2026/01/20
A93A01461AEN

REF 1300148011
REAGENT 1 18.5 mL
REAGENT 2 16 mL

IVD CE 2797

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Yumizen C560 Ferritin

- **Yumizen C560**

Diagnostic reagent for quantitative *in vitro* determination of Ferritin in serum or plasma by latex-enhanced immunoturbidimetry.

Intended Use (not for use in the USA)

Yumizen C560 Ferritin reagent is intended for the quantitative *in vitro* diagnostic determination of Ferritin in serum and plasma by latex-enhanced immunoturbidimetric assay.
Clinical laboratories use.
Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia and is also biomarker of inflammation.
Assessing physiologic and pathologic variations of ferritin in human serum and plasma is useful for screening or follow-up of these diseases.

Clinical Interest (1)

Ferritin is an iron-containing protein with a molecular weight of approximately 450000. It is found mainly in the human liver and spleen, where its function is to eliminate and store iron in the body, and is also found in small amounts in human serum. Consequently, the measurement of ferritin is considered to be useful in the diagnosis, treatment, assessment of disease progression, and postoperative prognosis for abnormality in iron metabolism such as iron deficiency anemia and hyperferremia as well as hepatitis and malignant tumors.
Yumizen C560 Ferritin is a latex-enhanced immunoturbidimetric assay developed to accurately and reproducibly measure Ferritin levels in serum and plasma samples.

Method (2)

When an antigen-antibody reaction occurs between ferritin in a sample and anti-ferritin antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change, with the magnitude of the change being proportional to the quantity of ferritin in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

Reagents

Yumizen C560 Ferritin is ready-to-use.

Reagent 1:

Buffer solution: Glycine buffer solution

Reagent 2:

Latex suspension: 0.07% w/v suspension of latex particles bound to anti-ferritin antibodies (rabbit)

- If used on other equipment, reagent cassettes should be capped and kept at 2-10°C.
  Care should be taken not to interchange the caps with others cassettes.
- Reagents with different lot numbers should not be interchanged or mixed.
- **Yumizen C560 Ferritin** should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

Handling

1. Remove the caps of the cassettes.
2. If present, remove foam by using a plastic pipette.
3. Place reagent R1 in the inner ring of the refrigerated reagent compartment, and reagent R2 in the outer ring of the refrigerated reagent compartment.

Yumizen C560 Ferritin

Calibrator

For calibration, use:
ABX Pentra Ferritin Cal (A11A01619) (not included)
4 x 1 mL

Control

For internal quality control, use:

- **ABX Pentra N MultiControl** (1300054414) (not included)
  10 x 5 mL (lyophilisate)
- **ABX Pentra P MultiControl** (1300054415) (not included)
  10 x 5 mL (lyophilisate)

Each control should be assayed daily and/or after a calibration.
The frequency of controls and the confidence intervals should correspond to laboratory guidelines and country-specific directives. You should follow federal, state and local guidelines for testing quality control materials. The results must be within the range of the defined confidence limits. Each laboratory should establish a procedure to follow if the results exceed these confidence limits.

Materials Required but not Provided

- Automated clinical chemistry analyzer: Yumizen C560
- Calibrator: **ABX Pentra Ferritin Cal** (A11A01619)
- Controls:
  ABX Pentra N MultiControl (1300054414)
  ABX Pentra P MultiControl (1300054415)
- Standard laboratory equipment.

Specimen

This device intended testing population is general population.

Specimen types

- Serum.
- Plasma in lithium heparin.

Anticoagulants other than those listed have not been tested by HORIBA and are therefore not recommended for use with this assay.
The blood collection tube type has no influence on the test result.

Stability (3)

- At 20-25°C: 7 days
- At 2-8°C: 7 days
- At -20°C: 1 year

Repeated freezing and thawing should be avoided.

Reference Range (4)

Because values could vary according to the age, the diet, the sex and the geographic repartition, each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

Women:	10 - 120 ng/mL (µg/L)
Men:	20 - 250 ng/mL (µg/L)
6 months - 15 years:	7 - 140 ng/mL (µg/L)

Clinical sensitivity and specificity, positive predictive value and negative predictive value are not commonly reported for this analyte. This is largely attributed to the fact that this analyte is not sole indicator for the intended purpose and patient treatment decision making. To arrive at a diagnosis and a course of treatment, results from others routine clinical chemistry tests should be used in conjunction with other diagnostic information and the attending health-care professional's evaluation of the patient's condition.

Storage and Stability

Stability before opening:

Stable up to the expiry date on the label if stored at 2-10°C. Store protected from light.

Stability after opening:

Refer to the paragraph "Performance on Yumizen C560".

Waste Management

- Please refer to local legal requirements.
- This reagent contains less than 0.1% of sodium azide as a preservative.

General Precautions

- This reagent is for professional *in vitro* diagnostic use only.
  For laboratory use.

