

New Hepcidin 25 (bioactive) HS

The gold standard in Hepcidin measurement

Available fully automated on our **DRG:HYBRID-XL®**, a Random Access Analyzer for Immunoassay and Clinical Chemistry or in the classical ELISA format

Hepcidin Patents

Product Patent Protected
 Pat. Number: US 8.304.197 B2 Canada 2.506.668
 US 7.320.894 B2 US 8.304.258 B2 *EU 07 723 512.5
 US 7.411.048 B2 EU 2 109 624 Pending
 US 7.649.081 B2 EU 603 43 464.9
 US 7.749.713 B2 EU 1.578.254
 US 7.998.691 B2 Japan 463835
 US 8.003.338 B2 Russia 2 359 268 C2
 US 8.017.737 B2 China 200380108964.8
 US 8.263.352 B2 Hong Kong 1114419

Benefits

- Easy and straight forward assay procedure (no extraction or centrifugation)
- Total assay time 2 hours
- High sensitivity
- Good correlation to Mass Spectrometry
- Two controls included in the kit

Principle of the test

The DRG Hepcidin-25 (bioactive) manual and Hybrid assays are solid phase enzyme-linked immunosorbent assays (ELISA) based on the principle of competitive binding. The microtiter wells are coated with a monoclonal (mouse) antibody directed towards an antigenic site of the Hepcidin-25 molecule. Endogenous Hepcidin-25 of a patient sample competes with a Hepcidin-25-biotin conjugate (Enzyme Conjugate) for binding to the coated antibody. Binding of the Enzyme Conjugate is detected by streptavidin peroxidase (Enzyme Complex). After addition of the substrate solution, the intensity of colour developed is inversely proportional to the concentration of Hepcidin-25 in the patient sample.

Background

Hepcidin is an iron homeostasis regulator peptide. The bioactive peptide Hepcidin-25 is generated predominantly in the liver by proteolytic cleavage of the C-terminal 25 amino acids of prohepcidin. Subsequent N-terminal processing of Hepcidin-25 results in smaller peptides of 20-24 amino acids that show greatly reduced activity and accumulate in the urine (Figure 1)

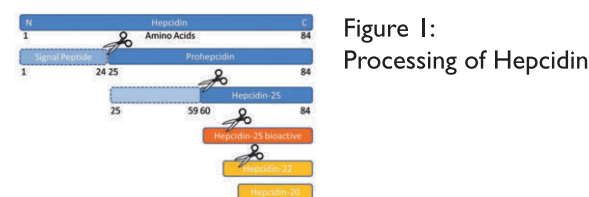


Figure 1: Processing of Hepcidin

Although originally identified as antimicrobial peptide, Hepcidin-25 is now established as a major regulator of dietary iron absorption and cellular iron release. Hepcidin exerts its regulatory function by counteracting the function of ferroportin, the major cellular iron exporter in the membrane of macrophages, hepatocytes and the basolateral site of enterocytes. Hepcidin-25 induces the internalization and degradation of ferroportin, resulting in increased intracellular iron stores, decreased dietary iron absorption and decreased circulating iron concentrations. Hepatocellular hepcidin synthesis decreases under conditions of increased demand for circulating iron like iron deficiency, hypoxia, anemia and erythropoiesis. In contrast, hepcidin synthesis is induced by iron overload, inflammation and infection (Figure 2)

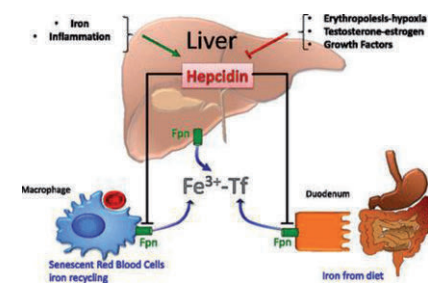


Figure 2: Molecular mechanisms of iron homeostasis

Clinical relevance

Serum Hepcidin-25 has been shown to add value to identify and differentiate specific disease conditions. Hepcidin deficiency causes hereditary hemochromatosis, characterized by body iron overload that may progress to liver cirrhosis. In addition, low Hepcidin-25 concentration can be induced by iron loading anemias and chronic hepatitis C. In contrast, high Hepcidin-25 levels have been found in iron-refractory iron-deficiency anemia, during infection, chronic kidney disease, and after intensive exercise, explaining the high iron deficiency among athletes.

