

PRODUCT INFORMATION

PS2683

616LPC

Please note that while Antithrombin III is present in PS2683 - Liquid Assayed Specific Protein Control Level 2 - lot 616LPC, targets and ranges are not available for this analyte at this time and will be added in due course.

INC111 (OCC106)

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

CAT. NO. PS2683

LOT NO. 616LPC

SIZE: 3 x 1ml

EXPIRY: 2022-11-28

GTIN: 05055273204902

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 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 2 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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LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 616LPC Size: 3 x 1 ml Expiry: 2022-11-28

Analyte	unit	Target	Range		methods
			low	high	
Albumin	g/l	40.6	34.5	46.7	Bromocresol Green (IFCC Cal.)
	g/dl	4.06	3.45	4.67	
	g/l	40.8	34.7	46.9	Bromocresol Purple (IFCC Cal.)
	g/dl	4.08	3.47	4.69	
	g/l	41.7	35.4	48.0	Nephelometric (IFCC Cal.)
	g/dl	4.17	3.54	4.80	
	g/l	41.6	35.4	47.8	Bromocresol Green (Non IFCC Cal.)
	g/dl	4.16	3.54	4.78	
	g/l	41.0	34.9	47.2	Turbidimetric Assays (IFCC Cal.)
	g/dl	4.10	3.49	4.71	
g/l	41.3	35.1	47.5	Turbidimetric Assays (Non IFCC Cal.)	
g/dl	4.13	3.51	4.75		
Alpha-1-Acid Glycoprotein	g/l	0.874	0.699	1.05	Turbidimetric (IFCC Cal.)
	mg/dl	87.4	69.9	105	Nephelometric (IFCC Cal.)
	g/l	0.888	0.710	1.07	
	mg/dl	88.8	71.0	107	
	g/l	0.893	0.714	1.07	Turbidimetric (Non IFCC Cal.)
mg/dl	89.3	71.4	107		
Alpha-1-Antitrypsin	g/l	1.17	0.936	1.40	Turbidimetric (IFCC Cal.)
	mg/dl	117	93.6	140	Nephelometric (IFCC Cal.)
	g/l	1.20	0.960	1.44	
	mg/dl	120	96.0	144	
	g/l	1.17	0.936	1.40	Turbidimetric (Non IFCC Cal.)
mg/dl	117	93.6	140		
Alpha-2-Macroglobulin	g/l	1.92	1.54	2.30	Nephelometric (IFCC Cal.)
	mg/dl	192	154	230	
Alpha-fetoprotein	KIU/l = IU/ml	31.1	24.9	37.3	Chemiluminescence (IFCC Cal.)
	ng/ml	37.6	30.1	45.1	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	30.3	24.2	36.4	
	ng/ml	36.7	29.3	44.1	
Anti Streptolysin O	IU/ml	169	135	203	Turbidimetric (IFCC Cal.)
	IU/ml	105	84.0	126	Neph. Beckman (IFCC Cal.)
	IU/ml	109	87.2	131	Neph. Beckman (Non IFCC Cal.)
	IU/ml	173	138	208	Siemens Nephelometric (Non IFCC Cal.)
	IU/ml	175	140	210	Siemens Nephelometric (IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	2.97	2.38	3.56	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	2.95	2.36	3.54	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	3.57	2.86	4.28	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	3.44	2.75	4.13	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	37.4	29.9	44.9	Vitros (IFCC Cal.)
	mg/l	45.9	36.7	55.1	Turbidimetric (IFCC Cal.)
	mg/l	44.1	35.3	52.9	Nephelometric (IFCC Cal.)

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 616LPC Size: 3 x 1 ml Expiry: 2022-11-28

Range						
Analyte	unit	Target	low	high	methods	
C-Reactive Protein	mg/l	46.4	37.1	55.7	Turbidimetric (Non IFCC Cal.)	
	mg/l	47.2	37.8	56.6	Beckman Turb Latex (IFCC Cal)	
	mg/l	45.3	36.2	54.4	Roche Turbidimetric	
Caeruloplasmin	g/l	0.344	0.258	0.430	Nephelometric (IFCC Cal.)	
	mg/dl	34.4	25.8	43.0		
	g/l	0.323	0.242	0.404	Turbidimetric (IFCC Cal.)	
	mg/dl	32.3	24.2	40.4		
	g/l	0.337	0.253	0.421	Nephelometric (Non IFCC Cal.)	
	mg/dl	33.7	25.3	42.1		
Complement C3	g/l	1.53	1.22	1.84	Turbidimetric (IFCC Cal.)	
	mg/dl	153	122	184		
	g/l	1.48	1.18	1.78	Nephelometric (IFCC Cal.)	
	mg/dl	148	118	178		
	g/l	1.57	1.26	1.88	Nephelometric (Non IFCC Cal.)	
	mg/dl	157	126	188		
Complement C4	g/l	1.58	1.26	1.90	Turbidimetric (Non IFCC Cal.)	
	mg/dl	158	126	190		
	g/l	1.53	1.22	1.84	Vitros 5.1 FS microtip assay	
	mg/dl	153	122	184		
	Complement C4	g/l	0.280	0.224	0.336	Turbidimetric (IFCC Cal.)
		mg/dl	28.0	22.4	33.6	
g/l		0.294	0.235	0.353	Nephelometric (IFCC Cal.)	
mg/dl		29.4	23.5	35.3		
g/l		0.273	0.218	0.328	Nephelometric (Non IFCC Cal.)	
mg/dl		27.3	21.8	32.8		
Ferritin	g/l	0.267	0.214	0.320	Turbidimetric (Non IFCC Cal.)	
	mg/dl	26.7	21.4	32.0		
	g/l	0.290	0.232	0.348	Vitros 5.1 FS microtip assay	
	mg/dl	29.0	23.2	34.8		
	Ferritin	ng/ml = µg/l	180	144	216	Turbidimetric (IFCC Cal.)
		ng/ml = µg/l	159	127	191	Turbidimetric (Non IFCC Cal.)
ng/ml = µg/l		217	174	260	Chemiluminescence (IFCC Cal.)	
ng/ml = µg/l		212	170	254	Chemiluminescence (Non IFCC Cal.)	
ng/ml = µg/l		153	122	184	Nephelometric (IFCC Cal.)	
Free Lambda Light Chains	mg/L	14.0	11.2	16.8	Nephelometric - Binding Site	
	mg/L	11.3	9.04	13.6	Nephelometric - Siemens	
	mg/L	12.3	9.84	14.8	Turbidimetric	
Haptoglobin	g/l	0.875	0.700	1.05	Nephelometric (IFCC Cal.)	
	mg/dl	87.5	70.0	105		
	g/l	0.888	0.710	1.07	Turbidimetric (IFCC Cal.)	
	mg/dl	88.8	71.0	107		
Haptoglobin	g/l	0.888	0.710	1.07	Turbidimetric (Non IFCC Cal.)	
	mg/dl	88.8	71.0	107		
	Immunoglobulin A	g/l	2.79	2.09	3.49	Turbidimetric (IFCC Cal.)
		mg/dl	279	209	349	

