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PRODUCT INFORMATION

PS2682

636LPC

Please note that while Antithrombin III is present in PS2682 - Liquid Assayed Specific Protein Control Level 1 - lot 636LPC, targets and ranges are not available for this analyte at this time and will be added in due course.

INC111 (OCC106)

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

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

CAT. NO. PS2682
SIZE: 3 x 1 ml
GTIN: 05055273204896
LOT NO. 636LPC
EXPIRY: 2023-01-28

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 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 1 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

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Dungloe, Donegal,
F94 TV06, Ireland

Rev. 18 Nov '22 me

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

Cat. No. PS2682 Lot No. 636LPC Size: 3 x 1 ml Expiry: 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	18.3	15.6	21.0	Bromocresol Green (IFCC Cal.)
	g/dl	1.83	1.56	2.10	
	g/l	17.4	14.8	20.0	Bromocresol Purple (IFCC Cal.)
	g/dl	1.74	1.48	2.00	
	g/l	18.3	15.6	21.0	Nephelometric (IFCC Cal.)
	g/dl	1.83	1.56	2.10	
	g/l	18.5	15.7	21.3	Bromocresol Green (Non IFCC Cal.)
	g/dl	1.85	1.57	2.13	
	g/l	18.1	15.4	20.8	Turbidimetric Assays (IFCC Cal.)
	g/dl	1.81	1.54	2.08	
	g/l	17.7	15.0	20.4	Turbidimetric Assays (Non IFCC Cal.)
	g/dl	1.77	1.50	2.04	
Alpha-1-Acid Glycoprotein	g/l	0.359	0.287	0.431	Turbidimetric (IFCC Cal.)
	mg/dl	35.9	28.7	43.1	
	g/l	0.390	0.312	0.468	Nephelometric (IFCC Cal.)
	mg/dl	39.0	31.2	46.8	
	g/l	0.347	0.278	0.416	Turbidimetric (Non IFCC Cal.)
	mg/dl	34.7	27.8	41.6	
Alpha-1-Antitrypsin	g/l	0.507	0.406	0.608	Turbidimetric (IFCC Cal.)
	mg/dl	50.7	40.6	60.8	
	g/l	0.516	0.413	0.619	Nephelometric (IFCC Cal.)
	mg/dl	51.6	41.3	61.9	
	g/l	0.529	0.423	0.635	Turbidimetric (Non IFCC Cal.)
	mg/dl	52.9	42.3	63.5	
Alpha-2-Macroglobulin	g/l	0.882	0.706	1.06	Turbidimetric (IFCC Cal.)
	mg/dl	88.2	70.6	106	
	g/l	0.828	0.662	0.994	Nephelometric (IFCC Cal.)
	mg/dl	82.8	66.2	99.4	
Alpha-fetoprotein	KIU/l = IU/ml	12.9	10.3	15.5	Chemiluminescence (IFCC Cal.)
	ng/ml	15.6	12.5	18.7	
	KIU/l = IU/ml	13.1	10.5	15.7	Chemiluminescence (Non IFCC Cal.)
	ng/ml	15.9	12.7	19.1	
Anti Streptolysin O	IU/ml	71.0	56.8	85.2	Turbidimetric (IFCC Cal.)
	IU/ml	75.4	60.3	90.5	Turbidimetric (Non IFCC Cal.)
	IU/ml	56.4	45.1	67.7	Neph. Beckman (IFCC Cal.)
	IU/ml	82.2	65.8	98.6	Siemens Nephelometric (IFCC Cal.)
	IU/ml	81.0	64.8	97.2	Siemens Nephelometric (Non IFCC Cal.)
Beta-2-microglobulin	µg/ml = mg/l	1.29	1.03	1.55	Nephelometric (IFCC Cal.)
	µg/ml = mg/l	1.31	1.05	1.57	Nephelometric (Non IFCC Cal.)
	µg/ml = mg/l	1.58	1.26	1.90	Turbidimetric (IFCC Cal.)
	µg/ml = mg/l	1.58	1.26	1.90	Turbidimetric (Non IFCC Cal.)
C-Reactive Protein	mg/l	19.1	15.3	22.9	Vitros (IFCC Cal.)

