

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

CAT. NO. PS2684

LOT NO. 573LPC

SIZE: 3 x 1 ml

EXPIRY: 2021-09-28

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.

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Cat. No. PS2684 Lot No. 573LPC Size: 3 x 1 ml Expiry: 2021-09-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	54.8	46.6	63.0	Bromocresol Green (IFCC Cal.)
	g/dl	5.48	4.66	6.30	
	g/l	55.8	47.4	64.2	Bromocresol Purple (IFCC Cal.)
	g/dl	5.58	4.74	6.42	
	g/l	54.3	46.2	62.4	Nephelometric (IFCC Cal.)
	g/dl	5.43	4.62	6.24	
	g/l	55.5	47.2	63.8	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.55	4.72	6.38	
	g/l	55.7	47.3	64.1	Bromocresol Purple (Non IFCC Cal.)
	g/dl	5.57	4.73	6.41	
	g/l	53.9	45.8	62.0	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.39	4.58	6.20	
Alpha-1-Acid Glycoprotein	g/l	1.25	1.00	1.50	Turbidimetric (IFCC Cal.)
	mg/dl	125	100	150	Nephelometric (IFCC Cal.)
	g/l	1.24	0.992	1.49	
	mg/dl	124	99.2	149	
Alpha-1-Antitrypsin	g/l	1.27	1.02	1.52	Turbidimetric (Non IFCC Cal.)
	mg/dl	127	102	152	
	g/l	2.09	1.67	2.51	Turbidimetric (IFCC Cal.)
	mg/dl	209	167	251	
	g/l	2.33	1.86	2.80	Nephelometric (IFCC Cal.)
	mg/dl	233	186	280	
Alpha-2-Macroglobulin	g/l	2.40	1.92	2.88	Nephelometric (Non IFCC Cal.)
	mg/dl	240	192	288	
	g/l	2.16	1.73	2.59	Turbidimetric (Non IFCC Cal.)
	mg/dl	216	173	259	
Alpha-fetoprotein	g/l	3.22	2.58	3.86	Turbidimetric (IFCC Cal.)
	mg/dl	322	258	386	
	g/l	3.33	2.66	4.00	Nephelometric (IFCC Cal.)
	mg/dl	333	266	400	
Alpha-fetoprotein	g/l	3.30	2.64	3.96	Turbidimetric (Non IFCC Cal.)
	mg/dl	330	264	396	
	KIU/l = IU/ml	58.8	47.0	70.6	Chemiluminescence (IFCC Cal.)
	ng/ml	71.1	56.9	85.3	Chemiluminescence (Non IFCC Cal.)
KIU/l = IU/ml	58.8	47.0	70.6		
ng/ml	71.1	56.9	85.3		
Anti Streptolysin O	IU/ml	375	300	450	Turbidimetric (IFCC Cal.)
	IU/ml	402	322	482	Turbidimetric (Non IFCC Cal.)
	IU/ml	253	202	304	Neph. Beckman (IFCC Cal.)
	IU/ml	245	196	294	Neph. Beckman (Non IFCC Cal.)

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Analyte	unit	Target	Range		methods
			low	high	
Anti Streptolysin O	IU/ml	393	314	472	Neph. Behring (Non IFCC Cal.)
	IU/ml	396	317	475	Neph. Behring (IFCC Cal.)
Antithrombin III	mg/l	389	292	486	Turbidimetric (IFCC Cal.)
	mg/dl	38.9	29.2	48.6	
Beta-2-microglobulin	µg/ml = mg/l	5.25	4.20	6.30	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	5.75	4.60	6.90	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.68	4.54	6.82	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.63	4.50	6.76	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	56.9	45.5	68.3	Vitros (IFCC Cal.)
	mg/l	68.9	55.1	82.7	Turbidimetric (IFCC Cal.)
	mg/l	68.2	54.6	81.8	Nephelometric (IFCC Cal.)
	mg/l	67.8	54.2	81.4	Nephelometric (Non IFCC Cal.)
	mg/l	68.6	54.9	82.3	Turbidimetric (Non IFCC Cal.)
	mg/l	72.3	57.8	86.8	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.541	0.433	0.649	Nephelometric (IFCC Cal.)
	mg/dl	54.1	43.3	64.9	
	g/l	0.532	0.426	0.638	Turbidimetric (IFCC Cal.)
	mg/dl	53.2	42.6	63.8	
	g/l	0.499	0.399	0.599	Nephelometric (Non IFCC Cal.)
	mg/dl	49.9	39.9	59.9	
	g/l	0.518	0.414	0.622	Turbidimetric (Non IFCC Cal.)
	mg/dl	51.8	41.4	62.2	
Complement C3	g/l	2.18	1.74	2.62	Turbidimetric (IFCC Cal.)
	mg/dl	218	174	262	
	g/l	2.12	1.70	2.54	Nephelometric (IFCC Cal.)
	mg/dl	212	170	254	
	g/l	2.24	1.79	2.69	Nephelometric (Non IFCC Cal.)
	mg/dl	224	179	269	
	g/l	2.16	1.73	2.59	Turbidimetric (Non IFCC Cal.)
	mg/dl	216	173	259	
Complement C4	g/l	1.99	1.59	2.39	Vitros 5.1 FS microtip assay
	mg/dl	199	159	239	
	g/l	0.535	0.428	0.642	Turbidimetric (IFCC Cal.)
	mg/dl	53.5	42.8	64.2	
	g/l	0.562	0.450	0.674	Nephelometric (IFCC Cal.)
	mg/dl	56.2	45.0	67.4	
	g/l	0.572	0.458	0.686	Nephelometric (Non IFCC Cal.)
	mg/dl	57.2	45.8	68.6	
Ferritin	g/l	0.520	0.416	0.624	Turbidimetric (Non IFCC Cal.)
	mg/dl	52.0	41.6	62.4	
	g/l	0.509	0.407	0.611	Vitros 5.1 FS microtip assay
	mg/dl	50.9	40.7	61.1	
	ng/ml = µg/l	297	238	356	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	289	231	347	Turbidimetric (Non IFCC Cal.)

