Urine/CSF Protein

FOR USE WITH
ARCHITECT

REF 7D79-22
REF 7D79-32

en
UPro
7D79
G95908R03
B7DS90

Revised March 2022.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

Urine/CSF Protein

INTENDED USE

The Urine/CSF Protein (UPro) assay is used for the quantitation of protein in human urine or cerebrospinal fluid (CSF). CSF protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous system.[1]

SUMMARY AND EXPLANATION OF THE TEST

The role of the renal system in the conservation of plasma proteins has been recognized for some time. Under normal physiological conditions small molecular weight proteins, such as insulin, pass through the glomeruli in relatively large amounts. Intermediate size proteins, such as transferrin and albumin, also pass through in relatively small amounts. Most of these proteins are reabsorbed in the renal tubules.[2, 3]

Most CSF protein originates by diffusion from plasma across the blood-CSF barrier. Elevated levels occur as a result of increased permeability of the blood-CSF barrier or with increased local synthesis of immunoglobulins.[4]

PRINCIPLES OF THE PROCEDURE

The UPro assay is a turbidimetric procedure in which benzethonium chloride is used as the protein denaturing agent. Proteins present in the urine or CSF are denatured by benzethonium chloride, resulting in the formation of a fine suspension which is quantitated turbidimetrically at 404 nm.

Methodology: Benzethonium chloride

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Urine/CSF Protein 7D79.

Supplied as a liquid, ready-to-use two-reagent kit.

REF	7D79-22	7D79-32
Σ	2244*	209*
R1	10 x 53 mL	3 x 18 mL
R2	10 x 15 mL	3 x 6 mL

*Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients	Concentration
R1	
Carbonate buffer	100 mmol/L
Sodium chloride	140 mmol/L
R2	
Benzethonium chloride	20 g/L

Inactive Ingredients: R1 contains sodium azide (0.05%) as a preservative.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[5-8]

The following warnings and precautions apply to R1	
WARNING	Contains potassium carbonate sesquihydrate, tetrasodium ethylenediaminetetraacetate and sodium azide.
H319	Causes serious eye irritation.
H316*	Causes mild skin irritation.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
Response	
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.
P332+P313*	If skin irritation occurs: Get medical advice / attention.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have been implemented.

The following warnings and precautions apply to R2	
WARNING	Contains benzethonium chloride.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves / protective clothing / eye protection.

Response	
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.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not use reagents beyond the expiration date.
- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Remove any air bubbles present in the reagents with a new applicator stick, or allow the reagents to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove bubbles.

  CAUTION: Bubbles may interfere with proper detection of reagent level in the cartridge and cause insufficient reagent aspiration which could impact results.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15-30°C	Until expiration date	
Onboard	System temperature	41 days (984 hours)	After 41 days (984 hours), the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Instability or deterioration should be suspected if there are precipitates, visible signs of leakage or contamination, turbidity, or if calibration or controls do not meet the appropriate package insert and/or ARCHITECT System Operations Manual criteria.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Urine/CSF Protein assay file must be installed on the ARCHITECT cSystem prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters or for a detailed description of system procedures, refer to the ARCHITECT System Operations Manual, Section 5.

Alternate Result Units

The Conventional result unit for the Urine/CSF Protein assay is mg/dL. The corresponding SI result unit is mg/L. To convert mg/dL to mg/L, multiply mg/dL by 10. To convert mg/L to mg/dL, divide mg/L by 10.

24 Hour Urinary Excretion

To convert results from mg/dL to mg/day (24 hour urinary excretion)

Where:

V = 24 hour urine volume (mL)

c = analyte concentration (mg/dL)

24 hour excretion = $[(V \times c) \div 100]$ mg/day

To convert results from mg/L to mg/day (24 hour urinary excretion)

Where:

V = 24 hour urine volume (mL)

c = analyte concentration (mg/L)

24 hour excretion = $[(V \times c) \div 1000]$ mg/day

When converting to units other than those listed, refer to the ARCHITECT System Operations Manual, Section 2.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Urine and cerebrospinal fluid are acceptable and verified specimen types. Samples for urinary/CSF protein should be collected before fluorescein is given or at least 24 hours later.[9]

Specimen Type	Special Conditions
Urine (24 hour is preferred, with no preservative)	Keep specimen on ice during collection. Centrifuge prior to analysis.[10] Avoid collection of specimens within 24 hours of intense exercise since this can falsely elevate protein excretion. Analyze fresh or store as indicated below.
CSF	Centrifuge specimen before analysis. Analyze fresh or store as indicated below. Specimen should not contain blood.[10]

Other specimen types have not been verified with this assay.

