

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

CAT. NO. PS2684

LOT NO. 533LPC

SIZE: 3 x 1 ml

EXPIRY: 2020-09-28

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.

(S) 15 Oct 18 pq

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

Cat. No. PS2684 Lot No. 533LPC Size: 3 x 1 ml Expiry: 2020-09-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	55.9	47.5	64.3	Bromocresol Green (IFCC Cal.)
	g/dl	5.59	4.75	6.43	
	g/l	56.1	47.7	64.5	Bromocresol Purple (IFCC Cal.)
	g/dl	5.61	4.77	6.45	
	g/l	56.6	48.1	65.1	Nephelometric (IFCC Cal.)
	g/dl	5.66	4.81	6.51	
	g/l	56.5	48.0	65.0	Bromocresol Green (Non IFCC Cal.)
	g/dl	5.65	4.80	6.50	
	g/l	55.6	47.3	63.9	Bromocresol Purple (Non IFCC Cal.)
	g/dl	5.56	4.73	6.39	
	g/l	56.3	47.9	64.7	Nephelometric (Non IFCC Cal.)
	g/dl	5.63	4.79	6.47	
	g/l	55.6	47.3	63.9	Turbidimetric Assays (IFCC Cal.)
	g/dl	5.56	4.73	6.39	
	g/l	57.9	49.2	66.6	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	5.79	4.92	6.66	
Alpha-1-Acid Glycoprotein	g/l	1.21	0.968	1.45	Turbidimetric (IFCC Cal.)
	mg/dl	121	96.8	145	
	g/l	1.26	1.01	1.51	Nephelometric (IFCC Cal.)
	mg/dl	126	101	151	
Alpha-1-Antitrypsin	g/l	1.17	0.936	1.40	Turbidimetric (Non IFCC Cal.)
	mg/dl	117	93.6	140	
	g/l	2.15	1.72	2.58	Turbidimetric (IFCC Cal.)
	mg/dl	215	172	258	
Alpha-2-Macroglobulin	g/l	2.49	1.99	2.99	Nephelometric (IFCC Cal.)
	mg/dl	249	199	299	
	g/l	2.22	1.78	2.66	Turbidimetric (Non IFCC Cal.)
	mg/dl	222	178	266	
Alpha-2-Macroglobulin	g/l	3.30	2.64	3.96	Turbidimetric (IFCC Cal.)
	mg/dl	330	264	396	
	g/l	3.24	2.59	3.89	Nephelometric (IFCC Cal.)
	mg/dl	324	259	389	
Alpha-fetoprotein	g/l	3.30	2.64	3.96	Turbidimetric (Non IFCC Cal.)
	mg/dl	330	264	396	
	KIU/l = IU/ml	55.4	44.3	66.5	Chemiluminescence (IFCC Cal.)
	ng/ml	67.0	53.6	80.4	
Alpha-fetoprotein	KIU/l = IU/ml	53.7	43.0	64.4	Chemiluminescence (Non IFCC Cal.)
	ng/ml	65.0	52.0	78.0	
Anti Streptolysin O	IU/ml	369	295	443	Turbidimetric (IFCC Cal.)
	IU/ml	364	291	437	Turbidimetric (Non IFCC Cal.)
	IU/ml	391	313	469	Neph. others (IFCC Cal.)
	IU/ml	405	324	486	Neph. others (Non IFCC Cal.)

