Ferritin

HumaCLIA SR

Chemiluminescence Immunoassay (CLIA) for the Quantitative Determination of Ferritin

Package Size

REF	85049	2 x 50 Tests	Complete Test Kit

IVD

Intended Purpose

Ferritin HumaCLIA SR is a chemiluminescent immunoassay (CLIA) for the quantitative determination of Ferritin levels in human serum and plasma (heparin, EDTA). It is used to determine the body's total iron storage capacity and as aid to diagnosis of iron deficiency or iron overload. Ferritin HumaCLIA SR is designed as an automated test for use with HumaCLIA systems. For laboratory professional use only.

Test Principle

Ferritin HumaCLIA SR is a sandwich assay using chemiluminescent microparticle immunoassay technology. Ferritin in the sample, magnetic microparticles coated with anti-Ferritin and anti-Ferritin acridinium-ester-labelled conjugate react to form a sandwich complex. The unbound materials are washed away from the solid phase in a magnetic field. The Pre-Trigger and Trigger Solution are then added to the reaction mixture and the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct proportional relationship exists between the concentration of Ferritin in the sample and the RLUs detected by the system. Results are determined via a calibration curve, which is instrument-specifically generated by 3-point calibration and a master curve provided via the reagent QR code.

Reagents and Contents

RGT	2x 50 tests	**Reagent Cartridge, labelled as Ferritin, 2 components** closed with screw caps which can be replaced with pierceable silicone caps	
PAR	3.5 ml	**Paramagnetic particles** (white compartment with white cap) Ready to use Anti-Ferritin (mouse) coated paramagnetic microparticles Tris buffer Preservative: Proclin 300	0.05%
CON	4.0 ml	**Acridinium-ester-labelled conjugate** (black compartment with black cap) Ready to use Anti-Ferritin acridinium-ester-labelled antibody (mouse) Phosphate buffer Preservative: Proclin 300	0.05%
CAL		**Calibrators, 1 vial/level**	
CAL 1	1.0 ml	**Calibrator 1** (transparent vial with green cap) Ready to use Tris buffer with protein stabilizers Preservative: Proclin 300	0.05%
CAL 2	1.0 ml	**Calibrator 2** (transparent vial with yellow cap) Ready to use Ferritin (human) in Tris buffer with protein stabilizers Preservative: Proclin 300	0.05%
CAL 3	1.0 ml	**Calibrator 3** (transparent vial with pink cap) Ready to use Ferritin (human) in Tris buffer with protein stabilizers Preservative: Proclin 300	0.05%

Additional materials recommended but not supplied with the kit

REF	
80050	Pre-Trigger Solution HumaCLIA SR (4x220 ml)
80055	Trigger Solution HumaCLIA SR (4x220 ml)
80060	Wash Buffer HumaCLIA SR (4x1l concentrate, 10x)
84850	Immunoassay Multi Control HumaCLIA SR (2x2x3 ml)
15910/10	Reaction Vessel HumaCLIA SR (1000 cuvettes/bag)
15910/15	Waste Box HumaCLIA SR (10 pcs/box)
	Deionized water

Automated Analyzers

REF	
15910	HumaCLIA 150

Storage / Stability

Unopened at 2-8°C		up to the stated expiration date
RGT	Opened at 2-8°C	28 days
	On-board at 2-8°C	28 days
CAL	Opened at 2-8°C	28 days

Store upright and protected from light.

Reagent preparation

The reagents in RGT are ready for use and can be used immediately without bringing them to room temperature. Prior to loading RGT on the system for the first time, resuspend the microparticles by gently inverting RGT 30 times. Avoid the formation of bubbles. For further information on reagent handling and precautions during system operation, refer to the HumaCLIA user manual.

Specimens

- Human serum or plasma (lithium heparin, sodium heparin and potassium EDTA) are the recommended samples. Other anticoagulants have not been validated.
- Store specimens at room temperature (20-25°C) for no longer than 24 hours.
- For longer storage times, specimens can be stored at 2-8°C for up to 10 days. Serum specimens can be stored at -20°C for up to 60 days. The specimen may be freeze-thawed for up to three times. Thoroughly mix thawed samples.
- Centrifuge the specimens.
- Ensure complete clotting of serum specimens prior to centrifugation (clotting time of at least 1 hour). For patients undergoing heparin (anticoagulant) treatment, prolong the time for clot formation in serum specimens.
- Centrifuge lipemic specimens and only use the supernatant.
- Ensure that residual fibrin and cellular matter have been removed by centrifugation prior to analysis.
- Do not use heat-inactivated samples.

Procedure

Follow the procedure exactly as described.

Procedural Notes

1. Do not use the reagents after the expiration date.
2. Do not mix reagents from different kits or lot numbers.
3. Avoid the formation of foam or bubbles with all reagents.
4. Bring specimens, CAL and controls to room temperature (20...25°C) before use.
5. Make sure to prevent cross-contamination when handling specimens.
6. Due to the possible evaporation, on-board specimens and calibrators should be measured within 2 hours.

Assay Procedure

1. Refer to the HumaCLIA user manual for detailed information on preparing the system.
2. The instrument scans the RGT barcode for the lot-specific parameters.
3. If necessary, perform a calibration by placing CAL 1, CAL 2, and CAL 3 in the calibrator rack in the sample loader. Close the calibrators after the calibration. CAL values are lot specific and shown in the software.
4. Load the samples. The required volume for each measurement is 28 µl, plus the sample container dead volume.
5. Click RUN. The HumaCLIA system performs the assay and calculates the results.