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Analyte	unit	Target	Range		methods
			low	high	
Immunoglobulin A	g/l	2.97	2.23	3.71	Nephelometric (IFCC Cal.)
	mg/dl	297	223	371	
	g/l	2.92	2.19	3.65	Nephelometric (Non IFCC Cal.)
	mg/dl	292	219	365	
	g/l	2.82	2.12	3.53	Turbidimetric (Non IFCC Cal.)
	mg/dl	282	212	352	
	g/l	3.00	2.25	3.75	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	300	225	375	
Immunoglobulin E	KIU/l = IU/ml	175	140	210	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	157	126	188	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	153	122	184	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	13.2	10.8	15.6	Turbidimetric (IFCC Cal.)
	mg/dl	1320	1080	1560	
	g/l	13.7	11.2	16.2	Nephelometric (IFCC Cal.)
	mg/dl	1370	1120	1620	
	g/l	13.4	11.0	15.8	Nephelometric (Non IFCC Cal.)
	mg/dl	1340	1100	1580	
	g/l	13.4	11.0	15.8	Turbidimetric (Non IFCC Cal.)
	mg/dl	1340	1100	1580	
Immunoglobulin M	g/l	14.9	12.2	17.6	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	1490	1220	1760	
	g/l	1.08	0.864	1.30	Turbidimetric (IFCC Cal.)
	mg/dl	108	86.4	130	
	g/l	1.14	0.912	1.37	Nephelometric (IFCC Cal.)
	mg/dl	114	91.2	137	
	g/l	1.12	0.896	1.34	Nephelometric (Non IFCC Cal.)
	mg/dl	112	89.6	134	
Kappa Light Chain	g/l	1.07	0.856	1.28	Turbidimetric (Non IFCC Cal.)
	mg/dl	107	85.6	128	
	g/l	1.11	0.888	1.33	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	111	88.8	133	
	g/l	11.2	8.98	13.5	Nephelometric - Beckman
	mg/dl	1123	898	1350	
Lambda Light Chain	g/l	3.22	2.58	3.86	Nephelometric - Siemens
	mg/dl	322	258	386	
	g/l	3.38	2.70	4.06	Turbidimetric
	mg/dl	338	270	406	
Prealbumin	g/l	6.02	4.82	7.22	Nephelometric - Beckman
	mg/dl	602	482	722	
	g/l	1.82	1.46	2.18	Nephelometric - Siemens
	mg/dl	182	146	218	
Prealbumin	g/l	1.86	1.49	2.23	Turbidimetric
	mg/dl	186	149	223	
Prealbumin	g/l	0.228	0.182	0.274	Nephelometric (IFCC Cal.)
	mg/dl	22.8	18.2	27.4	

LIQUID ASSAYED SPECIFIC PROTEIN CONTROL - LEVEL 2 (SP CONTROL 2)

Cat. No. PS2683 Lot No. 616LPC Size 3 x 1ml Expiry: 2022-11-28

Range					
Analyte	unit	Target	low	high	methods
Prealbumin	g/l	0.228	0.182	0.274	Turbidimetric (IFCC Cal.)
	mg/dl	22.8	18.2	27.4	
	g/l	0.228	0.182	0.274	Turbidimetric (Non IFCC Cal.)
	mg/dl	22.8	18.2	27.4	
Protein Total	g/l	64.0	51.2	76.8	Biuret reaction end point
	g/dl	6.40	5.12	7.68	
Retinol Binding Protein	mg/l	37.0	29.6	44.4	Nephelometric (IFCC Cal.)
	mg/l	36.3	29.0	43.6	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	30.9	23.2	38.6	Turbidimetric (Non IFCC Cal.)
	U/ml	27.1	20.3	33.9	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	2.70	2.16	3.24	Turbidimetric (IFCC Cal.)
	mg/dl	270	216	324	
	g/l	2.73	2.18	3.28	Turbidimetric (Non IFCC Cal.)
	mg/dl	273	218	328	
	g/l	2.66	2.13	3.19	Nephelometric (IFCC Cal.)
mg/dl	266	213	319		