Magnetic Luminex® Performance Assay Human Clusterin Kit

Catalog Number: LHK2937
Pack Size: 100 Tests

SPECIFICATIONS AND USE

Recommended Sample Types
- Serum, EDTA plasma, heparin plasma, and urine.

Microparticle Region
- Region-20

Components
- Microparticle Concentrate (Part 894302) is supplied as a 100X concentrated stock (0.075 mL) with preservatives.
- Biotin-Antibody Concentrate (Part 894313) is supplied as a 100X concentrated stock solution (0.075 mL) with preservatives.

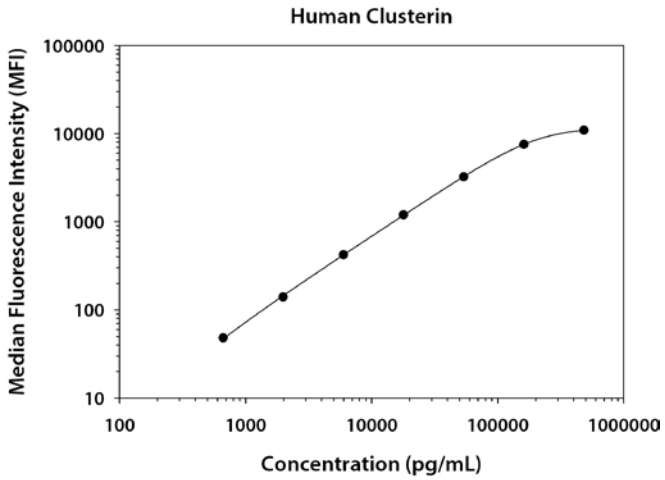
Other Supplies Required
- Magnetic Luminex Performance Assay Human Kidney Biomarker Base Kit (Catalog Number LHK000).

Storage
- Store the unopened kit at 2-8 °C. Do not use past the expiration date on the label.
- **Avoid freezing microparticles.**
- **Protect microparticles from light.**

Instructions for Use
- Refer to the Base Kit insert for the Magnetic Luminex Performance Assay procedure.

TYPICAL DATA

This human Clusterin standard curve is provided only for demonstration. A standard curve must be generated each time an assay is run, utilizing values from the Standard Value Card included in the Base Kit.



Standard	pg/mL	MFI	Average	Corrected
Blank	0	45 45	45	——
1	483,800	10,977 10,990	10,984	10,939
2	161,267	7534 7666	7600	7555
3	53,756	3231 3343	3287	3242
4	17,919	1219 1263	1241	1196
5	5973	464 467	466	421
6	1991	182 187	185	140
7	664	91 95	93	48

PERFORMANCE CHARACTERISTICS

All data were collected with assays run as a multiplex.

Sensitivity - The Minimum Detectable Dose (MDD) was determined by adding two standard deviations to the mean MFI of twenty zero standard replicates and calculating the corresponding concentration.

Thirty-two assays were evaluated, and the MDD of human Clusterin ranged from 22.0-64.3 pg/mL. The mean MDD was 47.0 pg/mL.

CORRELATION

This assay has been correlated to the respective Quantikine® ELISA kit with a slope of 0.9-1.1 and an R^2 value greater than 0.9.

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Intra-assay Precision (precision within an assay) - Three samples of known concentration were tested twenty times on one plate to assess precision within an assay.

Inter-assay Precision (precision between assays) - Three samples of known concentration were tested in separate assays to assess precision between assays. Assays were performed by at least three technicians using two lots of components.

	Intra-assay Precision				Inter-assay Precision		
Sample	1	2	3		1	2	3
n	20	20	20		72	70	72
Mean (pg/mL)	4238	25,590	202,050		3865	24,072	155,466
Standard Deviation	107	292	3663		522	2681	16,631
% CV	2.5	1.1	1.8		13.5	11.1	10.7

Linearity - Samples containing and/or spiked with high concentrations of Clusterin were serially diluted to evaluate assay linearity.

		Serum (n=4)	EDTA plasma (n=4)	Heparin plasma (n=4)	Urine (n=4)
1:2	Average % of Expected	96	99	90	93
	Range (%)	93-98	96-101	89-91	91-95
1:4	Average % of Expected	95	97	93	97
	Range (%)	93-97	95-101	92-94	95-99
1:8	Average % of Expected	96	98	93	97
	Range (%)	94-97	95-104	90-96	96-99

Specificity - This assay recognizes natural and recombinant human Clusterin. The assay was tested for cross-reactivity and interference with the following factors. Less than 0.5% cross-reactivity and interference was observed.

Recombinant human:				Recombinant mouse:	Other recombinants:	Recombinant human multiplex partners:
ApoA1	Cathepsin O	CXCL2/GROβ	HPRG	Clusterin	bovine Osteopontin	Cystatin C
ApoA2	Cathepsin S	CXCL3/GROγ	IFN-γ	Cystatin C		Lipocalin-2/NGAL
ApoB	Cathepsin V	CXCL5/ENA-78	Lipocalin-1	CXCL10/IP-10/CRG-2	**Natural human proteins:**	Osteopontin (OPN)
ApoB100	Cathepsin Z	CXCL6/GCP-2	MMP-3	HGF		CXCL10/IP-10
ApoC1	CCL2/MCP-1	CXCL7/NAP-2	MMP-7	Lipocalin-2/NGAL	α1-Acid Glycoprotein	HGF
ApoC2	CCL5/RANTES	CXCL8/IL-8	MMP-9	Osteopontin (OPN)	Kininogen	Fetuin A
ApoD	Cystatin A	CXCL9/MIG	MSP	TIM-1/KIM-1/HAVCR		RBP4
ApoE	Cystatin B	CXCL11/I-TAC	Plasminogen			TFF3
ApoH	Cystatin E/M	CXCL12/SDF-1	Serpin A1	**Recombinant rat:**		TIM-1/KIM-1/HAVCR
ApoM	Cystatin F	CXCL13/BLC/BCA-1	TIM-3			
Cathepsin A	Cystatin S	Enterokinase	TIM-4	Clusterin		
Cathepsin B	Cystatin SA	Fetuin B	TFF-1	Fetuin A		
Cathepsin C	Cystatin SN	Fibronectin	TFF-2	TIM-1/KIM-1/HAVCR		
Cathepsin D	Clusterin-like 1	HAI-1	Thrombin			
Cathepsin E	COX-2	HAI-2				
Cathepsin F	CRP	HGF R/c-MET				
Cathepsin L	CXCL1/GROα	HGF Activator				

TECHNICAL HINTS

- Protect the microparticles and streptavidin-PE from light at all times.
- Refer to the Base Kit Standard Value Card for reconstitution volume and values of the reconstituted standard.
- Diluted microparticles cannot be stored. Make a fresh dilution of microparticles each time the assay is run.
- The use of a magnetic device made to accommodate a microplate is necessary for washing.
- Discrepancies may exist in values obtained for the same analyte utilizing different technologies.

Luminex Performance Assays afford the user the benefit of multianalyte analysis of biomarkers in a complex sample. A single, multipurpose diluent is used to optimize recovery, linearity, and reproducibility. Such a multipurpose diluent may not optimize any single analyte to the same degree that a unique diluent selected for analysis of that analyte can optimize conditions. Therefore, some performance characteristics may be more variable than those for assays designed specifically for single analyte analysis.