RANDOX

PRODUCT INFORMATION

PS2684

586LPC

Please note that while Antithrombin III is present in PS2684 - Liquid Assayed Specific Protein Control Level 3 - lot 586LPC, targets and ranges are not available for this analyte.

CCS6790

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

CAT. NO. PS2684 **LOT NO.** 586LPC
SIZE: 3 x 1 ml **EXPIRY:** 2023-06-28
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. 586LPC Size: 3 x 1 ml Expiry: 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	63.8	54.2	73.4	Bromocresol Green (IFCC Cal.)
	g/dl	6.38	5.42	7.34	
	g/l	65.8	55.9	75.7	Bromocresol Purple (IFCC Cal.)
	g/dl	6.58	5.59	7.57	
	g/l	65.2	55.4	75.0	Nephelometric (IFCC Cal.)
	g/dl	6.52	5.54	7.50	
	g/l	67.4	57.3	77.5	Bromocresol Green (Non IFCC Cal.)
	g/dl	6.74	5.73	7.75	
	g/l	65.9	56.0	75.8	Turbidimetric Assays (IFCC Cal.)
	g/dl	6.59	5.60	7.58	
Alpha-1-Acid Glycoprotein	g/l	1.44	1.15	1.73	Turbidimetric (IFCC Cal.)
	mg/dl	144	115	173	
	g/l	1.53	1.22	1.84	Nephelometric (IFCC Cal.)
	mg/dl	153	122	184	
	g/l	1.50	1.20	1.80	Turbidimetric (Non IFCC Cal.)
	mg/dl	150	120	180	
Alpha-1-Antitrypsin	g/l	1.98	1.58	2.38	Turbidimetric (IFCC Cal.)
	mg/dl	198	158	238	
	g/l	2.11	1.69	2.53	Nephelometric (IFCC Cal.)
	mg/dl	211	169	253	
	g/l	1.97	1.58	2.36	Turbidimetric (Non IFCC Cal.)
	mg/dl	197	158	236	
Alpha-2-Macroglobulin	g/l	3.10	2.48	3.72	Nephelometric (IFCC Cal.)
	mg/dl	310	248	372	
Alpha-fetoprotein	KIU/l = IU/ml	42.9	34.3	51.5	Chemiluminescence (IFCC Cal.)
	ng/ml	51.9	41.5	62.3	
	KIU/l = IU/ml	43.1	34.5	51.7	Chemiluminescence (Non IFCC Cal.)
	ng/ml	52.2	41.7	62.7	
Anti Streptolysin O	IU/ml	335	268	402	Turbidimetric (IFCC Cal.)
	IU/ml	349	279	419	Turbidimetric (Non IFCC Cal.)
	IU/ml	221	177	265	Neph. Beckman (IFCC Cal.)
	IU/ml	352	282	422	Siemens Nephelometric (IFCC Cal.)
	IU/ml	345	276	414	Siemens Nephelometric (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	5.00	4.00	6.00	Chemiluminescence (IFCC Cal.)
	µg/ml = mg/l	4.63	3.70	5.56	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	4.60	3.68	5.52	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	5.30	4.24	6.36	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	5.19	4.15	6.23	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	45.9	36.7	55.1	Vitros (IFCC Cal.)
	mg/l	72.5	58.0	87.0	Turbidimetric (IFCC Cal.)
	mg/l	71.2	57.0	85.4	Nephelometric (IFCC Cal.)
	mg/l	72.3	57.8	86.8	Turbidimetric (Non IFCC Cal.)