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Range					
Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	333	266	400	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	335	268	402	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	321	257	385	Enzyme Immunoassay (Non IFCC Cal.)
	ng/ml = µg/l	268	214	322	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	29.0	23.2	34.8	Nephelometric - Binding Site
	mg/L	19.8	15.8	23.8	Nephelometric - Siemens
	mg/L	26.1	20.9	31.3	Turbidimetric
Haptoglobin	g/l	1.89	1.51	2.27	Nephelometric (IFCC Cal.)
	mg/dl	189	151	227	
	g/l	2.00	1.60	2.40	Turbidimetric (IFCC Cal.)
	mg/dl	200	160	240	
	g/l	1.89	1.51	2.27	Nephelometric (Non IFCC Cal.)
	mg/dl	189	151	227	
	g/l	2.00	1.60	2.40	Turbidimetric (Non IFCC Cal.)
mg/dl	200	160	240		
Immunoglobulin A	g/l	3.52	2.64	4.40	Turbidimetric (IFCC Cal.)
	mg/dl	352	264	440	
	g/l	3.70	2.78	4.63	Nephelometric (IFCC Cal.)
	mg/dl	370	278	462	
	g/l	3.85	2.89	4.81	Nephelometric (Non IFCC Cal.)
	mg/dl	385	289	481	
	g/l	3.54	2.66	4.43	Turbidimetric (Non IFCC Cal.)
	mg/dl	354	266	442	
Immunoglobulin E	g/l	3.48	2.61	4.35	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	348	261	435	
	KIU/l = IU/ml	223	178	268	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	213	170	256	Nephelometric (Non IFCC Cal.)
Immunoglobulin G	KIU/l = IU/ml	226	181	271	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	210	168	252	Turbidimetric (Non IFCC Cal.)
	g/l	20.8	17.1	24.5	Turbidimetric (IFCC Cal.)
	mg/dl	2080	1710	2450	
	g/l	20.5	16.8	24.2	Nephelometric (IFCC Cal.)
	mg/dl	2050	1680	2420	
	g/l	20.7	17.0	24.4	Nephelometric (Non IFCC Cal.)
	mg/dl	2070	1700	2440	
Immunoglobulin M	g/l	20.9	17.1	24.7	Turbidimetric (Non IFCC Cal.)
	mg/dl	2090	1710	2470	
	g/l	20.6	16.9	24.3	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2060	1690	2430	
	g/l	2.58	2.06	3.10	Turbidimetric (IFCC Cal.)
	mg/dl	258	206	310	
	g/l	2.71	2.17	3.25	Nephelometric (IFCC Cal.)
	mg/dl	271	217	325	
Immunoglobulin M	g/l	2.67	2.14	3.20	Nephelometric (Non IFCC Cal.)
	mg/dl	267	214	320	
	g/l	2.62	2.10	3.14	Turbidimetric (Non IFCC Cal.)
	mg/dl	262	210	314	

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Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin M	g/l	2.56	2.05	3.07	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	256	205	307	
Kappa Light Chain	g/l	17.3	13.8	20.7	Nephelometric - Beckman
	mg/dl	1728	1380	2070	
	g/l	5.20	4.16	6.24	Nephelometric - Siemens
	mg/dl	520	416	624	
	g/l	5.55	4.44	6.66	Turbidimetric
mg/dl	555	444	666		
Lambda Light Chain	g/l	8.82	7.06	10.6	Nephelometric - Beckman
	mg/dl	882	706	1060	
	g/l	2.70	2.16	3.24	Nephelometric - Siemens
	mg/dl	270	216	324	
	g/l	2.83	2.26	3.40	Turbidimetric
mg/dl	283	226	340		
Prealbumin	g/l	0.525	0.420	0.630	Nephelometric (IFCC Cal.)
	mg/dl	52.5	42.0	63.0	
	g/l	0.514	0.411	0.617	Turbidimetric (IFCC Cal.)
	mg/dl	51.4	41.1	61.7	
	g/l	0.539	0.431	0.647	Nephelometric (Non IFCC Cal.)
	mg/dl	53.9	43.1	64.7	
Protein Total	g/l	92.7	74.2	111	Biuret reaction end point
	g/dl	9.27	7.42	11.1	
Retinol Binding Protein	mg/l	85.3	68.2	102	Nephelometric (IFCC Cal.)
	mg/l	84.3	67.4	101	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	84.4	67.5	101	Turbidimetric (Non IFCC Cal.)
	U/ml	90.6	72.5	109	Latex (Non-IFCC Cal.)
	U/ml	90.0	72.0	108	Neph. Beckman (Non IFCC Cal.)
	U/ml	63.1	50.5	75.7	Neph. Behring (Non IFCC Cal.)
Transferrin	g/l	3.51	2.81	4.21	Turbidimetric (IFCC Cal.)
	mg/dl	351	281	421	
	g/l	3.53	2.82	4.24	Turbidimetric (Non IFCC Cal.)
	mg/dl	353	282	424	
	g/l	3.39	2.71	4.07	Nephelometric (IFCC Cal.)
	mg/dl	339	271	407	
g/l	3.69	2.95	4.43	Nephelometric (Non IFCC Cal.)	
mg/dl	369	295	443		