

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

CAT. NO. PS2684

LOT NO. 539LPC

SIZE: 3 x 1 ml

EXPIRY: 2021-03-28

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 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.

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 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 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 08 Oct 19 pq

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Cat. No. PS2684 Lot No. 539LPC Size: 3 x 1 ml Expiry: 2021-03-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	55.4	47.1	63.7	Bromocresol Green (IFCC Cal.)
	g/dl	5.54	4.71	6.37	
	g/l	55.6	47.3	63.9	Bromocresol Purple (IFCC Cal.)
	g/dl	5.56	4.73	6.39	
	g/l	55.4	47.1	63.7	Nephelometric (IFCC Cal.)
	g/dl	5.54	4.71	6.37	
	g/l	55.5	47.2	63.8	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.55	4.72	6.38	
	g/l	55.4	47.1	63.7	Bromocresol Purple (Non IFCC Cal.)
	g/dl	5.54	4.71	6.37	
	g/l	55.2	46.9	63.5	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.52	4.69	6.35	
Alpha-1-Acid Glycoprotein	g/l	1.40	1.12	1.68	Turbidimetric (IFCC Cal.)
	mg/dl	140	112	168	
	g/l	1.44	1.15	1.73	Nephelometric (IFCC Cal.)
	mg/dl	144	115	173	
Alpha-1-Antitrypsin	g/l	1.39	1.11	1.67	Turbidimetric (Non IFCC Cal.)
	mg/dl	139	111	167	
	g/l	2.12	1.70	2.54	Turbidimetric (IFCC Cal.)
	mg/dl	212	170	254	
Alpha-2-Macroglobulin	g/l	2.36	1.89	2.83	Nephelometric (IFCC Cal.)
	mg/dl	236	189	283	
	g/l	2.09	1.67	2.51	Turbidimetric (Non IFCC Cal.)
	mg/dl	209	167	251	
Alpha-fetoprotein	g/l	3.02	2.42	3.62	Turbidimetric (IFCC Cal.)
	mg/dl	302	242	362	
	g/l	3.20	2.56	3.84	Nephelometric (IFCC Cal.)
	mg/dl	320	256	384	
Anti Streptolysin O	g/l	2.86	2.29	3.43	Turbidimetric (Non IFCC Cal.)
	mg/dl	286	229	343	
	KIU/l = IU/ml	56.3	45.0	67.6	Chemiluminescence (IFCC Cal.)
	ng/ml	68.1	54.5	81.7	
Anti Streptolysin O	KIU/l = IU/ml	57.0	45.6	68.4	Chemiluminescence (Non IFCC Cal.)
	ng/ml	69.0	55.2	82.8	
	IU/ml	360	288	432	Turbidimetric (IFCC Cal.)
	IU/ml	348	278	418	Turbidimetric (Non IFCC Cal.)
	IU/ml	237	190	284	Neph. Beckman (IFCC Cal.)
	IU/ml	228	182	274	Neph. Beckman (Non IFCC Cal.)
Anti Streptolysin O	IU/ml	384	307	461	Neph. Behring (IFCC Cal.)
	IU/ml	383	306	460	Neph. Behring (Non IFCC Cal.)