The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

For additional information on specimen conditions, refer to the Interference section of this package insert.

Preparation for Analysis

Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Frozen specimens must be completely thawed before mixing.

Mix thawed specimens thoroughly.

Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.

Specimen Storage

Analyze fresh specimens if possible.

Specimen Type	Storage Temperature	Maximum Storage Time
Urine	20-25°C	24 hours[11]
	2-8°C	7 days[11, 12]
	-20°C*	1 month[11]
CSF	20-25°C	24 hours[11]
	2-8°C	6 days[11, 12]
	-20°C*	> 1 year[11]

*A tolerance of ± 10% (± 2°C) is assumed not to change the stability of the specimen. (W. Guder, personal communication, August 6, 2001).

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

7D79 Urine/CSF Protein Reagent Kit

Materials Required but not Provided

- 1E71 Urine/CSF Protein Calibrator
- Control material
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

For sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert. Minimum sample volume is calculated by the system and printed on the Order List Report. Ensure adequate sample volume is present prior to running the test.

Specimen Dilution Procedures

The ARCHITECT cSystems have an automatic dilution feature; for additional information, refer to the ARCHITECT System Operations Manual, Section 2.

Specimens with protein values exceeding the 200 mg/dL (2,000 mg/L) are flagged and may be diluted by following the Manual Dilution Procedure, or the Automatic Dilution Protocol provided in the assay parameters. If an Automatic Dilution Protocol is not provided, refer to the ARCHITECT System Operations Manual, Section 2 for configuration information, and verify results according to your laboratory's standard operating procedures.

Automated Dilution Protocol

When using the Automated Dilution Protocol, the system performs a 1:2 or 1:10 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

1. Dilute the specimen with saline (0.85% to 0.90% NaCl).
2. Enter the dilution factor in the Patient or Control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor. If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result.

$$\text{Manual Dilution Factor} = \frac{\text{(Volume of Specimen + Volume of Dilution Reagent)}}{\text{Volume of Specimen}}$$

If a diluted specimen result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

Calibration is stable for approximately 41 days (984 hours), but is required with each change in reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

For information on calibrator standardization, refer to the Urine/CSF Protein Calibrator package insert.

For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls {normal and abnormal} are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may be different from the data presented.

Calculation

For additional information on results calculations, refer to the ARCHITECT System Operations Manual, Appendix C.

Interpretation of Results

As with all analyte determinations, the Urine/CSF Protein assay value should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

Homogentisic acid in urine samples at concentrations above 0.37 g/L (2.2 mmol/L) can cause incorrect results.

A list of substances and conditions known to affect the level of urinary and CSF protein in vivo is given by Young.[13]

EXPECTED VALUES

Reference Range

Urine	
Random[10]	1 to 14 mg/dL (10 to 140 mg/L)
24 hour, at rest[10]	50 to 80 mg/day
24 hour excretion[14]	< 300 mg/day*
Spot Urine Protein-to-Creatinine Ratio[14]	< 200 mg/g

*To minimize false positives, National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (K/DOQI) recommends an upper limit of 300 mg/day.

In normal pregnancy, protein excretion may increase harmlessly to 200 to 300 mg/day.[15]

CSF[10]	Range (mg/dL)	Range (mg/L)
Premature	15 to 130	150 to 1,300
Full-term newborn	40 to 120	400 to 1,200
< 1 month	20 to 80	200 to 800
General	15 to 40	150 to 400
Lumbar fluid	15 to 45	150 to 450

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

SPECIFIC PERFORMANCE CHARACTERISTICS

Reportable Range

The reportable range for Urine/CSF Protein is 6.8 mg/dL (68 mg/L) to 200.0 mg/dL (2,000 mg/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-P.[16]

Limit of Quantitation (LOQ)

The LOQ for Urine/CSF Protein is 6.75 mg/dL (67.5 mg/L). The LOQ is the analyte concentration at which the CV = 20%.