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Range					
Analyte	unit	Target	low	high	methods
Anti Streptolysin O	IU/ml	249	199	299	Neph. Beckman (IFCC Cal.)
	IU/ml	244	195	293	Neph. Beckman (Non IFCC Cal.)
Antithrombin III	mg/l	390	273	507	Turbidimetric (IFCC Cal.)
	mg/dl	39.0	27.3	50.7	
Beta-2-microglobulin	µg/ml = mg/l	5.10	4.08	6.12	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	5.55	4.44	6.66	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	5.82	4.66	6.98	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.88	4.70	7.06	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.73	4.58	6.88	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	6.34	5.07	7.61	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	54.8	43.8	65.8	Vitros (IFCC Cal.)
	mg/l	67.1	53.7	80.5	Turbidimetric (IFCC Cal.)
	mg/l	68.4	54.7	82.1	Nephelometric (IFCC Cal.)
	mg/l	66.5	53.2	79.8	Turbidimetric (Non IFCC Cal.)
	mg/l	70.1	56.1	84.1	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.736	0.552	0.920	Nephelometric (IFCC Cal.)
	mg/dl	73.6	55.2	92.0	
	g/l	0.578	0.434	0.722	Turbidimetric (IFCC Cal.)
	mg/dl	57.8	43.4	72.2	
	g/l	0.704	0.528	0.880	Nephelometric (Non IFCC Cal.)
	mg/dl	70.4	52.8	88.0	
	g/l	0.563	0.422	0.704	Turbidimetric (Non IFCC Cal.)
	mg/dl	56.3	42.2	70.4	
	g/l	0.511	0.383	0.639	Neph. Beckman (IFCC Cal.)
	mg/dl	51.1	38.3	63.9	
Complement C3	g/l	0.589	0.442	0.736	Randox Immunoturbidimetric
	mg/dl	58.9	44.2	73.6	
	g/l	2.28	1.82	2.74	Turbidimetric (IFCC Cal.)
	mg/dl	228	182	274	
	g/l	2.19	1.75	2.63	Nephelometric (IFCC Cal.)
	mg/dl	219	175	263	
	g/l	2.30	1.84	2.76	Nephelometric (Non IFCC Cal.)
	mg/dl	230	184	276	
	g/l	2.31	1.85	2.77	Turbidimetric (Non IFCC Cal.)
	mg/dl	231	185	277	
Complement C4	g/l	2.24	1.79	2.69	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	224	179	269	
	g/l	0.487	0.390	0.584	Turbidimetric (IFCC Cal.)
	mg/dl	48.7	39.0	58.4	
	g/l	0.521	0.417	0.625	Nephelometric (IFCC Cal.)
	mg/dl	52.1	41.7	62.5	
	g/l	0.525	0.420	0.630	Nephelometric (Non IFCC Cal.)
	mg/dl	52.5	42.0	63.0	
	g/l	0.469	0.375	0.563	Turbidimetric (Non IFCC Cal.)
	mg/dl	46.9	37.5	56.3	
	g/l	0.475	0.380	0.570	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	47.5	38.0	57.0	

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Range					
Analyte	unit	Target	low	high	methods
Ferritin	ng/ml = µg/l	290	232	348	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	297	238	356	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	318	254	382	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	315	252	378	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	271	217	325	Nephelometric (IFCC Cal.)
Free Lambda Light Chains	mg/L	33.8	27.0	40.6	Nephelometric - Beckman
	mg/L	28.6	22.9	34.3	Nephelometric - Binding Site
	mg/L	17.7	14.2	21.2	Nephelometric - Siemens
	mg/L	27.2	21.8	32.6	Turbidimetric
Haptoglobin	g/l	1.92	1.54	2.30	Nephelometric (IFCC Cal.)
	mg/dl	192	154	230	
	g/l	1.97	1.58	2.36	Turbidimetric (IFCC Cal.)
	mg/dl	197	158	236	
	g/l	1.89	1.51	2.27	Nephelometric (Non IFCC Cal.)
	mg/dl	189	151	227	
Immunoglobulin A	g/l	1.97	1.58	2.36	Turbidimetric (Non IFCC Cal.)
	mg/dl	197	158	236	
	g/l	3.32	2.49	4.15	Turbidimetric (IFCC Cal.)
	mg/dl	332	249	415	
	g/l	3.57	2.68	4.46	Nephelometric (IFCC Cal.)
	mg/dl	357	268	446	
Immunoglobulin E	g/l	3.64	2.73	4.55	Nephelometric (Non IFCC Cal.)
	mg/dl	364	273	455	
	g/l	3.27	2.45	4.09	Turbidimetric (Non IFCC Cal.)
	mg/dl	327	245	409	
	g/l	3.38	2.54	4.23	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	338	254	422	
Immunoglobulin G	g/l	196	157	235	Fluorimetric (Non IFCC Cal.)
	mg/dl	198	158	238	Chemiluminescence (Non IFCC Cal.)
	g/l	195	156	234	Nephelometric (Non IFCC Cal.)
	mg/dl	204	163	245	Enzyme Immunoassay (Non IFCC Cal.)
	g/l	199	159	239	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	18.6	15.3	21.9	Turbidimetric (IFCC Cal.)
	mg/dl	1860	1530	2190	
	g/l	18.9	15.5	22.3	Nephelometric (IFCC Cal.)
	mg/dl	1890	1550	2230	
	g/l	19.1	15.7	22.5	Nephelometric (Non IFCC Cal.)
	mg/dl	1910	1570	2250	
	g/l	18.3	15.0	21.6	Turbidimetric (Non IFCC Cal.)
	mg/dl	1830	1500	2160	
Immunoglobulin G	g/l	19.0	15.6	22.4	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	1900	1560	2240	