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Analyte	unit	Target	Range		methods
			low	high	
Anti-thrombin III	mg/l	381	286	476	Turbidimetric (IFCC Cal.)
	mg/dl	38.1	28.6	47.6	
Beta-2-microglobulin	µg/ml = mg/l	5.55	4.44	6.66	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	5.69	4.55	6.83	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	5.95	4.76	7.14	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	6.06	4.85	7.27	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.98	4.78	7.18	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	53.8	43.0	64.6	Vitros (IFCC Cal.)
	mg/l	67.6	54.1	81.1	Turbidimetric (IFCC Cal.)
	mg/l	68.2	54.6	81.8	Nephelometric (IFCC Cal.)
	mg/l	69.2	55.4	83.0	Nephelometric (Non IFCC Cal.)
	mg/l	66.9	53.5	80.3	Turbidimetric (Non IFCC Cal.)
	mg/l	71.8	57.4	86.2	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.555	0.416	0.694	Nephelometric (IFCC Cal.)
	mg/dl	55.5	41.6	69.4	
	g/l	0.509	0.382	0.636	Turbidimetric (IFCC Cal.)
	mg/dl	50.9	38.2	63.6	
	g/l	0.534	0.401	0.667	Nephelometric (Non IFCC Cal.)
	mg/dl	53.4	40.1	66.7	
	g/l	0.474	0.356	0.592	Turbidimetric (Non IFCC Cal.)
	mg/dl	47.4	35.6	59.2	
Complement C3	g/l	1.83	1.46	2.20	Turbidimetric (IFCC Cal.)
	mg/dl	183	146	220	
	g/l	1.81	1.45	2.17	Nephelometric (IFCC Cal.)
	mg/dl	181	145	217	
	g/l	1.80	1.44	2.16	Nephelometric (Non IFCC Cal.)
	mg/dl	180	144	216	
	g/l	1.87	1.50	2.24	Turbidimetric (Non IFCC Cal.)
	mg/dl	187	150	224	
Complement C4	g/l	1.82	1.46	2.18	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	182	146	218	
	g/l	0.442	0.354	0.530	Turbidimetric (IFCC Cal.)
	mg/dl	44.2	35.4	53.0	
	g/l	0.475	0.380	0.570	Nephelometric (IFCC Cal.)
	mg/dl	47.5	38.0	57.0	
	g/l	0.474	0.379	0.569	Nephelometric (Non IFCC Cal.)
	mg/dl	47.4	37.9	56.9	
g/l	0.421	0.337	0.505	Turbidimetric (Non IFCC Cal.)	
mg/dl	42.1	33.7	50.5		
Ferritin	g/l	0.429	0.343	0.515	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	42.9	34.3	51.5	
	ng/ml = µg/l	288	230	346	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	298	238	358	Turbidimetric (Non IFCC Cal.)
ng/ml = µg/l	314	251	377	Chemiluminescence (IFCC Cal.)	

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Range						
Analyte	unit	Target	low	high	methods	
Ferritin	ng/ml = µg/l	324	259	389	Chemiluminescence (Non IFCC Cal.)	
	ng/ml = µg/l	290	232	348	Nephelometric (IFCC Cal.)	
Free Lambda Light Chains	mg/L	22.1	17.7	26.5	Nephelometric - Siemens	
	mg/L	27.8	22.2	33.4	Nephelometric - Binding Site	
	mg/L	25.7	20.6	30.8	Turbidimetric	
Haptoglobin	g/l	1.87	1.50	2.24	Nephelometric (IFCC Cal.)	
	mg/dl	187	150	224		
	g/l	1.88	1.50	2.26	Turbidimetric (IFCC Cal.)	
	mg/dl	188	150	226		
	g/l	1.87	1.50	2.24	Nephelometric (Non IFCC Cal.)	
	mg/dl	187	150	224		
Immunoglobulin A	g/l	3.49	2.62	4.36	Turbidimetric (IFCC Cal.)	
	mg/dl	349	262	436		
	g/l	3.69	2.77	4.61	Nephelometric (IFCC Cal.)	
	mg/dl	369	277	461		
	g/l	3.91	2.93	4.89	Nephelometric (Non IFCC Cal.)	
	mg/dl	391	293	489		
Immunoglobulin E	g/l	3.44	2.58	4.30	Turbidimetric (Non IFCC Cal.)	
	mg/dl	344	258	430		
	g/l	3.58	2.69	4.48	Vitros 5.1 FS Microtip (Non IFCC)	
	mg/dl	358	269	447		
	Immunoglobulin E	KIU/l = IU/ml	193	154	232	Fluorimetric (Non IFCC Cal.)
		KIU/l = IU/ml	184	147	221	Chemiluminescence (Non IFCC Cal.)
KIU/l = IU/ml		179	143	215	Nephelometric (Non IFCC Cal.)	
KIU/l = IU/ml		171	137	205	Enzyme Immunoassay (Non IFCC Cal.)	
KIU/l = IU/ml		191	153	229	Turbidimetric (Non IFCC Cal.)	
Immunoglobulin G	g/l	18.0	14.8	21.2	Turbidimetric (IFCC Cal.)	
	mg/dl	1800	1480	2120		
	g/l	18.3	15.0	21.6	Nephelometric (IFCC Cal.)	
	mg/dl	1830	1500	2160		
	g/l	18.8	15.4	22.2	Nephelometric (Non IFCC Cal.)	
	mg/dl	1880	1540	2220		
Immunoglobulin G	g/l	17.9	14.7	21.1	Turbidimetric (Non IFCC Cal.)	
	mg/dl	1790	1470	2110		
	g/l	18.9	15.5	22.3	Vitros 5.1 FS Microtip (Non IFCC)	
	mg/dl	1890	1550	2230		
	Immunoglobulin M	g/l	2.63	2.10	3.16	Turbidimetric (IFCC Cal.)
		mg/dl	263	210	316	
g/l		2.74	2.19	3.29	Nephelometric (IFCC Cal.)	
mg/dl		274	219	329		
g/l		2.81	2.25	3.37	Nephelometric (Non IFCC Cal.)	
mg/dl	281	225	337			
Immunoglobulin M	g/l	2.63	2.10	3.16	Turbidimetric (Non IFCC Cal.)	
	mg/dl	263	210	316		

