/l	3.44	2.75	4.13	Turbidimetric
	mg/dl	344	275	413	
	g/l	3.15	2.52	3.78	Nephelometric - Siemens
	mg/dl	315	252	378	
	g/l	11.4	9.12	13.7	Nephelometric - Beckman
	mg/dl	1140	912	1370	
Lambda Light Chain	g/l	5.43	4.34	6.52	Nephelometric - Beckman
	mg/dl	543	434	652	
	g/l	1.64	1.31	1.97	Nephelometric - Siemens
	mg/dl	164	131	197	
Prealbumin	g/l	0.353	0.282	0.424	Nephelometric (IFCC Cal.)
	mg/dl	35.3	28.2	42.4	
	g/l	0.320	0.256	0.384	Turbidimetric (IFCC Cal.)
	mg/dl	32.0	25.6	38.4	
Prealbumin	g/l	0.342	0.274	0.410	Nephelometric (Non IFCC Cal.)
	mg/dl	34.2	27.4	41.0	
	g/l	0.319	0.255	0.383	Turbidimetric (Non IFCC Cal.)
	mg/dl	31.9	25.5	38.3	
Protein Total	g/l	64.7	51.8	77.6	Biuret reaction end point
	g/dl	6.47	5.18	7.76	
Retinol Binding Protein	mg/l	46.0	36.8	55.2	Nephelometric (IFCC Cal.)
	mg/l	46.0	36.8	55.2	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	58.3	46.6	70.0	Turbidimetric (Non IFCC Cal.)
	U/ml	61.8	49.4	74.2	Latex (Non-IFCC Cal.)
	U/ml	62.4	49.9	74.9	Neph. Beckman (Non IFCC Cal.)
	U/ml	49.6	39.7	59.5	Neph. Behring (Non IFCC Cal.)
	U/ml	77.1	61.7	92.5	Randox Immunoturbidimetric
Transferrin	g/l	2.44	1.95	2.93	Turbidimetric (IFCC Cal.)
	mg/dl	244	195	293	
	g/l	2.44	1.95	2.93	Turbidimetric (Non IFCC Cal.)
	mg/dl	244	195	293	



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Range					
Analyte	unit	Target	low	high	methods
Transferrin	g/l	2.28	1.82	2.74	Nephelometric (IFCC Cal.)
	mg/dl	228	182	274	
	g/l	2.48	1.98	2.98	Nephelometric (Non IFCC Cal.)
	mg/dl	248	198	298	