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Range					
Analyte	unit	Target	low	high	methods
Immunoglobulin M	g/l	2.64	2.11	3.17	Turbidimetric (IFCC Cal.)
	mg/dl	264	211	317	
	g/l	2.73	2.18	3.28	Nephelometric (IFCC Cal.)
	mg/dl	273	218	328	
	g/l	2.75	2.20	3.30	Nephelometric (Non IFCC Cal.)
	mg/dl	275	220	330	
	g/l	2.66	2.13	3.19	Turbidimetric (Non IFCC Cal.)
	mg/dl	266	213	319	
Kappa Light Chain	g/l	2.60	2.08	3.12	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	260	208	312	
	g/l	16.1	12.9	19.3	Nephelometric - Beckman
	mg/dl	1610	1290	1930	
	g/l	4.47	3.58	5.36	Nephelometric - Siemens
	mg/dl	447	358	536	
	g/l	4.98	3.98	5.98	Turbidimetric
	mg/dl	498	398	598	
Lambda Light Chain	g/l	8.24	6.59	9.89	Nephelometric - Beckman
	mg/dl	824	659	989	
	g/l	2.40	1.92	2.88	Nephelometric - Siemens
	mg/dl	240	192	288	
	g/l	2.56	2.05	3.07	Turbidimetric
	mg/dl	256	205	307	
Prealbumin	g/l	0.521	0.417	0.625	Nephelometric (IFCC Cal.)
	mg/dl	52.1	41.7	62.5	
	g/l	0.480	0.384	0.576	Turbidimetric (IFCC Cal.)
	mg/dl	48.0	38.4	57.6	
	g/l	0.506	0.405	0.607	Nephelometric (Non IFCC Cal.)
	mg/dl	50.6	40.5	60.7	
Protein Total	g/l	0.482	0.386	0.578	Turbidimetric (Non IFCC Cal.)
	mg/dl	48.2	38.6	57.8	
	g/l	92.0	73.6	110	Biuret reaction end point
	g/dl	9.20	7.36	11.0	
Retinol Binding Protein	mg/l	74.5	59.6	89.4	Nephelometric (IFCC Cal.)
	mg/l	71.8	57.4	86.2	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	85.5	68.4	103	Turbidimetric (Non IFCC Cal.)
	U/ml	91.4	73.1	110	Latex (Non-IFCC Cal.)
	U/ml	120	96.0	144	Randox Immunoturbidimetric
	U/ml	115	92.0	138	Neph. Beckman (Non IFCC Cal.)
	U/ml	71.8	57.4	86.2	Neph. Behring (Non IFCC Cal.)
	U/ml				
Transferrin	g/l	3.65	2.92	4.38	Turbidimetric (IFCC Cal.)
	mg/dl	365	292	438	
	g/l	3.70	2.96	4.44	Turbidimetric (Non IFCC Cal.)
	mg/dl	370	296	444	
	g/l	3.45	2.76	4.14	Nephelometric (IFCC Cal.)
	mg/dl	345	276	414	

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Range					
Analyte	unit	Target	low	high	methods
Transferrin	g/l	3.57	2.86	4.28	Nephelometric (Non IFCC Cal.)
	mg/dl	357	286	428	