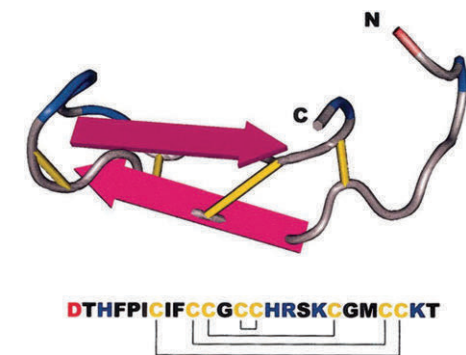


Figure 3: Secondary structure of Hepcidin-25 (Ganz T 2003; Blood)

Hepcidin 25 (bioactive) HS ELISA

A high sensitive, fast and user-friendly Elisa for the quantification of Hepcidin-25 in human serum and plasma

Ordering informations

Description	Code	Size
Hepcidin 25 (bioactive) HS ELISA	EIA-5782	96 Wells

Intended use

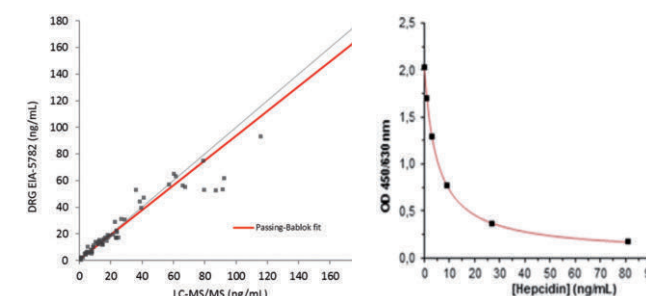
The **DRG Hepcidin ELISA** is an enzyme immunoassay for the quantitative *in vitro diagnostic* measurement of Hepcidin in serum and plasma.

Assay characteristics

- Assay Principle: Competitive ELISA
- Sensitivity:
 - Limit of Blank (LoB): 0,153 ng/mL
 - Limit of detection (LoD): 0,30 ng/mL
 - Limit of Quantification (LoQ): 1,15 ng/mL
- Dynamic Range: 0.30 - 81 ng/mL of Hepcidin
- Total Assay Time: approx. 2 hours (60/30/20 min.)
- Sample Volume: 20 µl of Serum or Plasma (EDTA, Citrate, Heparin)
- Mean Intra Assay Precision: 2,71 %
- Mean Inter Assay Precision: 11,39 %

Method comparison

DRG Hepcidin EIA-5782 showed good correlation to LC-MS/MS
 N=59, $y=0,928x + 0,768$; $r=0,964$; $r^2 = 0,929$



Example of a typical standard curve

Standard	Optical Units (450 nm)
Standard 0 (0 ng/mL)	2.03
Standard 1 (1 ng/mL)	1.70
Standard 2 (3 ng/mL)	1.29
Standard 3 (9 ng/mL)	0.77
Standard 4 (27 ng/mL)	0.37
Standard 5 (81 ng/mL)	0.17

Precision

Inter-Assay Precision

Sample	n	Mean (ng/mL)	CV (%)
1	40	3.2	14.35
2	40	21.93	9.5
3	40	59.63	13.62

Intra-Assay Precision

Sample	n	Mean (ng/mL)	CV (%)
1	20	5.78	5.31
2	20	9.48	5.68
3	20	20.20	5.50

Linearity

	Sample 1	Sample 2	Sample 3
Concentration (ng/mL)	14.7	27.3	59.0
Average Recovery	103.1	92.1	98.4
Range of Recovery (%)	from	92.5	87.9
	to	114.6	95.2

Recovery

	Sample 1	Sample 2	Sample 3
Concentration (ng/mL)	20.8	27.3	59.2
Average Recovery	99.6	94.4	98.0
Range of Recovery (%)	from	88.2	88.4
	to	111.8	105.8

Specificity

Analyte	% Cross-Reactivity
Prohepcidin	< 0.001
Insulin	< 0.001
Hepcidin-22	24.2
Hepcidin-22	87.7

Normal Values

Males and Females	
N	102
Range (ng/mL)	0.43 - 44.20
Mean (ng/mL)	11.16
2.5 th - 95.5 th Percentile	0.91 - 33.55
Median (ng/mL)	11.16

New Hepcidin 25 (bioactive) HS

Fully automated on our **DRG:HYBRID-XL®**, a Random Access Analyzer for Immunoassay and Clinical Chemistry



Innovation

DRG proudly presents state of the art and functionality with the **DRG:HYBRID-XL®** analyzer. This innovative and unique technology allows the simultaneous measurement of immunoassays and clinical chemistry parameters including turbidimetric tests in one sample.

The **DRG:HYBRID-XL** analyser was designed to offer high quality results at low sample throughput for dedicated parameters efficiently and cost effectively.

All reagent are ready to use and come provided in proprietary reagent cartridges with one test. This eliminates waste and ensures stability of the reagents.

In addition the **DRG:HYBRID-XL** offers key functionality:

- 12-month stability from the production date
- Fully automated pipetting from the primary tube with Liquid Level detection included
- 40 cartridge positions with random access function
- Up to 40 sample positions
- On board Sample pre-dilution
- Connection to LIS/HOST
- STAT function
- Standard 13 to 16 mm Sample tubes + barcodes
- Dedicated 8 mm DRG Samples tubes

Efficiency

DRG:HYBRID-XL is designed as a benchtop unit with a small footprint. This allows the processing of samples in multiple environments, automatically and efficiently. The analyser is incredibly quiet and is designed to be very user and service friendly. Very few consumables that can be changed quickly along with a short start-up time allow for a quick turn around between runs. The analyser will display immediate determinations as soon as the sample has been processed and typically generating results in 10 minutes (clinical chemistry) and 60 Minutes (Immunoassay).



