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

CAT. NO. PS2682
SIZE: 3 x 1ml
GTIN: 05055273204896
LOT NO. 453LPC
EXPIRY: 2018-02-28

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 Kappa and 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.

PREPARATION
The Liquid Protein Controls are supplied ready for use.

MATERIALS PROVIDED
Liquid Protein Control - Level 1 3 x 1ml

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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Cat. No. PS2682 Lot No. 453LPC Size: 3 x 1ml Expiry: 2018-02-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	17.8	15.1	20.5	Bromocresol Green (IFCC Cal.)
	g/dl	1.78	1.51	2.05	
	g/l	17.8	15.1	20.5	Bromocresol Purple (IFCC Cal.)
	g/dl	1.78	1.51	2.05	
	g/l	18.7	15.9	21.5	Nephelometric (IFCC Cal.)
	g/dl	1.87	1.59	2.15	
	g/l	18.3	15.6	21.0	Bromocresol Green (Non IFCC Cal.)
	g/dl	1.83	1.56	2.10	
	g/l	17.6	15.0	20.2	Bromocresol Purple (Non IFCC Cal.)
	g/dl	1.76	1.50	2.02	
	g/l	18.2	15.5	20.9	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.82	1.55	2.09	
	g/l	18.2	15.5	20.9	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	1.82	1.55	2.09	
Alpha-1-Acid Glycoprotein	g/l	0.501	0.401	0.601	Turbidimetric (IFCC Cal.)
	mg/dl	50.1	40.1	60.1	
	g/l	0.544	0.435	0.653	Nephelometric (IFCC Cal.)
	mg/dl	54.4	43.5	65.3	
	g/l	0.558	0.446	0.670	Nephelometric (Non IFCC Cal.)
	mg/dl	55.8	44.6	67.0	
	g/l	0.495	0.396	0.594	Turbidimetric (Non IFCC Cal.)
	mg/dl	49.5	39.6	59.4	
Alpha-1-Antitrypsin	g/l	0.601	0.481	0.721	Turbidimetric (IFCC Cal.)
	mg/dl	60.1	48.1	72.1	
	g/l	0.622	0.498	0.746	Nephelometric (IFCC Cal.)
	mg/dl	62.2	49.8	74.6	
	g/l	0.629	0.503	0.755	Nephelometric (Non IFCC Cal.)
	mg/dl	62.9	50.3	75.5	
	g/l	0.582	0.466	0.698	Turbidimetric (Non IFCC Cal.)
	mg/dl	58.2	46.6	69.8	
Alpha-2-Macroglobulin	g/l	0.914	0.731	1.10	Turbidimetric (IFCC Cal.)
	mg/dl	91.4	73.1	110	
	g/l	0.849	0.679	1.02	Nephelometric (IFCC Cal.)
	mg/dl	84.9	67.9	102	
	g/l	0.867	0.694	1.04	Nephelometric (Non IFCC Cal.)
	mg/dl	86.7	69.4	104	
	g/l	0.887	0.710	1.06	Turbidimetric (Non IFCC Cal.)
	mg/dl	88.7	71.0	106	
Alphafoetoprotein	KIU/l = IU/ml	15.9	12.7	19.1	Chemiluminescence (IFCC Cal.)
	ng/ml	19.2	15.4	23.0	
	KIU/l = IU/ml	16.0	12.8	19.2	Chemiluminescence (Non IFCC Cal.)
	ng/ml	19.4	15.5	23.3	