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Cat. No. PS2682 Lot No. 636LPC Size: 3 x 1 ml Expiry: 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
C-Reactive Protein	mg/l	20.3	16.2	24.4	Turbidimetric (IFCC Cal.)
	mg/l	18.6	14.9	22.3	Nephelometric (IFCC Cal.)
	mg/l	19.9	15.9	23.9	Turbidimetric (Non IFCC Cal.)
	mg/l	18.7	15.0	22.4	Beckman Turb Latex (IFCC Cal)
	mg/l	18.1	14.5	21.7	Roche Turbidimetric IFCC
Caeruloplasmin	g/l	0.140	0.105	0.175	Nephelometric (IFCC Cal.)
	mg/dl	14.0	10.5	17.5	
	g/l	0.145	0.109	0.181	Nephelometric (Non IFCC Cal.)
	mg/dl	14.5	10.9	18.1	
	g/l	0.104	0.078	0.130	Turbidimetric (Non IFCC Cal.)
	mg/dl	10.4	7.80	13.0	
Complement C3	g/l	0.672	0.538	0.806	Turbidimetric (IFCC Cal.)
	mg/dl	67.2	53.8	80.6	
	g/l	0.632	0.506	0.758	Nephelometric (IFCC Cal.)
	mg/dl	63.2	50.6	75.8	
	g/l	0.661	0.529	0.793	Nephelometric (Non IFCC Cal.)
	mg/dl	66.1	52.9	79.3	
	g/l	0.685	0.548	0.822	Turbidimetric (Non IFCC Cal.)
	mg/dl	68.5	54.8	82.2	
	g/l	0.701	0.561	0.841	Vitros 5.1 FS microtip assay
	mg/dl	70.1	56.1	84.1	
Complement C4	g/l	0.119	0.095	0.143	Turbidimetric (IFCC Cal.)
	mg/dl	11.9	9.50	14.3	
	g/l	0.128	0.102	0.154	Nephelometric (IFCC Cal.)
	mg/dl	12.8	10.2	15.4	
	g/l	0.119	0.095	0.143	Nephelometric (Non IFCC Cal.)
	mg/dl	11.9	9.50	14.3	
	g/l	0.112	0.090	0.134	Turbidimetric (Non IFCC Cal.)
	mg/dl	11.2	9.00	13.4	
	g/l	0.127	0.102	0.152	Vitros 5.1 FS microtip assay
	mg/dl	12.7	10.2	15.2	
Ferritin	ng/ml = µg/l	81.0	64.8	97.2	Turbidimetric (IFCC Cal.)
	ng/ml = µg/l	71.4	57.1	85.7	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	95.9	76.7	115	Chemiluminescence (IFCC Cal.)
	ng/ml = µg/l	94.9	75.9	114	Chemiluminescence (Non IFCC Cal.)
Free Lambda Light Chains	mg/L	6.43	5.14	7.72	Nephelometric - Binding Site
	mg/L	5.79	4.63	6.95	Nephelometric - Siemens
	mg/L	6.19	4.95	7.43	Turbidimetric
Haptoglobin	g/l	0.373	0.298	0.448	Nephelometric (IFCC Cal.)
	mg/dl	37.3	29.8	44.8	
	g/l	0.392	0.314	0.470	Turbidimetric (IFCC Cal.)
	mg/dl	39.2	31.4	47.0	
	g/l	0.395	0.316	0.474	Turbidimetric (Non IFCC Cal.)
	mg/dl	39.5	31.6	47.4	
Immunoglobulin A	g/l	1.28	0.960	1.60	Turbidimetric (IFCC Cal.)
	mg/dl	128	96.0	160	

