COPPER
Hitachi User Defined Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
AD071	2 X 40 ml	COPPER	2 - 8 °C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Copper in serum and plasma on Hitachi® automated analysers.

PRINCIPLE OF THE TEST: [1]

Copper forms with 4-(3, 5-dibromo-2pyridylazo)-N-ethyl-N-sulfopropylanine a chelate complex. The increase of absorbance of this complex can be measured and is proportional to the concentration of total copper in the sample.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read and follow instructions for use. Deviations from the described procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Light pink liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination: do not use the reagent pack and contact your distributor.

Safety Precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

This instrument is designed to run on Hitachi® clinical chemistry analysers. Refer to relevant users manual or laboratory internal practice for routine maintenance procedures. See enclosed application sheet.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	Acetate Buffer pH 5.0	0.2 mol/l
	4-(-3,5-dibromo-2-pyridylazo) -N-ethyl-N-sulfoprpylaniline	0.02 mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 is ready to use.
Before use, mix reagent by gently inverting the bottle.

If stored and handled properly, components are stable until expiry date stated on label.

TYPE OF SPECIMEN: [2]

Use serum or heparin plasma as specimen.

It is recommended to follow NCCLS procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Serum/plasma should be separated from cells within 2 hours after collection.
Stability: up to 48 hours at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Calibrator	AD983	Hitachi® Analyser	N/A
General Chemistry Control Level 1	AD922	Hitachi®Consumables	N/A
General Chemistry Control Level 2	AD932	General Laboratory Equipment	N/A

Assay Procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

Calibration:
Using the recommended calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Control results are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At some intervals chosen by the laboratory.

CALCULATION:

The analyser automatically calculates the copper concentration in the sample.

(Conversion factor: µg/dl x 0.157 = µmol/l)

EXPECTED VALUES: [1]

In serum	Adult Man	70 – 140 µg/dl
	Adult Women	80 – 155 µg/dl

Each laboratory should establish its own reference range. Copper results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance evaluation can vary with the instrument used. Data obtained in each individual laboratory may differ from results obtained in-house.

Linearity:
This assay is linear up to 500 µg/dl. For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Precision.

Test 15	Mean *(mmol/l)*	Max *(mmol/l)*	Min *(mmol/l)*	*SD*	*% CV*
Level 1	32.0	33.2	30.9	0.61	1.90

BIBLIOGRAPHY:

1. Abe A., Yamashita S., Noma A., Clin Chem., 552-554, 35 (1989)
2. C. A. Burtis, E.R. Ashwood. Tietz Fund. Of Clin. Chem. 5th ed. 30:54 and 973

SYMBOLS:

The following symbols are used in the labelling of Audit Diagnostics systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer		
CE	CE Mark - Device complies with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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