

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

CAT. NO. PS2682 **LOT NO.** 666LPC
SIZE: 3 x 1 ml **EXPIRY:** 2024-06-28
GTIN: 05055273204896

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 I, 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. Allow the control to come to room temperature before analysis.

MATERIALS PROVIDED

Liquid Protein Control - Level I 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.

EC	REP
----	-----

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 29 Nov '22 me

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 666LPC Size 3 x 1ml Expiry 2024-06-28

Range					
Analyte	unit	Target	low	high	methods
Albumin	g/l	22.1	18.8	25.4	Bromocresol Green (IFCC Cal.)
	g/dl	2.21	1.88	2.54	
	g/l	21.3	18.1	24.5	Bromocresol Purple (IFCC Cal.)
	g/dl	2.13	1.81	2.45	
	g/l	23.0	19.6	26.5	Nephelometric (IFCC Cal.)
	g/dl	2.30	1.96	2.64	
	g/l	22.3	19.0	25.6	Bromocresol Green (Non IFCC Cal.)
	g/dl	2.23	1.90	2.56	
	g/l	21.2	18.0	24.4	Turbidimetric Assays (IFCC Cal.)
	g/dl	2.12	1.80	2.44	
	g/l	21.4	18.2	24.6	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	2.14	1.82	2.46	
Alpha-1-Acid Glycoprotein	g/l	0.574	0.459	0.689	Turbidimetric (IFCC Cal.)
	mg/dl	57.4	45.9	68.9	Nephelometric (IFCC Cal.)
	g/l	0.599	0.479	0.719	
	mg/dl	59.9	47.9	71.9	Turbidimetric (Non IFCC Cal.)
	g/l	0.561	0.449	0.673	
Alpha-1-Antitrypsin	mg/dl	56.1	44.9	67.3	Turbidimetric (IFCC Cal.)
	g/l	0.469	0.375	0.563	
	mg/dl	46.9	37.5	56.3	Nephelometric (IFCC Cal.)
	g/l	0.490	0.392	0.588	
	mg/dl	49.0	39.2	58.8	Turbidimetric (Non IFCC Cal.)
Alpha-2-Macroglobulin	g/l	0.426	0.341	0.511	
	mg/dl	42.6	34.1	51.1	Nephelometric (IFCC Cal.)
	g/l	1.09	0.872	1.31	
	mg/dl	109	87.2	131	Chemiluminescence (IFCC Cal.)
	KIU/l = IU/ml	14.9	11.9	17.9	
Alphafoetoprotein	ng/ml	18.0	14.4	21.6	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	14.9	11.9	17.9	
	ng/ml	18.0	14.4	21.6	Turbidimetric (IFCC Cal.)
	IU/ml	92.2	73.8	111	
Anti Streptolysin O	IU/ml	95.9	76.7	115	Turbidimetric (Non IFCC Cal.)
	IU/ml	68.3	54.6	82.0	
	IU/ml	65.4	52.3	78.5	Neph. Beckman (IFCC Cal.)
	IU/ml	98.4	78.7	118	
	IU/ml	101	80.8	121	Neph. Beckman (Non IFCC Cal.)
	IU/ml	101	80.8	121	
	IU/ml	101	80.8	121	Siemens Nephelometric (IFCC Cal.)
Antithrombin III	IU/ml	101	80.8	121	Siemens Nephelometric (Non IFCC Cal.)
	mg/l	105	78.8	131	Colorimetric
Beta-2-microglobulin	mg/dl	10.5	7.88	13.1	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.46	1.17	1.75	
	µg/ml = mg/l	1.48	1.18	1.78	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.73	1.38	2.08	
	µg/ml = mg/l	1.71	1.37	2.05	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.71	1.37	2.05	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 666LPC Size 3 x 1ml Expiry 2024-06-28

Range					
Analyte	unit	Target	low	high	methods
C-Reactive Protein	mg/l	23.6	18.9	28.3	Vitros (IFCC Cal.)
	mg/l	24.5	19.6	29.4	Turbidimetric (IFCC Cal.)
	mg/l	22.1	17.7	26.5	Nephelometric (IFCC Cal.)
	mg/l	24.4	19.5	29.3	Turbidimetric (Non IFCC Cal.)
	mg/l	23.6	18.9	28.3	Roche Turbidimetric Gen 3 (IFCC Cal.)
	mg/l	23.5	18.8	28.2	Roche Turbidimetric Gen 3 (non-IFCC Cal.)
	mg/l	23.7	19.0	28.4	Roche Turbidimetric Latex (IFCC Cal.)
	mg/l	23.9	19.1	28.7	Roche Turbidimetric Latex (non-IFCC Cal.)
	mg/l	21.7	17.4	26.0	Beckman Turb Latex (IFCC Cal)
	mg/l	23.3	18.6	28.0	Roche Turbidimetric CRP4 (IFCC Cal.)
Caeruloplasmin	g/l	0.205	0.154	0.256	Nephelometric (IFCC Cal.)
	mg/dl	20.5	15.4	25.6	
	g/l	0.179	0.134	0.224	Nephelometric (Non IFCC Cal.)
	mg/dl	17.9	13.4	22.4	
	g/l	0.150	0.113	0.187	Turbidimetric (Non IFCC Cal.)
Complement C3	mg/dl	15.0	11.3	18.7	
	g/l	0.944	0.755	1.13	Turbidimetric (IFCC Cal.)
	mg/dl	94.4	75.5	113	
	g/l	0.901	0.721	1.08	Nephelometric (IFCC Cal.)
	mg/dl	90.1	72.1	108	
	g/l	0.931	0.745	1.12	Nephelometric (Non IFCC Cal.)
	mg/dl	93.1	74.5	112	
	g/l	0.972	0.778	1.17	Turbidimetric (Non IFCC Cal.)
Complement C4	mg/dl	97.2	77.8	117	
	g/l	0.940	0.752	1.13	Vitros 5.1 FS microtip assay
	mg/dl	94.0	75.2	113	
	g/l	0.175	0.140	0.210	Turbidimetric (IFCC Cal.)
	mg/dl	17.5	14.0	21.0	
	g/l	0.186	0.149	0.223	Nephelometric (IFCC Cal.)
	mg/dl	18.6	14.9	22.3	
	g/l	0.181	0.145	0.217	Nephelometric (Non IFCC Cal.)
Ferritin	mg/dl	18.1	14.5	21.7	
	g/l	0.167	0.134	0.200	Turbidimetric (Non IFCC Cal.)
	mg/dl	16.7	13.4	20.0	
	g/l	0.181	0.145	0.217	Vitros 5.1 FS microtip assay
Free Lambda Light Chains	mg/dl	18.1	14.5	21.7	
	mg/L	7.74	6.19	9.29	Nephelometric - Binding Site
	mg/L	8.90	7.12	10.7	Nephelometric - Siemens
	mg/L	7.09	5.67	8.51	Turbidimetric
Haptoglobin	g/l	0.548	0.438	0.658	Nephelometric (IFCC Cal.)
	mg/dl	54.8	43.8	65.8	
	g/l	0.575	0.460	0.690	Turbidimetric (IFCC Cal.)
	mg/dl	57.5	46.0	69.0	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 666LPC Size 3 x 1ml Expiry 2024-06-28

