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 classic 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	
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 4638350	
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	*Pending

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 an antimicrobial peptide, Hepcidin-25 is now established as a major regulator of dietary iron absorption and cellular iron releases, 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)

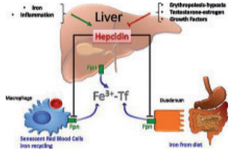


Figure 2: Molecular mechanisms of iron homeostasis

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.

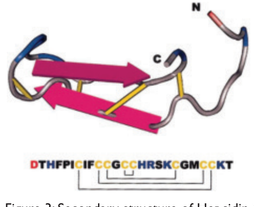


Figure 3: Secondary structure of Hepcidin-25 (Ganz T 2003; Blood)

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 information

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

Intended use

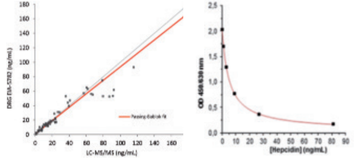
The **DRG Hepcidin ELISA** is an enzyme immunoassay for the quantitative measurement of Hepcidin in serum and plasma. **R**esearch **U**se **O**nly in USA. Not for use in diagnostic procedures.

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/m
- 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=0,928 x +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	86.8
	to	114.6	95.2	105.8

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	87.4
	to	111.8	105.8	108.7

Specificity

Analyte	% Cross-Reactivity
Prohepcidin	< 0.001
Insulin	< 0.001
Hepcidin-22	24.2
Hepcidin-20	87.7

New

Hepcidin 25 (bioactive) HS

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

Research Use Only in USA. Not for use in diagnostic procedures.

Innovation

DRG proudly presents state of the art 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 reagents are ready to use and come 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:
- Reagents have 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 quick turn around between runs. The analyzer will display immediate determinations as soon as the sample has been processed and typically generates results in 10 minutes (Clinical Chemistry) and 60 minutes (Immunoassay).

Hepcidin 25 (bioactive) HS

Fully automated

DRG:HYBRiD•XL®

Ordering information

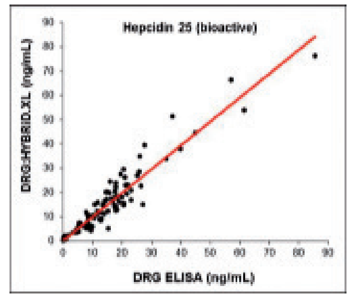
Name	Code	Size
Hepcidin 25 (bioactive)	HYE-5769	40 tests

Assay characteristcs 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 µl of Serum or Plasma (EDTA, Citrate, Heparin)
- Mean Intra Assay Precision: 2,55 %
- Mean Inter Assay Precision: 13,68 %

Method comparison

DRG Hepcidin HYE-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	88.6
	to	110.1	109.1	98,8	108.4

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	97.0
	to	112.3	105.8	106.0	106.7

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

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

Prenatal Supervision

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

Saliva Diagnostics

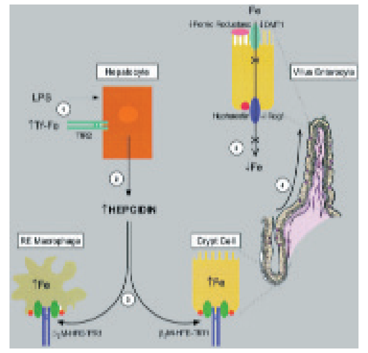
Cortisol
Estradiol
Testosterone
DHEA
Progesterone
17a-OH Progesterone

Diabetes/Obesity

Insulin
C-Peptid
Proinsulin
Leptin

Iron Metabolism

Hepcidin



Bone Metabolism

25-OH Vitamin D Total

Hypertension

Renin
Aldosterone

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.

DRG Diagnostics

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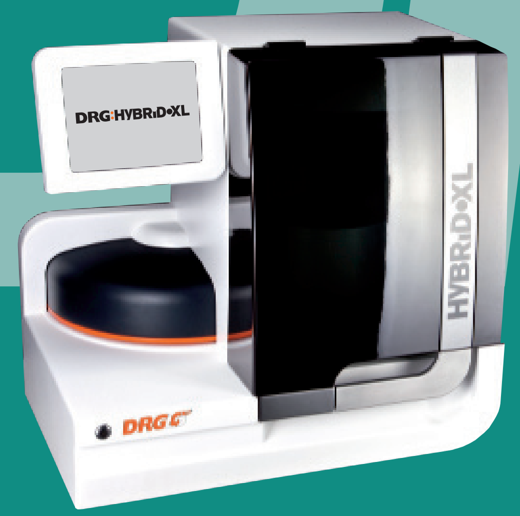
Iron Metabolism
Hepcidin 25 (bioactive) HS

Fully Automated ELISA



DRG

RUO in USA, not for use in diagnostic procedures