CORMAY MYOGLOBIN

DIAGNOSTIC KIT FOR DETERMINATION OF MYOGLOBIN CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY MYOGLOBIN	1 x 56 ml	6-301

INTRODUCTION
Myoglobin (Mb) is a hemo-protein present in cardiac and skeletal muscle cells and is released into blood circulation when these cells are damaged. The determination of serum Mb level is useful in the diagnosis of myocardial in infarction, muscular dystrophy, myositis and myopathy, and also for the assessment of treatment and disease prognosis.

METHOD PRINCIPLE
When an antigen-antibody reaction occurs between Mb in a sample and anti-Mb antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of Mb in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS
Package

1-Reagent	1 x 42 ml
2-Reagent	1 x 14 ml

The reagents are stable up to the kit expiry date printed on the package when stored at 2-10°C. On board stability of the reagents depends on type of analyser used for analysis. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with anti-Mb (rabbit) antibodies (pH 7.3) glycine buffer solution (pH 9.0)	0.12 w/v%

Warnings and notes
- Product for in vitro diagnostic use only.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT
- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN
Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin, citric acid).
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request.

These reagents may be used directly in Hitachi 911/912 analysers. Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [3]

serum, plasma	< 70 ng/ml

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL II (Cat. No 4-290) with each batch of samples.
For the calibration of automatic analyzers systems the CORMAY MYOGLOBIN CALIBRATORS kit (Cat. No 4-279) is recommended. Calibrators and 0.9% NaCl should be used for calibration.
Calibration stability depends on type of analyser used for analysis. The calibration curve should be prepared with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analysers Hitachi 912 and Hitachi 917. Results may vary if a different instrument is used.

- **Sensitivity:** 0.09 ng/ml.

- **Linearity:** up to 800 ng/ml.
  For higher concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.96 g/dl, ascorbate up to 500 mg/l, bilirubin up to 62 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	37.12	1.10	2.96
level 2	483.66	2.57	0.53

Reproducibility (day to day) n = 21	Mean [ng/ml]	SD [ng/ml]	CV [%]
level 1	77.0	1.703	2.2
level 2	364.4	6.004	1.6

- **Method comparison**

A comparison between myoglobin values determined at Hitachi 912 (y) and at Advia 1650 (x) using 20 samples gave following results:
y = 1.0379 x + 9.6841 ng/ml;
R = 0.9986 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Galvin J. P. et al.: Particle enhanced photometric immunoassay systems., Clin. Lab. Assays (Pap. Annu. Clin. Lab. Assays Conf.), 4th, 73 (1983).
2. Singer J. M. et al.: The latex fixation test. I. Application to the serologic diagnosis of rheumatoid arthritis, Amer. J. Med., 21, 888 (1956).
3. Silva dos Santos E., Pereira M. P. et al.: Electrical Cardioversion and Myocardial Injury: Evaluation by New Cardiac Injury Markers., Arquivos Brasileiros de Cardiologia - 86, 3, 2006.

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