

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

CAT. NO. PS2683

LOT NO. 545LPC

SIZE: 3 x 1ml

EXPIRY: 2021-06-28

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

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.

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

Cat. No. PS2683 Lot No. 545LPC Size: 3 x 1 ml Expiry: 2021-06-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	38.0	32.3	43.7	Bromocresol Green (IFCC Cal.)
	g/dl	3.80	3.23	4.37	
	g/l	35.7	30.3	41.1	Bromocresol Purple (IFCC Cal.)
	g/dl	3.57	3.03	4.11	
	g/l	38.2	32.5	43.9	Nephelometric (IFCC Cal.)
	g/dl	3.82	3.25	4.39	
	g/l	38.8	33.0	44.6	Bromocresol Green (Non IFCC Cal.)
	g/dl	3.88	3.30	4.46	
	g/l	38.1	32.4	43.8	Bromocresol Purple (Non IFCC Cal.)
	g/dl	3.81	3.24	4.38	
	g/l	37.5	31.9	43.1	Turbidimetric Assays (IFCC Cal.)
	g/dl	3.75	3.19	4.31	
g/l	39.9	33.9	45.9	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	3.99	3.39	4.59		
Alpha-1-Acid Glycoprotein	g/l	0.906	0.725	1.09	Turbidimetric (IFCC Cal.)
	mg/dl	90.6	72.5	109	
	g/l	0.946	0.757	1.14	Nephelometric (IFCC Cal.)
	mg/dl	94.6	75.7	114	
g/l	0.949	0.759	1.14	Turbidimetric (Non IFCC Cal.)	
mg/dl	94.9	75.9	114		
Alpha-1-Antitrypsin	g/l	1.42	1.14	1.70	Turbidimetric (IFCC Cal.)
	mg/dl	142	114	170	
	g/l	1.48	1.18	1.78	Nephelometric (IFCC Cal.)
	mg/dl	148	118	178	
	g/l	1.44	1.15	1.73	Nephelometric (Non IFCC Cal.)
	mg/dl	144	115	173	
g/l	1.41	1.13	1.69	Turbidimetric (Non IFCC Cal.)	
mg/dl	141	113	169		
Alpha-2-Macroglobulin	g/l	2.04	1.63	2.45	Turbidimetric (IFCC Cal.)
	mg/dl	204	163	245	
	g/l	2.05	1.64	2.46	Nephelometric (IFCC Cal.)
	mg/dl	205	164	246	
g/l	2.03	1.62	2.44	Turbidimetric (Non IFCC Cal.)	
mg/dl	203	162	244		
Alpha-fetoprotein	KIU/l = IU/ml	37.5	30.0	45.0	Chemiluminescence (IFCC Cal.)
	ng/ml	45.4	36.3	54.5	
	KIU/l = IU/ml	37.1	29.7	44.5	Chemiluminescence (Non IFCC Cal.)
	ng/ml	44.9	35.9	53.9	
Anti Streptolysin O	IU/ml	240	192	288	Turbidimetric (IFCC Cal.)
	IU/ml	238	190	286	Turbidimetric (Non IFCC Cal.)
	IU/ml	153	122	184	Neph. Beckman (IFCC Cal.)
	IU/ml	156	125	187	Neph. Beckman (Non IFCC Cal.)

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

Cat. No. PS2683 Lot No. 545LPC Size: 3 x 1 ml Expiry: 2021-06-28

Range					
Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	266	213	319	Neph. Behring (IFCC Cal.)
	IU/ml	265	212	318	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	280	196	364	Turbidimetric (IFCC Cal.)
	mg/dl	28.0	19.6	36.4	
Beta-2-microglobulin	µg/ml = mg/l	4.08	3.26	4.90	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	3.82	3.06	4.58	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	3.81	3.05	4.57	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	4.09	3.27	4.91	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	4.07	3.26	4.88	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	47.4	37.9	56.9	Vitros (IFCC Cal.)
	mg/l	46.0	36.8	55.2	Turbidimetric (IFCC Cal.)
	mg/l	43.5	34.8	52.2	Nephelometric (IFCC Cal.)
	mg/l	44.2	35.4	53.0	Nephelometric (Non IFCC Cal.)
	mg/l	45.3	36.2	54.4	Turbidimetric (Non IFCC Cal.)
	mg/l	47.4	37.9	56.9	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.321	0.241	0.401	Nephelometric (IFCC Cal.)
	mg/dl	32.1	24.1	40.1	
	g/l	0.330	0.248	0.412	Turbidimetric (IFCC Cal.)
	mg/dl	33.0	24.8	41.2	
	g/l	0.299	0.224	0.374	Turbidimetric (Non IFCC Cal.)
	mg/dl	29.9	22.4	37.4	
	g/l	0.246	0.185	0.307	Neph. Beckman (IFCC Cal.)
mg/dl	24.6	18.5	30.7		
Complement C3	g/l	1.24	0.992	1.49	Turbidimetric (IFCC Cal.)
	mg/dl	124	99.2	149	
	g/l	1.21	0.968	1.45	Nephelometric (IFCC Cal.)
	mg/dl	121	96.8	145	
	g/l	1.21	0.968	1.45	Nephelometric (Non IFCC Cal.)
	mg/dl	121	96.8	145	
	g/l	1.25	1.00	1.50	Turbidimetric (Non IFCC Cal.)
	mg/dl	125	100	150	
Complement C4	g/l	0.295	0.236	0.354	Turbidimetric (IFCC Cal.)
	mg/dl	29.5	23.6	35.4	
	g/l	0.317	0.254	0.380	Nephelometric (IFCC Cal.)
	mg/dl	31.7	25.4	38.0	
	g/l	0.313	0.250	0.376	Nephelometric (Non IFCC Cal.)
	mg/dl	31.3	25.0	37.6	
	g/l	0.280	0.224	0.336	Turbidimetric (Non IFCC Cal.)
	mg/dl	28.0	22.4	33.6	
Ferritin	ng/ml = µg/l	201	161	241	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	202	162	242	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	218	174	262	Chemiluminescence (IFCC Cal.)