Yumizen C560 Ferritin

- For prescription use only.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 1 and 2 (R1 and R2):**
  Warning: This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (5).
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
- Do not pipette by mouth.
- Do not replenish the reagents.
- Do not swallow. Avoid contact with skin and mucous membranes.
- Observe the standard laboratory precautions for use.
- The reagent cassettes are disposable and should be disposed of in accordance with the local legal requirements.
- Please refer to the SDS associated with the reagent.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- It is the user's responsibility to verify that this document is applicable to the reagent used.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Performance on Yumizen C560

Lot to Lot Variability

The recovery of samples (serum and plasma) done during QC release of three consecutive lots of reagent shows that the lot to lot variability is within specification: < 10%.

Serum, plasma

The performance data listed below have been obtained on the Yumizen C560 analyzer.

Number of tests: approximately 131 tests

On Board Reagent Stability

Once opened, the reagent cassette placed in the refrigerated Yumizen C560 compartment is stable for 30 days.

Sample volume: 15 µL/test

Lowest Detectable Level

The lowest detectable level represents the lowest measurable level of analyte that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample. The lowest detectable level is estimated at 4.4 ng/mL.

Limit of Quantitation

The limit of quantitation is determined according to CLSI (NCCLS), EP17-A2 protocol (6) and equals 10 ng/mL.

Accuracy and Precision

Repeatability (within-run precision)

Repeatability according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (7) with samples tested 20 times:

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value ng/mL	CV %
Control specimen 1	100.92	0.5
Control specimen 2	213.76	0.7
Specimen 1	26.05	4.9
Specimen 2	208.02	0.8
Specimen 3	483.25	0.4

Reproducibility (total precision)

Reproducibility according to the recommendations found in the CLSI (NCCLS), EP05-A3 protocol (7) with samples tested in duplicate for 20 days (2 series per day):

- 2 controls
- 3 specimens (low / medium / high levels)

	Mean value ng/mL	CV %
Control specimen 1	102.18	0.9
Control specimen 2	221.00	0.8
Specimen 1	24.48	4.0
Specimen 2	199.91	1.7
Specimen 3	421.05	1.3

Measuring Range

The assay confirmed a measuring range from 10 ng/mL to 650 ng/mL.

Yumizen C560 Ferritin

The measuring range is extended up to 2600 ng/mL with the automatic post-dilution.
The reagent linearity has been assessed up to 650 ng/mL according to the recommendations found in the CLSI (NCCLS), EP06-Ed2 protocol (8).

Correlation

Patient samples: Serum
Number of patient samples: 109
Specimens are correlated with a commercial reagent taken as reference according to the recommendations found in the CLSI (NCCLS), EP09c protocol (9).
Values ranged from 13.26 ng/mL to 615.08 ng/mL.
The equation for the allometric line obtained using Passing-Bablok regression procedure (10) is:
Y = 0.9735 X + 2.346 (ng/mL)
with a correlation coefficient r^2 = 0.994.

Interferences

Haemoglobin:	No significant influence is observed up to 579 µmol/L (1000 mg/dL).
Triglycerides:	No significant influence is observed up to a triglyceride concentration of 6.78 mmol/L (592.81 mg/dL).
Total Bilirubin:	No significant influence is observed up to 1628.20 µmol/L (95.25 mg/dL).
Direct Bilirubin:	No significant influence is observed up to 724.60 µmol/L (42.39 mg/dL).
Rheumatoid Factor:	No significant influence is observed up to 359.00 IU/mL.

Other limitations are given by Young as a list of drugs and preanalytical variables known to affect this methodology (11, 12).

Prozone Effect

No antigen excess has been detected up to a concentration of 3400 ng/mL.

Calibration Stability

The reagent is calibrated on Day 0. The calibration stability is checked by testing 2 control specimens.
The calibration stability is 15 days.
Note: A recalibration is recommended when reagent lots change, and when quality control results fall outside the range established.

Conversion Factor

ng/mL = µg/L

Reference

1. Thomas L. Ed. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellshaft, (1998): 278-281.
2. Simo M, Joven J, Cliville X, Sans T, Automated latex agglutination immunoassay of serum ferritin with a centrifugal analyzer, Clin. Chem. (1994) **40**: 625-629.
3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO publication WHO/DIL/LAB/99.1 Rev.2: 31 (2002).
4. Roberts WL, McMillin GA, Burtis CA, Bruns DE, Reference Information for the Clinical Laboratory, TIETZ Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed. Burtis CA, Ashwood ER, Bruns DE, (Elsevier Saunders eds. St Louis, USA), (2006): 2269.
5. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
6. Evaluation of detection capability for clinical laboratory measurement procedures. Approved Guideline, 2nd ed., CLSI (NCCLS) document EP17-A2 (2012) **32** (8).
7. Evaluation of Precision of Quantitative Measurement Procedures. Approved Guideline, CLSI (NCCLS) document EP05-A3 (2014) **24** (25).
8. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd Edition, CLSI (NCCLS) guideline EP06-Ed2 (2020) **40** (16).
9. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. Approved Guideline, 3rd ed., CLSI (NCCLS) document EP09c (2018) **38** (12).
10. Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J. Clin. Chem. Clin. Biochem. (1983) **21**: 709-720.
11. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, Washington, DC, AACC Press (2000).
12. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd Edition, Washington, DC, AACC Press (1997) **3**: 120-132.