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Analyte	unit	Target	low	high	methods
Immunoglobulin M	g/l	2.53	2.02	3.04	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	253	202	304	
Kappa Light Chain	g/l	15.2	12.2	18.2	Nephelometric - Beckman
	mg/dl	1520	1220	1820	
	g/l	4.98	3.98	5.98	Turbidimetric
	mg/dl	498	398	598	
	g/l	4.62	3.70	5.54	Nephelometric - Siemens
mg/dl	462	370	554		
Lambda Light Chain	g/l	2.62	2.10	3.14	Turbidimetric
	mg/dl	262	210	314	
	g/l	7.89	6.31	9.47	Nephelometric - Beckman
	mg/dl	789	631	947	
	g/l	2.48	1.98	2.98	Nephelometric - Siemens
mg/dl	248	198	298		
Prealbumin	g/l	0.516	0.413	0.619	Nephelometric (IFCC Cal.)
	mg/dl	51.6	41.3	61.9	
	g/l	0.458	0.366	0.550	Turbidimetric (IFCC Cal.)
	mg/dl	45.8	36.6	55.0	
	g/l	0.472	0.378	0.566	Nephelometric (Non IFCC Cal.)
	mg/dl	47.2	37.8	56.6	
Protein Total	g/l	90.4	72.3	108	Biuret reaction end point
	g/dl	9.04	7.23	10.8	
Retinol Binding Protein	mg/l	69.5	55.6	83.4	Nephelometric (IFCC Cal.)
	mg/l	69.7	55.8	83.6	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	80.0	64.0	96.0	Turbidimetric (Non IFCC Cal.)
	U/ml	83.2	66.6	100	Latex (Non-IFCC Cal.)
	U/ml	97.7	78.2	117	Neph. Beckman (Non IFCC Cal.)
	U/ml	63.8	51.0	76.6	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	3.35	2.68	4.02	Turbidimetric (IFCC Cal.)
	mg/dl	335	268	402	
	g/l	3.38	2.70	4.06	Turbidimetric (Non IFCC Cal.)
	mg/dl	338	270	406	
	g/l	3.21	2.57	3.85	Nephelometric (IFCC Cal.)
	mg/dl	321	257	385	
g/l	3.12	2.50	3.74	Nephelometric (Non IFCC Cal.)	
mg/dl	312	250	374		