Interference

Interference studies were conducted using CLSI protocol NCCLS EP7-P.[17]

Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Target (mg/L)	Observed (% of Target)
Acetic acid (8.5 N)	6.25 mL/dL (531 mmol/L)	4	65.5	655	66.4
Ascorbate	200 mg/dL (11.35 mmol/L)	4	66.7	667	99.6
Boric acid	250 mg/dL (40.43 mmol/L)	4	67.3	673	100.1
Glucose	1,000 mg/dL (55.5 mmol/L)	4	65.6	656	102.1
Hydrochloric acid (6 N)	2.5 mL/dL (150 mmol/L)	4	66.0	660	43.8
Nitric acid (6 N)	5.0 mL/dL (300 mmol/L)	4	66.8	668	72.5
Sodium carbonate	1.25 g/dL (117.94 mmol/L)	4	65.6	656	101.1
Sodium fluoride	400 mg/dL (95.26 mmol/L)	4	66.4	664	97.8
Sodium oxalate	60 mg/dL (4.47 mmol/L)	4	66.3	663	99.7

Solutions at the concentrations listed were prepared by adding each interfering substance individually to a human urine pool.

The following drugs were tested for interference at the concentrations indicated using an acceptance criteria of ± 10% from the target value.

Interfering Substance	Interferent Concentration	N	Target (mg/dL)	Observed (% of Target)
Homogentisic Acid	0.37 g/L (2.2 mmol/L)	3	14.0	108.2
	0.75 g/L (4.5 mmol/L)	3	14.0	112.8
Iohexol	18 g/L (21.9 mmol/L)	3	14.7	97.7

Interferences from medications or endogenous substances may affect results.[13]

Precision

The precision of the Urine/CSF Protein assay is ≤ 7.8% Total CV. Studies were performed using CLSI protocol NCCLS EP5-A.[18]

Representative data from studies are summarized below.

Urine			
Control		Level 1	Level 2
N		80	80
Mean (mg/dL)		15.7	55.6
Mean (mg/L)		157.0	556.0
Within Run	SD (mg/dL)	0.56	0.77
	SD (mg/L)	5.6	7.7
	%CV	3.6	1.4
Between Run	SD (mg/dL)	0.48	0.63
	SD (mg/L)	4.8	6.3
	%CV	3.0	1.1
Between Day	SD (mg/dL)	0.30	0.51
	SD (mg/L)	3.0	5.1
	%CV	1.9	0.9
Total	SD (mg/dL)	0.79	1.12
	SD (mg/L)	7.9	11.2
	%CV	5.0	2.0

Representative data from studies using CLSI protocol NCCLS EP10-A[19] are summarized below.

CSF			
Control		Level 1	Level 2
N		50	50
Mean (mg/dL)		32.4	78.0
Mean (mg/L)		324.0	780.0
Within Run	SD (mg/dL)	0.54	0.43
	SD (mg/L)	5.4	4.3
	%CV	1.7	0.6
Between Run	SD (mg/dL)	0.62	1.52
	SD (mg/L)	6.2	15.2
	%CV	1.9	2.0
Between Day	SD (mg/dL)	0.00	0.69
	SD (mg/L)	0.0	6.9
	%CV	0.0	0.9
Total	SD (mg/dL)	0.82	1.73
	SD (mg/L)	8.2	17.3
	%CV	2.5	2.2

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.[20]

Urine and CSF results from the Urine/CSF Protein assay on the AEROSET System were compared with those from a commercially available benzethonium chloride methodology.

Urine and CSF results from the Urine/CSF Protein assay on an ARCHITECT cSystem were compared with those from the Urine/CSF Protein assay on the AEROSET System.