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Cat. No. PS2682 Lot No. 453LPC Size: 3 x 1ml Expiry: 2018-02-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Anti Streptolysin O	IU/ml	92.7	69.5	116	Turbidimetric (IFCC Cal.)
	IU/ml	94.6	71.0	118	Turbidimetric (Non IFCC Cal.)
	IU/ml	66.7	50.0	83.4	Neph. Beckman (IFCC Cal.)
	IU/ml	67.3	50.5	84.1	Neph. Beckman (Non IFCC Cal.)
	IU/ml	107	80.3	134	Neph. Behring (IFCC Cal.)
	IU/ml	105	78.8	131	Neph. Behring (Non IFCC Cal.)
Antithrombin III	mg/l	98.4	73.8	123	Turbidimetric (IFCC Cal.)
	mg/dl	9.84	7.38	12.3	
Beta-2-microglobulin	µg/ml = mg/l	1.70	1.36	2.04	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	1.73	1.38	2.08	Chemiluminescence (Non IFCC Cal.)
	µg/ml = mg/l	1.59	1.27	1.91	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.75	1.40	2.10	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.82	1.46	2.18	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.79	1.43	2.15	Turbidimetric (Non IFCC Cal.)
	µg/ml = mg/l	1.59	1.27	1.91	Randox Immunoturbidimetric
C-Reactive Protein	mg/l	24.5	19.6	29.4	Vitros (IFCC Cal.)
	mg/l	23.8	19.0	28.6	Turbidimetric (IFCC Cal.)
	mg/l	21.3	17.0	25.6	Nephelometric (IFCC Cal.)
	mg/l	26.5	21.2	31.8	Vitros (Non IFCC Cal.)
	mg/l	21.3	17.0	25.6	Nephelometric (Non IFCC Cal.)
	mg/l	23.3	18.6	28.0	Turbidimetric (Non IFCC Cal.)
	mg/l	23.4	18.7	28.1	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.157	0.126	0.188	Nephelometric (IFCC Cal.)
	mg/dl	15.7	12.6	18.8	
	g/l	0.175	0.140	0.210	Turbidimetric (IFCC Cal.)
	mg/dl	17.5	14.0	21.0	
	g/l	0.159	0.127	0.191	Nephelometric (Non IFCC Cal.)
	mg/dl	15.9	12.7	19.1	
	g/l	0.179	0.143	0.215	Turbidimetric (Non IFCC Cal.)
	mg/dl	17.9	14.3	21.5	
	g/l	0.149	0.119	0.179	Neph. Beckman (IFCC Cal.)
	mg/dl	14.9	11.9	17.9	
	g/l	0.175	0.140	0.210	Randox Immunoturbidimetric
	mg/dl	17.5	14.0	21.0	
Complement C3	g/l	0.744	0.595	0.893	Turbidimetric (IFCC Cal.)
	mg/dl	74.4	59.5	89.3	
	g/l	0.752	0.602	0.902	Nephelometric (IFCC Cal.)
	mg/dl	75.2	60.2	90.2	
	g/l	0.770	0.616	0.924	Nephelometric (Non IFCC Cal.)
	mg/dl	77.0	61.6	92.4	
	g/l	0.747	0.598	0.896	Turbidimetric (Non IFCC Cal.)
	mg/dl	74.7	59.8	89.6	
	g/l	0.788	0.630	0.946	Vitros 5.1 FS microtip assay
	mg/dl	78.8	63.0	94.6	
	g/l	0.811	0.649	0.973	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	81.1	64.9	97.3	

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Cat. No. PS2682 Lot.No. 453LPC Size: 3 x 1ml Expiry: 2018-02-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Complement C4	g/l	0.156	0.125	0.187	Turbidimetric (IFCC Cal.)
	mg/dl	15.6	12.5	18.7	
	g/l	0.169	0.135	0.203	Nephelometric (IFCC Cal.)
	mg/dl	16.9	13.5	20.3	
	g/l	0.169	0.135	0.203	Nephelometric (Non IFCC Cal.)
	mg/dl	16.9	13.5	20.3	
	g/l	0.155	0.124	0.186	Turbidimetric (Non IFCC Cal.)
	mg/dl	15.5	12.4	18.6	
	g/l	0.169	0.135	0.203	Vitros 5.1 FS microtip assay
	mg/dl	16.9	13.5	20.3	
Ferritin	ng/ml = µg/l	96.5	77.2	116	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	97.4	77.9	117	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	110	88.0	132	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	119	95.2	143	Chemiluminescence (Non IFCC Cal.)
	ng/ml = µg/l	100	80.0	120	Nephelometric (IFCC Cal.)
Free Kappa Light Chains	mg/L	6.69	5.35	8.03	Nephelometric - Beckman
	mg/L	6.77	5.42	8.12	Nephelometric - Binding Site
	mg/L	3.15	2.52	3.78	Nephelometric - Siemens
	mg/L	6.41	5.13	7.69	Turbidimetric
Free Lambda Light Chains	mg/L	7.13	5.70	8.56	Nephelometric - Beckman
	mg/L	7.89	6.31	9.47	Nephelometric - Binding Site
	mg/L	7.14	5.71	8.57	Nephelometric - Siemens
	mg/L	6.69	5.35	8.03	Turbidimetric
Haptoglobin	g/l	0.508	0.406	0.610	Nephelometric (IFCC Cal.)
	mg/dl	50.8	40.6	61.0	
	g/l	0.503	0.402	0.604	Turbidimetric (IFCC Cal.)
	mg/dl	50.3	40.2	60.4	
	g/l	0.498	0.398	0.598	Nephelometric (Non IFCC Cal.)
	mg/dl	49.8	39.8	59.8	
	g/l	0.506	0.405	0.607	Turbidimetric (Non IFCC Cal.)
	mg/dl	50.6	40.5	60.7	
Immunoglobulin A	g/l	1.47	1.10	1.84	Turbidimetric (IFCC Cal.)
	mg/dl	147	110	184	
	g/l	1.52	1.14	1.90	Nephelometric (IFCC Cal.)
	mg/dl	152	114	190	
	g/l	1.53	1.15	1.91	Nephelometric (Non IFCC Cal.)
	mg/dl	153	115	191	
	g/l	1.47	1.10	1.84	Turbidimetric (Non IFCC Cal.)
	mg/dl	147	110	184	
	g/l	1.52	1.14	1.90	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	152	114	190	
	g/l	1.54	1.16	1.93	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	154	116	192	
Immunoglobulin E	KIU/l = IU/ml	68.9	55.1	82.7	Fluorimetric (Non IFCC Cal.)
	KIU/l = IU/ml	67.4	53.9	80.9	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	64.0	51.2	76.8	Nephelometric (Non IFCC Cal.)