Calibration

Master curve calibration: Every Ferritin HumaCLIA SR reagent kit has a QR code label containing lot specific information for the calibration. After a calibration, the calibration curve is updated based on a predefined master curve and stored by the instrument. All subsequent samples may be tested without further calibration.

Perform a new calibration in the following cases:

- after 28 days from the last calibration when using the same reagent lot.
- a reagent kit with a new lot number is used.
- the controls are out of range.
- required by pertinent regulations.

Calculation of the results

The HumaCLIA system automatically calculates the analyte concentration of each sample. The results are given in ng/ml.

Quality Control

The quality control should be run with Immunoassay Multi Control HumaCLIA SR or commercially available quality control materials covering at least two levels of analyte:

- once every 24 hours when the test is in use
- once per reagent kit
- after every calibration

Each laboratory should establish mean values and acceptable ranges when using commercially available quality control materials to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results.

The latest HUMAN lot-specific target values can be found in the target value sheet, accessible via:

https://www.human.de/products/clia/target-value-sheets

Reference Intervals

A study of Ferritin HumaCLIA SR assay on samples from280 apparently healthy people of various age groups yielded the following result:

	ng/ml	ng/ml
Females	13	150
Males	30	400

Each laboratory should establish its own reference interval.

Interpretation of Results

For diagnostic purposes, results should always be interpreted in combination with other medical findings, such as symptoms, results of other tests, clinical history.

Limitations

1. The use of serum separator (gel) blood collection tubes has been validated for use with this assay. However, it is not possible to survey all manufacturers or tube types.
2. If the results are inconsistent with other clinical aspects, additional testing might be required to confirm the result.
3. The results from an alternative assay (i.e. EIA or RIA) may not be equivalent and cannot be used interchangeably.
4. Sample dilution has not been validated for this assay.
5. Potential interference by commonly used pharmaceuticals have not been evaluated for this assay.
6. Potential cross-reactivity to Ferritin isoforms has not been evaluated for this assay.
7. As the Ferritin HumaCLIA SR assay does not use a biotin-labelled antibody complex, there is no risk of potential interference for the Ferritin values determined by the assay when analyzing samples containing biotin.
8. Elevated levels may be observed in acute or chronic inflammation or cancer.
9. Not for monitoring of cancer.

Analytical Performance Characteristics

Measurement range (displayed)		0.72-2000 ng/mL	
Samples outside the displayed range are marked as >higher or <lower than the 'measurement range (displayed)' on HumaCLIA Analyzer.			
Analytical measuring interval		3.74-1146 ng/mL	
Linearity interval		0.81-1146 ng/mL	
Limit of detection		0.72 ng/mL	
Limit of quantitation		3.74 ng/mL	
Hook effect excluded up to		71000 ng/mL	
Imprecision			
The precision of Ferritin HumaCLIA SR assay was evaluated according to CLSI EP05-A3. For determination of the repeatability and within lab precision each sample was run in duplicates per run, 2 runs per day, for 20 days (20x2x2). Data from this study are statistically interpreted and summarised below.			
Repeatability:			
Sample	Mean (ng/ml)	SD	% CV
1	14.83	0.82	5.53
2	49.40	2.80	5.66
3	92.78	2.57	2.77
4	173.58	8.75	5.04
5	199.23	11.88	5.96
6	429.60	23.26	5.42
7	895.61	45.61	5.09
Within lab:			
1	14.83	0.87	5.90
2	49.40	2.94	5.95
3	92.78	3.61	3.89
4	173.58	9.19	5.29
5	199.23	12.63	6.34
6	429.60	24.06	5.60
7	895.61	47.91	5.35

Traceability	WHO 3rd International Standard NIBSC code: 94/572
Interferences	
Interfering substances were added to a known sample. No interference was detected up to following concentrations:	
Bilirubin	65 mg/dl
Hemoglobin	500 mg/dl
Intralipid	3300 mg/dl
Total serum protein	9 g/dl
Rheumatoid factors	1200 IU/ml
HAMA	600 ng/ml
Biotin	50 ng/ml
Method comparison	
A comparison of the Ferritin HumaCLIA SR assay (y) with Roche cobas Ferritin assay (x) using 117 clinical samples provided the following correlations:	
Passing-Bablok regression	y = 1.139x – 20.886
Correlation coefficient (Kendall's Tau)	0.918
The sample concentrations were between 16.4 and 1988 ng/ml.	

Diagnostic Correlation

Based on clinical diagnose the HumaCLIA SR and Roche Elecsys Ferritin the tests showed a total agreement of 98.3% for females (n=116) and 95.6% for males (n=114).

Safety Notes

All patient specimens, reagents and calibrators should be handled as potentially infectious. All donor units of human origin have been tested for HBsAg, HIV and HCV-antibodies and found to be non-reactive using approved methods. All materials of animal origin avoid many risks associated with the use of human serum (e.g. Hepatitis B and C, HIV). Nevertheless, all material of human or animal origin should still be treated as potentially infectious material.

RGT CAL

H317 May cause an allergic skin reaction

P234 Keep only in original packaging.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

References

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3. Alfrey, C.P., et. al. 1967. Characteristics of Ferritin isolated from human marrow, spleen, liver and reticulocytes. Journal of Laboratory and Clinical Medicine, 70: 419-428.
4. Addison, G.M., et. al. 1972. An immunoradiometric assay for Ferritin in the serum of normal subjects and patients with iron deficiency and iron overload. Journal of Clinical Pathology, 25: 326-329.
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