Urine	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	61	74
Y-Intercept (mg/dL)	-0.264	-0.403
Y-Intercept (mg/L)	-2.64	-4.03
Correlation Coefficient	0.992	1.000
Slope	1.065	1.012
Range (mg/dL)*	2.20 to 91.87	2.00 to 197.80
Range (mg/L)*	22.0 to 918.7	20.0 to 1978.0

*AEROSET Range

CSF	AEROSET vs. Comparative Method	ARCHITECT vs. AEROSET
N	74	76
Y-Intercept (mg/dL)	5.762	1.292
Y-Intercept (mg/L)	57.62	12.92
Correlation Coefficient	0.997	0.998
Slope	0.985	1.031
Range (mg/dL)*	8.55 to 183.43	12.30 to 176.40
Range (mg/L)*	85.5 to 1834.3	123.0 to 1764.0

*AEROSET Range

BIBLIOGRAPHY

1. Tietz NW, editor. *Fundamentals of Clinical Chemistry*, 3rd ed. Philadelphia, PA: WB Saunders; 1987:336,339–341.
2. Zilva JF, Pannall PR. Plasma proteins and immunoglobulins. *Clinical Chemistry in Diagnosis and Treatment*. London, England: Lloyd-Luke; 1979:305–329.
3. First MR. Renal function. In: Kaplan LA, Pesce AJ, editors. *Clinical Chemistry Theory, Analysis, and Correlation*. St. Louis, MO: CV Mosby; 1984:418.
4. Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders; 1994:723–726.
5. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
6. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
7. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
8. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
9. Koumantakis G. Fluorescein interference with urinary creatinine and protein measurements. *Clin Chem* 1991;37(10):1799.
10. Tietz NW, editor. *Clinical Guide to Laboratory Tests*, 3rd ed. Philadelphia, PA: WB Saunders; 1995:520.
11. Guder WG, da Fonseca-Wollheim F, Heil W, et al. *The Quality of Diagnostic Samples*. Darmstadt, Germany: GIT Verlag; 2001:52–55.
12. US Pharmacopeial Convention, Inc. General notices. In: *US Pharmacopeia National Formulary*, 1995 ed (USP 23/NF 18). Rockville, MD: The US Pharmacopeial Convention, Inc; 1994:11.
13. Young DS. *Effects of Drugs on Clinical Laboratory Tests*, 4th ed. Washington, DC: AACC Press; 1995:3-498–3-511.
14. National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (K/DOQI). *K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification—Part 4 Definition and Classification of Stages of Chronic Kidney Disease, Guideline 1 Definition and Stages of Chronic Kidney Disease*. Accessed March 2, 2006 from: http://www.kidney.org/professionals/kdoqi/guidelines_ckd/p4_class_g1.htm.
15. Burtis CA, Ashwood ER, editors. *Tietz Textbook of Clinical Chemistry*, 2nd ed. Philadelphia, PA: WB Saunders; 1994:717–719.
16. Passey RB, Bee DE, Caffo A, et al. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline (EP6-P)*. Villanova, PA: The National Committee for Clinical Laboratory Standards, 1986.
17. National Committee for Clinical Laboratory Standards (NCCLS). *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS Document EP7-P. Villanova, PA: NCCLS; 1986.
18. National Committee for Clinical Laboratory Standards (NCCLS). *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.* NCCLS Document EP5-A. Wayne, PA: NCCLS; 1999.
19. Krouwer JS, Castañeda-Méndez K, Dawson JM, et al. Preliminary *Evaluation of Quantitative Clinical Laboratory Methods;* Approved Guideline (EP10-A). Wayne, PA: The National Committee for Clinical Laboratory Standards, 1998.
20. National Committee for Clinical Laboratory Standards (NCCLS). *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS Document (EP9-A). Wayne, PA: NCCLS; 1995.

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
MANUFACTURED FOR	Manufactured for
PRODUCT OF USA	Product of USA
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

The ARCHITECT cSystem family of instruments consists of c4000, c8000, and c16000 instruments.

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany
+49-6122-580

MANUFACTURED FOR

Abbott Laboratories

DISTRIBUTED IN THE USA BY

Abbott Laboratories
Abbott Park, IL 60064 USA

Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

Revised March 2022.