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Cat. No. PS2682 Lot No. 453LPC Size: 3 x 1ml Expiry: 2018-02-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin E	KIU/l = IU/ml	74.9	59.9	89.9	Enzyme Immunoassay (Non IFCC Cal.)
	KIU/l = IU/ml	65.8	52.6	79.0	Turbidimetric (Non IFCC Cal.)
	KIU/l = IU/ml	71.4	57.1	85.7	Randox Immunoturbidimetric
Immunoglobulin G	g/l	7.30	5.99	8.61	Turbidimetric (IFCC Cal.)
	mg/dl	730	599	861	
	g/l	7.59	6.22	8.96	Nephelometric (IFCC Cal.)
	mg/dl	759	622	896	
	g/l	7.56	6.20	8.92	Nephelometric (Non IFCC Cal.)
	mg/dl	756	620	892	
	g/l	7.26	5.95	8.57	Turbidimetric (Non IFCC Cal.)
	mg/dl	726	595	857	
	g/l	8.19	6.72	9.66	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	819	672	966	
	g/l	7.76	6.36	9.16	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	776	636	916	
Immunoglobulin M	g/l	0.584	0.467	0.701	Turbidimetric (IFCC Cal.)
	mg/dl	58.4	46.7	70.1	
	g/l	0.630	0.504	0.756	Nephelometric (IFCC Cal.)
	mg/dl	63.0	50.4	75.6	
	g/l	0.646	0.517	0.775	Nephelometric (Non IFCC Cal.)
	mg/dl	64.6	51.7	77.5	
	g/l	0.596	0.477	0.715	Turbidimetric (Non IFCC Cal.)
	mg/dl	59.6	47.7	71.5	
	g/l	0.658	0.526	0.790	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	65.8	52.6	79.0	
	g/l	0.598	0.478	0.718	Vitros 5.1 FS Microtip (Non IFCC)
	mg/dl	59.8	47.8	71.8	
Kappa Light Chain	g/l	6.13	4.90	7.36	Nephelometric - Beckman
	mg/dl	613	490	736	
	g/l	1.81	1.45	2.17	Nephelometric - Siemens
	mg/dl	181	145	217	
	g/l	1.88	1.50	2.26	Turbidimetric
	mg/dl	188	150	226	
Lambda Light Chain	g/l	3.34	2.67	4.01	Nephelometric - Beckman
	mg/dl	334	267	401	
	g/l	1.02	0.820	1.22	Nephelometric - Siemens
	mg/dl	102	82.0	122	
	g/l	1.05	0.840	1.26	Turbidimetric
	mg/dl	105	84.0	126	
Prealbumin	g/l	0.098	0.069	0.127	Nephelometric (IFCC Cal.)
	mg/dl	9.80	6.90	12.7	
	g/l	0.098	0.069	0.127	Turbidimetric (IFCC Cal.)
	mg/dl	9.80	6.90	12.7	
	g/l	0.096	0.067	0.125	Nephelometric (Non IFCC Cal.)
	mg/dl	9.60	6.70	12.5	
	g/l	0.100	0.070	0.130	Turbidimetric (Non IFCC Cal.)
	mg/dl	10.0	7.00	13.0	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	37.1	29.7	44.5	Biuret reaction end point
	g/dl	3.71	2.97	4.45	
Retinol Binding Protein	mg/l	16.5	13.2	19.8	Nephelometric (IFCC Cal.)
	mg/l	16.8	13.4	20.2	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	22.1	17.7	26.5	Turbidimetric (Non IFCC Cal.)
	U/ml	19.2	15.4	23.0	Neph. Behring (Non IFCC Cal.)
	U/ml	<20.0	-	-	Neph. Beckman (Non IFCC Cal.)
Transferrin	g/l	1.48	1.18	1.78	Turbidimetric (IFCC Cal.)
	mg/dl	148	118	178	
	g/l	1.50	1.20	1.80	Turbidimetric (Non IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.50	1.20	1.80	Nephelometric (IFCC Cal.)
	mg/dl	150	120	180	
	g/l	1.52	1.22	1.82	Nephelometric (Non IFCC Cal.)
	mg/dl	152	122	182	