

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

CAT. NO. PS2683 **LOT NO.** 565LPC
SIZE: 3 x 1ml **EXPIRY:** 2022-12-28
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.

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

Cat. No. PS2683 Lot. No. 565LPC Size 3 x 1 ml Expiry 2022-12-28

Analyte	unit	Target	Range		methods	
			low	high		
Albumin	g/l	38.9	33.1	44.7	Bromocresol Green (IFCC Cal.)	
	g/dl	3.89	3.31	4.47		
	g/l	40.0	34.0	46.0	Bromocresol Purple (IFCC Cal.)	
	g/dl	4.00	3.40	4.60		
	g/l	38.0	32.3	43.7	Nephelometric (IFCC Cal.)	
	g/dl	3.80	3.23	4.37		
	g/l	40.0	34.0	46.0	Bromocresol Green (Non IFCC Cal.)	
	g/dl	4.00	3.40	4.60		
	g/l	39.1	33.2	45.0	Bromocresol Purple (Non IFCC Cal.)	
	g/dl	3.91	3.32	4.50		
	g/l	37.8	32.1	43.5	Turbidimetric Assays (IFCC Cal.)	
	g/dl	3.78	3.21	4.35		
	g/l	38.3	32.6	44.0	Turbidimetric Assays (Non IFCC Cal.)	
	g/dl	3.83	3.26	4.40		
Alpha-1-Acid Glycoprotein	g/l	0.905	0.724	1.09	Turbidimetric (IFCC Cal.)	
	mg/dl	90.5	72.4	109		
	g/l	0.914	0.731	1.10	Nephelometric (IFCC Cal.)	
	mg/dl	91.4	73.1	110		
Alpha-1-Antitrypsin	g/l	0.920	0.736	1.10	Turbidimetric (Non IFCC Cal.)	
	mg/dl	92.0	73.6	110		
	g/l	1.65	1.32	1.98	Turbidimetric (IFCC Cal.)	
	mg/dl	165	132	198		
g/l	1.77	1.42	2.12	Nephelometric (IFCC Cal.)		
mg/dl	177	142	212			
Alpha-1-Antitrypsin	g/l	1.61	1.29	1.93	Nephelometric (Non IFCC Cal.)	
	mg/dl	161	129	193		
	g/l	1.66	1.33	1.99	Turbidimetric (Non IFCC Cal.)	
	mg/dl	166	133	199		
Alpha-2-Macroglobulin	g/l	1.94	1.55	2.33	Turbidimetric (IFCC Cal.)	
	mg/dl	194	155	233		
	g/l	2.00	1.60	2.40	Nephelometric (IFCC Cal.)	
	mg/dl	200	160	240		
Alpha-2-Macroglobulin	g/l	1.93	1.54	2.32	Turbidimetric (Non IFCC Cal.)	
	mg/dl	193	154	232		
	Alphafoetoprotein	KIU/l = IU/ml	36.5	29.2	43.8	Chemiluminescence (IFCC Cal.)
		ng/ml	44.2	35.3	53.1	
KIU/l = IU/ml		36.3	29.0	43.6	Chemiluminescence (Non IFCC Cal.)	
Anti Streptolysin O	ng/ml	43.9	35.1	52.7		
	IU/ml	231	185	277	Turbidimetric (IFCC Cal.)	
	IU/ml	237	190	284	Turbidimetric (Non IFCC Cal.)	
	IU/ml	153	122	184	Neph. Beckman (IFCC Cal.)	
Anti Streptolysin O	IU/ml	153	122	184	Neph. Beckman (Non IFCC Cal.)	

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

Cat. No. PS2683 Lot. No. 565LPC Size 3 x 1 ml Expiry 2022-12-28

Range					
Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	232	186	278	Neph. Behring (IFCC Cal.)
	IU/ml	231	185	277	Neph. Behring (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	3.89	3.11	4.67	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	4.41	3.53	5.29	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	4.33	3.46	5.20	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	4.22	3.38	5.06	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	47.9	38.3	57.5	Vitros (IFCC Cal.)
	mg/l	46.0	36.8	55.2	Turbidimetric (IFCC Cal.)
	mg/l	40.9	32.7	49.1	Nephelometric (IFCC Cal.)
	mg/l	45.8	36.6	55.0	Turbidimetric (Non IFCC Cal.)
	mg/l	46.9	37.5	56.3	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.432	0.324	0.540	Nephelometric (IFCC Cal.)
	mg/dl	43.2	32.4	54.0	
	g/l	0.377	0.283	0.471	Turbidimetric (IFCC Cal.)
	mg/dl	37.7	28.3	47.1	
	g/l	0.308	0.231	0.385	Nephelometric (Non IFCC Cal.)
	mg/dl	30.8	23.1	38.5	
	g/l	0.356	0.267	0.445	Turbidimetric (Non IFCC Cal.)
	mg/dl	35.6	26.7	44.5	
Complement C3	g/l	1.46	1.17	1.75	Turbidimetric (IFCC Cal.)
	mg/dl	146	117	175	
	g/l	1.45	1.16	1.74	Nephelometric (IFCC Cal.)
	mg/dl	145	116	174	
	g/l	1.49	1.19	1.79	Nephelometric (Non IFCC Cal.)
	mg/dl	149	119	179	
	g/l	1.45	1.16	1.74	Turbidimetric (Non IFCC Cal.)
	mg/dl	145	116	174	
Complement C4	g/l	0.367	0.294	0.440	Turbidimetric (IFCC Cal.)
	mg/dl	36.7	29.4	44.0	
	g/l	0.388	0.310	0.466	Nephelometric (IFCC Cal.)
	mg/dl	38.8	31.0	46.6	
	g/l	0.378	0.302	0.454	Nephelometric (Non IFCC Cal.)
	mg/dl	37.8	30.2	45.4	
	g/l	0.347	0.278	0.416	Turbidimetric (Non IFCC Cal.)
	mg/dl	34.7	27.8	41.6	
Ferritin	ng/ml = µg/l	184	147	221	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	204	163	245	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	198	158	238	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	202	162	242	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light	mg/L	21.4	17.1	25.7	Nephelometric - Binding Site