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Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	225	180	270	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	197	158	236	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	21.4	17.1	25.7	Nephelometric - Beckman
	mg/L	20.0	16.0	24.0	Nephelometric - Binding Site
	mg/L	18.9	15.1	22.7	Nephelometric - Siemens
	mg/L	18.4	14.7	22.1	Turbidimetric
Haptoglobin	g/l	1.25	1.00	1.50	Nephelometric (IFCC Cal.)
	mg/dl	125	100	150	
	g/l	1.26	1.01	1.51	Turbidimetric (IFCC Cal.)
	mg/dl	126	101	151	
	g/l	1.23	0.984	1.48	Nephelometric (Non IFCC Cal.)
	mg/dl	123	98.4	148	
Immunoglobulin A	g/l	2.35	1.76	2.94	Turbidimetric (IFCC Cal.)
	mg/dl	235	176	294	
	g/l	2.44	1.83	3.05	Nephelometric (IFCC Cal.)
	mg/dl	244	183	305	
	g/l	2.64	1.98	3.30	Nephelometric (Non IFCC Cal.)
	mg/dl	264	198	330	
	g/l	2.35	1.76	2.94	Turbidimetric (Non IFCC Cal.)
	mg/dl	235	176	294	
Immunoglobulin E	g/l	2.44	1.83	3.05	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	244	183	305	
	KIU/l = IU/ml	130	104	156	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	125	100	150	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	124	99.0	149	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	117	93.6	140	Enzyme Immunoassay (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	128	102	154	Turbidimetric (Non IFCC Cal.)
	g/l	12.2	10.0	14.4	Turbidimetric (IFCC Cal.)
	mg/dl	1220	1000	1440	
	g/l	12.5	10.3	14.8	Nephelometric (IFCC Cal.)
	mg/dl	1250	1030	1470	
	g/l	12.6	10.3	14.9	Nephelometric (Non IFCC Cal.)
	mg/dl	1260	1030	1490	
	g/l	12.2	10.0	14.4	Turbidimetric (Non IFCC Cal.)
mg/dl	1220	1000	1440		
Immunoglobulin M	g/l	12.8	10.5	15.1	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	1280	1050	1510	
	g/l	1.77	1.42	2.12	Turbidimetric (IFCC Cal.)
	mg/dl	177	142	212	
	g/l	1.86	1.49	2.23	Nephelometric (IFCC Cal.)
	mg/dl	186	149	223	
	g/l	1.86	1.49	2.23	Nephelometric (Non IFCC Cal.)
	mg/dl	186	149	223	
Immunoglobulin M	g/l	1.79	1.43	2.15	Turbidimetric (Non IFCC Cal.)
	mg/dl	179	143	215	

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Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin M	g/l	1.73	1.38	2.08	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	173	138	208	
Kappa Light Chain	g/l	10.00	8.00	12.0	Nephelometric - Beckman
	mg/dl	1000	800	1200	
	g/l	3.22	2.58	3.86	Nephelometric - Siemens
	mg/dl	322	258	386	
	g/l	3.38	2.70	4.06	Turbidimetric
mg/dl	338	270	406		
Lambda Light Chain	g/l	1.76	1.41	2.11	Turbidimetric
	mg/dl	176	141	211	
	g/l	1.72	1.38	2.06	Nephelometric - Siemens
	mg/dl	172	138	206	
	g/l	5.33	4.26	6.40	Nephelometric - Beckman
mg/dl	533	426	640		
Prealbumin	g/l	0.319	0.255	0.383	Nephelometric (IFCC Cal.)
	mg/dl	31.9	25.5	38.3	
	g/l	0.310	0.248	0.372	Turbidimetric (IFCC Cal.)
	mg/dl	31.0	24.8	37.2	
	g/l	0.306	0.245	0.367	Nephelometric (Non IFCC Cal.)
	mg/dl	30.6	24.5	36.7	
Protein Total	g/l	63.0	50.4	75.6	Biuret reaction end point
	g/dl	6.30	5.04	7.56	
Retinol Binding Protein	mg/l	46.3	37.0	55.6	Nephelometric (IFCC Cal.)
	mg/l	49.4	39.5	59.3	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	55.0	44.0	66.0	Turbidimetric (Non IFCC Cal.)
	U/ml	42.5	34.0	51.0	Fluoroimmunoassay (Non IFCC Cal.)
	U/ml	56.7	45.4	68.0	Latex (Non-IFCC Cal.)
	U/ml	52.9	42.3	63.5	Neph. Beckman (Non IFCC Cal.)
	U/ml	44.2	35.4	53.0	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	2.25	1.80	2.70	Turbidimetric (IFCC Cal.)
	mg/dl	225	180	270	
	g/l	2.26	1.81	2.71	Turbidimetric (Non IFCC Cal.)
	mg/dl	226	181	271	
	g/l	2.16	1.73	2.59	Nephelometric (IFCC Cal.)
	mg/dl	216	173	259	
g/l	2.23	1.78	2.68	Nephelometric (Non IFCC Cal.)	
mg/dl	223	178	268		