Range					
Analyte	unit	Target	low	high	methods
Haptoglobin	g/l	0.585	0.468	0.702	Turbidimetric (Non IFCC Cal.)
	mg/dl	58.5	46.8	70.2	
Immunoglobulin A	g/l	1.63	1.22	2.04	Turbidimetric (IFCC Cal.)
	mg/dl	163	122	204	
	g/l	1.61	1.21	2.01	Nephelometric (IFCC Cal.)
	mg/dl	161	121	201	
	g/l	1.59	1.19	1.99	Nephelometric (Non IFCC Cal.)
	mg/dl	159	119	199	
	g/l	1.61	1.21	2.01	Turbidimetric (Non IFCC Cal.)
	mg/dl	161	121	201	
Immunoglobulin E	g/l	1.62	1.22	2.03	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	162	122	202	
Immunoglobulin E	KIU/l = IU/ml	86.9	69.5	104	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	74.4	59.5	89.3	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	68.5	54.8	82.2	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	8.52	6.99	10.1	Turbidimetric (IFCC Cal.)
	mg/dl	852	699	1005	
	g/l	8.43	6.91	9.95	Nephelometric (IFCC Cal.)
	mg/dl	843	691	995	
	g/l	8.42	6.90	9.94	Nephelometric (Non IFCC Cal.)
	mg/dl	842	690	994	
	g/l	8.57	7.03	10.1	Turbidimetric (Non IFCC Cal.)
	mg/dl	857	703	1011	
Immunoglobulin G	g/l	8.78	7.20	10.4	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	878	720	1036	
Immunoglobulin M	g/l	0.667	0.534	0.800	Turbidimetric (IFCC Cal.)
	mg/dl	66.7	53.4	80.0	
	g/l	0.706	0.565	0.847	Nephelometric (IFCC Cal.)
	mg/dl	70.6	56.5	84.7	
	g/l	0.688	0.550	0.826	Nephelometric (Non IFCC Cal.)
	mg/dl	68.8	55.0	82.6	
	g/l	0.660	0.528	0.792	Turbidimetric (Non IFCC Cal.)
	mg/dl	66.0	52.8	79.2	
Immunoglobulin M	g/l	0.702	0.562	0.842	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	70.2	56.2	84.2	
Kappa Light Chain	g/l	1.99	1.59	2.39	Nephelometric - Siemens
	mg/dl	199	159	239	
	g/l	2.00	1.60	2.40	Turbidimetric
	mg/dl	200	160	240	
Lambda Light Chain	g/l	3.73	2.98	4.48	Nephelometric - Beckman
	mg/dl	373	298	448	
	g/l	1.13	0.900	1.36	Nephelometric - Siemens
	mg/dl	113	90.0	136	
	g/l	1.09	0.870	1.31	Turbidimetric
	mg/dl	109	87.0	131	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 1 (SP CONTROL 1)

Cat. No. PS2682 Lot. No. 666LPC Size 3 x 1ml Expiry 2024-06-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.102	0.082	0.122	Nephelometric (IFCC Cal.)
	mg/dl	10.2	8.20	12.2	
	g/l	0.088	0.070	0.106	Turbidimetric (IFCC Cal.)
	mg/dl	8.80	7.00	10.6	
	g/l	0.093	0.074	0.112	Turbidimetric (Non IFCC Cal.)
	mg/dl	9.30	7.40	11.2	
Protein Total	g/l	40.1	32.1	48.1	Biuret reaction end point
	g/dl	4.01	3.21	4.81	
Retinol Binding Protein	mg/l	21.3	17.0	25.6	Nephelometric (IFCC Cal.)
	mg/l	21.5	17.2	25.8	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	15.6	11.7	19.5	Turbidimetric (Non IFCC Cal.)
	U/ml	14.7	11.0	18.4	Nephelometric (Non IFCC Cal.)
Transferrin	g/l	1.50	1.20	1.80	Turbidimetric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.50	1.20	1.80	Turbidimetric (Non IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.40	1.12	1.68	Nephelometric (IFCC Cal.)
	mg/dl	140	112	168	