Hepcidin 25 (bioactive) HS

Fully automated

DRG:HYBRID-XL®

Ordering informations

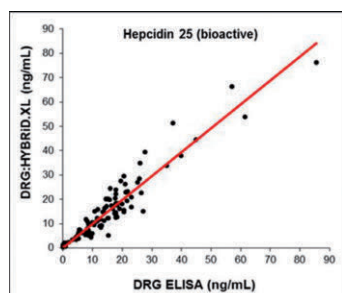
Name	Code	Size
Hepcidin 25 (bioactive)	HYE-5769	40 tests

Assay characteristics Hepcidin-25 (bioactive) ELISA

- Assay Principle: Competitive ELISA
- Sensitivity:
 - Limit of Blank (LoB): 0,82 ng/mL
 - Limit of detection (LoD): 1,67 ng/mL
 - Limit of Quantification (LoQ): 2,62 ng/mL
- Dynamic Range: 1,67-81 ng/mL
- Total Assay Time: 2 hours (60/30/30 min)
- Sample Volume: 100 µ of Serum or Plasma (EDTA, Citrate, Heparin)
- Mean Intra Assay Precision: 2,55 %
- Mean Inter Assay Precision: 13,68 %

Method comparison

DRG Hepcidin EIA-5769 shows good correlation to Hepcidin-25 (bioactive) HS manual ELISA (EIA-5782)
 $N=101; Y=0,982 x; R=0,947; r^2=0,897$



Linearity

Sample	1	2	3	4
Concentration (ng/mL)	24.10	36.45	44.95	77.15
Average Recovery	103.3	104.0	95.0	98.17
Range of Recovery (%)	from	96.8	101.0	90.6
	to	110.1	109.1	98.8

Recovery

Sample	1	2	3	4
Concentration (ng/mL)	1.98	4.35	7.25	18.00
Average Recovery	100.6	100.0	101.5	100.2
Range of Recovery (%)	from	89.7	96.3	96.5
	to	112.3	105.8	106.0

Precision Intra Assay Precision

Sample	n	Mean (ng/mL)	CV (%)
1	40	25.31	1.09
2	40	39.48	4.04
3	40	56.56	2.78
4	40	68.11	2.29

Inter Assay Precision

Sample	n	Mean (ng/mL)	CV (%)
1	80	25.31	14.97
2	80	39.48	13.70
3	80	56.56	13.82
4	80	68.11	12.22

Specificity

Analyte	% Cross-Reactivity
Prohepcidin	< 0.001
Hepcidin-22	26.8
Hepcidin-20	67.6
Insulin	< 0.001

Normal Values

Population	Males	Females
n	49	48
Age (years)	20 - 71	19 - 74
Range (ng/mL)	< 1.67 - 49.75	< 1.67 - 56.70
Mean (ng/mL)	15.42	12.90
2.5 th - 97.5 th Percentile	< 1.67 - 47.29	< 1.67 - 49.37
Median (ng/mL)	9.85	9.45

DRG ELISAS

Oncology

CYFRA 21-1
 CA 72-4
 CA 15-3
 CA 125
 CA 19-9
 CEA
 TPS
 TPA
 PSA
 free PSA
 NSE
 Chromogranin

Gyn. Endocrinology

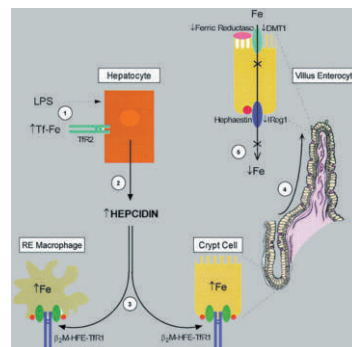
Estradiol
 Progesterone
 17α-OH Progesterone
 DHEA-S
 Testosterone
 DHEA
 Estrone
 Androstendione
 DHT
 SHBG
 DHEA
 LH, FSH, PRL

Prenatal Supervision

PAPP-A
 Free β HCG
 AFP
 Free Estriol
 HCG
 HPL
 PLGF

Saliva Diagnostics

Cortisol
 Estradiol
 Testosterone
 DHEA
 Progesterone
 17α-OH Progesterone



Diabetes/Obesity

Insulin
 C-Peptide
 Proinsulin
 Leptin

Iron Metabolism

Hepcidin

ELISAS that perform

DRG develops and manufactures ELISAS for use in clinical and research laboratories. The experience of our production and management team guarantees to provide high quality products, competitive prices and excellent customer service.

DRG works to DIN EN ISO 9001:2008, ISO 13485:2012/AC:2012 and ISO 13485:2003 under CMDCAS standard, certified by TÜV Rheinland Product Safety GmbH, an indication of our commitment to customer service, quality control and improved health care.

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Iron Metabolism Hepcidin 25 (bioactive) HS

Fully Automated ELISA



DRG