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

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Range					
Analyte	unit	Target	low	high	methods
Free Lambda Light Chains	mg/L	15.8	12.6	19.0	Nephelometric - Siemens
	mg/L	20.7	16.6	24.8	Turbidimetric
Haptoglobin	g/l	1.41	1.13	1.69	Nephelometric (IFCC Cal.)
	mg/dl	141	113	169	
	g/l	1.51	1.21	1.81	Turbidimetric (IFCC Cal.)
	mg/dl	151	121	181	
	g/l	1.40	1.12	1.68	Nephelometric (Non IFCC Cal.)
	mg/dl	140	112	168	
Immunoglobulin A	g/l	2.41	1.81	3.01	Turbidimetric (IFCC Cal.)
	mg/dl	241	181	301	
	g/l	2.51	1.88	3.14	Nephelometric (IFCC Cal.)
	mg/dl	251	188	314	
	g/l	2.52	1.89	3.15	Nephelometric (Non IFCC Cal.)
	mg/dl	252	189	315	
Immunoglobulin E	g/l	2.41	1.81	3.01	Turbidimetric (Non IFCC Cal.)
	mg/dl	241	181	301	
	g/l	2.41	1.81	3.01	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	241	181	301	
	KIU/l = IU/ml	162	130	194	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	157	126	188	Nephelometric (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	146	117	175	Turbidimetric (Non IFCC Cal.)
	g/l	13.7	11.2	16.2	Turbidimetric (IFCC Cal.)
	mg/dl	1370	1120	1620	
	g/l	14.0	11.5	16.5	Nephelometric (IFCC Cal.)
	mg/dl	1400	1150	1650	
	g/l	13.7	11.2	16.2	Nephelometric (Non IFCC Cal.)
	mg/dl	1370	1120	1620	
	g/l	13.9	11.4	16.4	Turbidimetric (Non IFCC Cal.)
mg/dl	1390	1140	1640		
Immunoglobulin M	g/l	13.7	11.2	16.2	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1370	1120	1620	
	g/l	1.66	1.33	1.99	Turbidimetric (IFCC Cal.)
	mg/dl	166	133	199	
	g/l	1.72	1.38	2.06	Nephelometric (IFCC Cal.)
	mg/dl	172	138	206	
	g/l	1.66	1.33	1.99	Nephelometric (Non IFCC Cal.)
	mg/dl	166	133	199	
Kappa Light Chain	g/l	1.67	1.34	2.00	Turbidimetric (Non IFCC Cal.)
	mg/dl	167	134	200	
	g/l	1.68	1.34	2.02	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	168	134	202	
	g/l	10.6	8.46	12.7	Nephelometric - Beckman
	mg/dl	1057	846	1270	
Kappa Light Chain	g/l	3.47	2.78	4.16	Nephelometric - Siemens
	mg/dl	347	278	416	

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

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Range					
Analyte	unit	Target	low	high	methods
Kappa Light Chain	g/l	3.60	2.88	4.32	Turbidimetric
	mg/dl	360	288	432	
Lambda Light Chain	g/l	5.45	4.36	6.54	Nephelometric - Beckman
	mg/dl	545	436	654	
	g/l	1.83	1.46	2.20	Nephelometric - Siemens
	mg/dl	183	146	220	
	g/l	1.77	1.42	2.12	Turbidimetric
mg/dl	177	142	212		
Prealbumin	g/l	0.428	0.342	0.514	Nephelometric (IFCC Cal.)
	mg/dl	42.8	34.2	51.4	
	g/l	0.391	0.313	0.469	Turbidimetric (IFCC Cal.)
	mg/dl	39.1	31.3	46.9	
Protein Total	g/l	67.1	53.7	80.5	Biuret reaction end point
	g/dl	6.71	5.37	8.05	
Retinol Binding Protein	mg/l	63.3	50.6	76.0	Nephelometric (IFCC Cal.)
	mg/l	68.1	54.5	81.7	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	75.1	60.1	90.1	Turbidimetric (Non IFCC Cal.)
	U/ml	76.7	61.4	92.0	Latex (Non-IFCC Cal.)
	U/ml	69.6	55.7	83.5	Neph. Beckman (Non IFCC Cal.)
	U/ml	66.3	53.0	79.6	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	2.55	2.04	3.06	Turbidimetric (IFCC Cal.)
	mg/dl	255	204	306	
	g/l	2.58	2.06	3.10	Turbidimetric (Non IFCC Cal.)
	mg/dl	258	206	310	
Transferrin	g/l	2.51	2.01	3.01	Nephelometric (IFCC Cal.)
	mg/dl	251	201	301	