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Cat. No. PS2682 Lot No. 636LPC Size: 3 x 1 ml Expiry: 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Immunoglobulin A	g/l	1.29	0.968	1.61	Nephelometric (IFCC Cal.)
	mg/dl	129	96.8	161	
	g/l	1.27	0.953	1.59	Nephelometric (Non IFCC Cal.)
	mg/dl	127	95.3	159	
	g/l	1.25	0.938	1.56	Turbidimetric (Non IFCC Cal.)
	mg/dl	125	93.8	156	
	g/l	1.30	0.975	1.63	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	130	97.5	163	
Immunoglobulin E	KIU/l = IU/ml	76.4	61.1	91.7	Chemiluminescence (Non IFCC Cal.)
	KIU/l = IU/ml	74.1	59.3	88.9	Nephelometric (Non IFCC Cal.)
	KIU/l = IU/ml	66.8	53.4	80.2	Turbidimetric (Non IFCC Cal.)
Immunoglobulin G	g/l	5.85	4.80	6.90	Turbidimetric (IFCC Cal.)
	mg/dl	585	480	690	
	g/l	5.93	4.86	7.00	Nephelometric (IFCC Cal.)
	mg/dl	593	486	700	
	g/l	5.95	4.88	7.02	Nephelometric (Non IFCC Cal.)
	mg/dl	595	488	702	
	g/l	5.89	4.83	6.95	Turbidimetric (Non IFCC Cal.)
	mg/dl	589	483	695	
	g/l	6.64	5.44	7.84	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	664	544	784	
Immunoglobulin M	g/l	0.475	0.380	0.570	Turbidimetric (IFCC Cal.)
	mg/dl	47.5	38.0	57.0	
	g/l	0.490	0.392	0.588	Nephelometric (IFCC Cal.)
	mg/dl	49.0	39.2	58.8	
	g/l	0.494	0.395	0.593	Nephelometric (Non IFCC Cal.)
	mg/dl	49.4	39.5	59.3	
	g/l	0.471	0.377	0.565	Turbidimetric (Non IFCC Cal.)
	mg/dl	47.1	37.7	56.5	
	g/l	0.490	0.392	0.588	Vitros 5.1 FS Microtip (IFCC)
	mg/dl	49.0	39.2	58.8	
Kappa Light Chain	g/l	4.99	3.99	5.99	Nephelometric - Beckman
	mg/dl	499	399	599	
	g/l	1.43	1.14	1.72	Nephelometric - Siemens
	mg/dl	143	114	172	
	g/l	1.46	1.17	1.75	Turbidimetric
	mg/dl	146	117	175	
Lambda Light Chain	g/l	2.73	2.18	3.28	Nephelometric - Beckman
	mg/dl	273	218	328	
	g/l	0.824	0.660	0.990	Nephelometric - Siemens
	mg/dl	82.4	66.0	99.0	
	g/l	0.712	0.570	0.850	Turbidimetric
	mg/dl	71.2	57.0	85.0	
Prealbumin	g/l	0.100	0.080	0.120	Nephelometric (IFCC Cal.)
	mg/dl	10.0	8.00	12.0	
	g/l	0.097	0.078	0.116	Turbidimetric (IFCC Cal.)
	mg/dl	9.70	7.80	11.6	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Prealbumin	g/l	0.100	0.080	0.120	Turbidimetric (Non IFCC Cal.)
	mg/dl	10.0	8.00	12.0	
Protein Total	g/l	33.3	26.6	40.0	Biuret reaction end point
	g/dl	3.33	2.66	4.00	
Retinol Binding Protein	mg/l	15.3	12.2	18.4	Nephelometric (IFCC Cal.)
	mg/l	15.8	12.6	19.0	Nephelometric (Non IFCC Cal.)
Rheumatoid Factor	U/ml	12.4	9.30	15.5	Turbidimetric (Non IFCC Cal.)
	U/ml	12.4	9.30	15.5	Siemens Nephelometric (Non IFCC Cal.)
Transferrin	g/l	1.20	0.960	1.44	Turbidimetric (IFCC Cal.)
	mg/dl	120	96.0	144	
	g/l	1.20	0.960	1.44	Turbidimetric (Non IFCC Cal.)
	mg/dl	120	96.0	144	
	g/l	1.14	0.912	1.37	Nephelometric (IFCC Cal.)
	mg/dl	114	91.2	137	

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