Abbott

UPro Urine/CSF—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **UPro** Type: **Photometric** Version: †
Number: **1044**
Run controls for onboard reagents by: **Lot**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **End up**

	Primary	Secondary	Read times
Wavelength:	**404** /	**700**	Main: **19 – 32**

Last required read: **32**
Absorbance range: ___ – ___ Color correction: ___ – ___
Sample blank type: **Self** Blank: **14 – 16**

O Reaction definition ● Reagent / Sample O Validity checks

Reagent: **UPRO0** Reagent volume: R1 **200** R2 **40**
Diluent: **Saline** Water volume: R1 ___ R2 ___
Diluent dispense mode: **Type 0** Dispense mode: R1 **Type 0** R2 **Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**9.6**	___	___	___	=	**1:1.00**	●
1:2 :	**4.8**	___	___	___	=	**1:1.96**	O
1:10 :	**20.0**	**9.6**	**180**	___	=	**1:10.00**	O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **End Subtraction**

	A	B
Read time:	**31 – 31**	**25 – 25**
Calculation limits:	**-0.0400 – 9.9000**	

Maximum absorbance variation: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **UPro** Calibration method: **Spline**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **UPro**

	Calibrator level:	Concentration:
Blank:	**Water**	**0**†††
Cal 1:	**UPro1**	‡
Cal 2:	**UPro2**	‡
Cal 3:	**UPro3**	‡
Cal 4:	**UPro4**	‡
Cal 5:	**UPro5**	‡

Replicates: **3** [Range 1 – 3]

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: **UPro**

Calibrator level	Sample	Diluted sample	Diluent	Water
Blank: **Water**	**9.6**	___	___	___
Cal 1: **UPro1**	**9.6**	___	___	___
Cal 2: **UPro2**	**9.6**	___	___	___
Cal 3: **UPro3**	**9.6**	___	___	___
Cal 4: **UPro4**	**9.6**	___	___	___
Cal 5: **UPro5**	**9.6**	___	___	___

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **984** (hours)
Calibration type:
Adjust type: **None**

O Calibrators O Volumes O Intervals ● Validity checks

Blank absorbance range: _____ – _____
Span: **Blank** – **Blank**
Span absorbance range: _____ – _____
Expected cal factor: **0.00**
Expected cal factor tolerance %: **0**

Configure assay parameters — SmartWash

O General O Calibration ● SmartWash O Results O Interpretation

Assay: **UPro**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**AMIK9**	**Detergent A**	**345**	**1**
R1	**DIG00**	**Detergent A**	**345**	**1**
R1	**VANCO**	**Detergent A**	**345**	**1**
R1	**GENT9**	**Detergent A**	**345**	**1**
R1	**TOBRA**	**Detergent A**	**345**	**1**
R1	**DGT0B**	**Detergent A**	**345**	**1**
R2	**AMIK9**	**Detergent A**	**345**	**1**
R2	**DIG00**	**Detergent A**	**345**	**1**
R2	**VANCO**	**Detergent A**	**345**	**1**
R2	**GENT9**	**Detergent A**	**345**	**1**
R2	**TOBRA**	**Detergent A**	**345**	**1**
R2	**DGT0B**	**Detergent A**	**345**	**1**
R2	**CREAC**	**Detergent A**	**345**	**1**
***Sample probe**		**Detergent A**		
Cuvette	**TP**	**Detergent A**	**345**	
Cuvette	**UPro**	**Detergent A**	**345**	

*Sample Probe *Sample wash protocol* is **Maximum wash.**

UPro Urine/CSF—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **UPro** Assay number: **1044**
Dilution default range: Result units: **mg/dL**
Low-Linearity: **6.8**‡‡
High-Linearity: **200.0**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME

Configure result units

Assay: **UPro**
Version: †
Result units: **mg/dL**
Decimal places: **1** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

UPro Urine/CSF—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **UPro** Assay number: **1044**
Dilution default range: Result units: **mg/L**
Low-Linearity: **68**‡‡
High-Linearity: **2000**
Gender and age specific ranges:

GENDER	AGE (UNITS)	NORMAL	EXTREME

Configure result units

Assay: **UPro**
Version: †
Result units: **mg/L**
Decimal places: **0** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

† Due to differences in instrument systems and unit configurations, version numbers may vary.
††† Displays the number of decimal places defined in the decimal places parameter field.
‡ Refer to the concentration specified on calibrator labeling or value sheet. These values are defined on the Configure calibrator set screen.
‡‡ The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.