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

Cat. No. PS2684 Lot No. 586LPC Size: 3 x 1 ml Expiry: 2023-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
C-Reactive Protein	mg/l	75.3	60.2	90.4	Beckman Turb Latex (IFCC Cal)
Caeruloplasmin	g/l	0.605	0.454	0.756	Nephelometric (IFCC Cal.)
	mg/dl	60.5	45.4	75.6	
	g/l	0.496	0.372	0.620	Turbidimetric (IFCC Cal.)
	mg/dl	49.6	37.2	62.0	
	g/l	0.540	0.405	0.675	Nephelometric (Non IFCC Cal.)
	mg/dl	54.0	40.5	67.5	
	g/l	0.468	0.351	0.585	Turbidimetric (Non IFCC Cal.)
	mg/dl	46.8	35.1	58.5	
Complement C3	g/l	2.54	2.03	3.05	Turbidimetric (IFCC Cal.)
	mg/dl	254	203	305	
	g/l	2.52	2.02	3.02	Nephelometric (IFCC Cal.)
	mg/dl	252	202	302	
	g/l	2.51	2.01	3.01	Nephelometric (Non IFCC Cal.)
	mg/dl	251	201	301	
	g/l	2.62	2.10	3.14	Turbidimetric (Non IFCC Cal.)
	mg/dl	262	210	314	
	g/l	2.56	2.05	3.07	Vitros 5.1 FS microtip assay
	mg/dl	256	205	307	
Complement C4	g/l	0.429	0.343	0.515	Turbidimetric (IFCC Cal.)
	mg/dl	42.9	34.3	51.5	
	g/l	0.454	0.363	0.545	Nephelometric (IFCC Cal.)
	mg/dl	45.4	36.3	54.5	
	g/l	0.440	0.352	0.528	Nephelometric (Non IFCC Cal.)
	mg/dl	44.0	35.2	52.8	
	g/l	0.410	0.328	0.492	Turbidimetric (Non IFCC Cal.)
	mg/dl	41.0	32.8	49.2	
	g/l	0.437	0.350	0.524	Vitros 5.1 FS microtip assay
	mg/dl	43.7	35.0	52.4	
Ferritin	ng/ml = µg/l	264	211	317	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	267	214	320	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	343	274	412	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	349	279	419	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	19.1	15.3	22.9	Nephelometric - Binding Site
	mg/L	17.6	14.1	21.1	Nephelometric - Siemens
	mg/L	16.0	12.8	19.2	Turbidimetric
Haptoglobin	g/l	1.55	1.24	1.86	Nephelometric (IFCC Cal.)
	mg/dl	155	124	186	
	g/l	1.58	1.26	1.90	Turbidimetric (IFCC Cal.)
	mg/dl	158	126	190	
	g/l	1.58	1.26	1.90	Nephelometric (Non IFCC Cal.)
	mg/dl	158	126	190	
	g/l	1.60	1.28	1.92	Turbidimetric (Non IFCC Cal.)
	mg/dl	160	128	192	
Immunoglobulin A	g/l	4.52	3.39	5.65	Turbidimetric (IFCC Cal.)
	mg/dl	452	339	565	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin A	g/l	4.87	3.65	6.09	Nephelometric (IFCC Cal.)
	mg/dl	487	365	609	
	g/l	4.68	3.51	5.85	Nephelometric (Non IFCC Cal.)
	mg/dl	468	351	585	
	g/l	4.54	3.41	5.68	Turbidimetric (Non IFCC Cal.)
	mg/dl	454	341	567	
	g/l	4.70	3.53	5.88	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	470	353	587	
Immunoglobulin E	KIU/l = IU/ml	255	204	306	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	239	191	287	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	225	180	270	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	23.5	19.3	27.7	Turbidimetric (IFCC Cal.)
	mg/dl	2350	1930	2770	
	g/l	23.5	19.3	27.7	Nephelometric (IFCC Cal.)
	mg/dl	2350	1930	2770	
	g/l	22.8	18.7	26.9	Nephelometric (Non IFCC Cal.)
	mg/dl	2280	1870	2690	
	g/l	23.6	19.4	27.8	Turbidimetric (Non IFCC Cal.)
	mg/dl	2360	1940	2780	
	g/l	24.9	20.4	29.4	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	2490	2040	2940	
Immunoglobulin M	g/l	1.77	1.42	2.12	Turbidimetric (IFCC Cal.)
	mg/dl	177	142	212	
	g/l	1.94	1.55	2.33	Nephelometric (IFCC Cal.)
	mg/dl	194	155	233	
	g/l	1.88	1.50	2.26	Nephelometric (Non IFCC Cal.)
	mg/dl	188	150	226	
	g/l	1.79	1.43	2.15	Turbidimetric (Non IFCC Cal.)
	mg/dl	179	143	215	
	g/l	1.75	1.40	2.10	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	175	140	210	
Kappa Light Chain	g/l	19.1	15.3	22.9	Nephelometric - Beckman
	mg/dl	1910	1530	2290	
	g/l	5.71	4.57	6.85	Nephelometric - Siemens
	mg/dl	571	457	685	
	g/l	5.86	4.69	7.03	Turbidimetric
	mg/dl	586	469	703	
Lambda Light Chain	g/l	10.5	8.42	12.6	Nephelometric - Beckman
	mg/dl	1053	842	1260	
	g/l	3.05	2.44	3.66	Nephelometric - Siemens
	mg/dl	305	244	366	
	g/l	3.32	2.66	3.98	Turbidimetric
	mg/dl	332	266	398	
Prealbumin	g/l	0.431	0.345	0.517	Nephelometric (IFCC Cal.)
	mg/dl	43.1	34.5	51.7	
	g/l	0.399	0.319	0.479	Turbidimetric (IFCC Cal.)
	mg/dl	39.9	31.9	47.9	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prealbumin	g/l	0.409	0.327	0.491	Turbidimetric (Non IFCC Cal.)
	mg/dl	40.9	32.7	49.1	
Protein Total	g/l	102	81.6	122	Biuret reaction end point
	g/dl	10.2	8.16	12.2	
Retinol Binding Protein	mg/l	65.1	52.1	78.1	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	46.2	34.7	57.8	Turbidimetric (Non IFCC Cal.)
	U/ml	39.2	29.4	49.0	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	4.65	3.72	5.58	Turbidimetric (IFCC Cal.)
	mg/dl	465	372	558	
	g/l	4.73	3.78	5.68	Turbidimetric (Non IFCC Cal.)
	mg/dl	473	378	568	
	g/l	4.66	3.73	5.59	Nephelometric (IFCC Cal.)
	mg/dl	466	373	559	

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