PROTEIN HS (PROTEIN HIGH SENSITIVE)

Diagnostic reagent for determination of Protein HS concentration.
Liquid. Monoreagent. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-252	60 mL
MH-253	40 mL

Changes made in the instructions for use are marked as grey.

INTENDED USE

The test is applied for the quantitative determination of Protein HS-Microprotein concentration in urine and cerebrospinal fluid (CSF).

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]

Proteins combine with pyrogallol red to form a color complex, the absorbance of which is measured at 600 nm. Sodium dodecylsulphate is added to increase accuracy in measuring proteins other than albumine (Watanabe).

TEST PARAMETERS

Method	: Colorimetric, Endpoint, Increasing Reaction, Biuret
Wavelength	: Hg 600 nm (580- 620)
Linearity	: 250 mg/dL

REAGENT COMPONENTS

Succinate buffer	≤ 0.08 M	pH 2.50,
Pyrogallol red	≤ 0.06 mM,	
Sodium molibdate	≤ 0.15 mM,	
Sodium oxalate	≤ 1.2 mM,	
Sodium benzoate	≤ 0.37 mM,	
SDS	≤ 0.12 mM.	

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [6]

Reagents are stable at +2/+8˚C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

It can be used in both urine and cerebrospinal fluid.

A rapid sample collection is not required but decrease in lipemia is necessary. Hemolysis should be avoided.

Tightly capped serum samples are stable for:
1 week at,+20/+25°C,
1 month at 2-8°C.

Samples that have been frozen and thawed should be thoroughly mixed before assay.

For sample collection and preparation, only use suitable tubes or collection containers. Only the samples listed below were tested and found acceptable:

Urine: Use random or 24-hour urine specimens. Use no preservatives. Refrigerate the sample during collection.

Cerebrospinal Fluid (CSF): No special additives are required. Blood in a CSF specimen invalidates the protein value. Samples for urinary/CSF protein should be collected before fluorescein is given or at least 24 hours later.

When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer. Centrifuge samples containing precipitates before performing the assay. Non centrifuged samples may produce elevated results.

Stability:

Urine:	1 day at +20/+25°C 7 days at +2/8°C 1 month at -20°C
CSF:	1 day at +20/+25°C 6 days at +2/+8°C 1 year at -20°C

Unit Conversion:
mg/dL x 10 = mg/L

REFERENCE INTERVAL (NORMAL VALUES) [1, 2, 3, 7]

Expected Values:

Urine:	24 hour	: < 140 mg/24 h
	Random	: < 150 mg/L

Values Obtained from Centrifuged Samples:
CSF:
Reference Interval According to Tietz: 150-450 mg/L

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

MicroProtein Control-I
Ref.No: VT-038

MicroProtein Control-II
Ref.No: VT-039

The assay requires the use of a MicroProtein Calibrator. We recommend:

MicroProtein Calibrator
Ref.No: VT-040

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 15 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is 1 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%]**:**[8] 7 mg/dL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 250 mg/dL.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[9]
Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
37.1 mg/dL	0.74	2.00	40
103.7 mg/dL	1.27	1.20	40

Repeatability (Day to Day) (Inter-Assay)

Mean Concentration	SD	CV%	n
38.01 mg/dL	0.79	2.00	40
100.09 mg/dL	2.46	2.00	40

*SD: Standard Deviation

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[10, 11]
Correlation with a comparative method is: r= 0.978
According to Passing-Bablok Fit:
Slope: 0.97
Intercept: -0.54

Interference:[3, 4, 12]
No significant interactions were observed for ascorbic acid up to the interferent concentration given.

Ascorbic Acid : ≤ 200 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD**:** For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

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Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr www.archem.com.tr
info@validity.com.tr www.validity.com.tr

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests