SIEMENS Healthineers

Urinary/Cerebrospinal Fluid Protein (UCFP)

Current Revision and Date[a]	Rev. 02, 2023-02	
Product Name	Atellica CH Urinary/Cerebrospinal Fluid Protein (UCFP)	REF 11097543 (1480 tests)
Abbreviated Product Name	Atellica CH UCFP	
Test Name/ID	UCFP	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica CH Urinary/Cerebrospinal Fluid Protein Calibrator (UCFP CAL)	REF 11099339
Specimen Types	Urine, cerebrospinal fluid (CSF)	
Sample Volume	6.3 µL	
Measuring Interval	6.0–250.0 mg/dL (60–2500 mg/L)	

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

CE

Intended Use

The Atellica® CH Urinary/Cerebrospinal Fluid Protein (UCFP) assay is for *in vitro* diagnostic use in the quantitative determination of total protein in human urine and cerebrospinal fluid using the Atellica® CI Analyzer.

Summary and Explanation

The Atellica CH UCFP assay allows direct quantitation of proteins in urine and cerebrospinal fluid specimens. The assay is an adaptation of pyrogallol red-molybdate method by Y. Fujita, I. Mori and S. Kitano.[1]

Measurement of the protein content in urine is used in diagnosis and treatment of kidney diseases.

Measurement of the protein content in cerebrospinal fluid is used in the diagnosis and treatment of central nervous system diseases.

Principles of the Procedure

In the reaction sequence, pyrogallol red combines with sodium molybdate to form a red complex with maximum absorbance at 470 nm. The protein in the sample reacts with this complex in acid solution to form a bluish-purple colored complex, which absorbs at 600 nm. The absorbance at 600 nm is directly proportional to the concentration of protein in the sample. The analyte concentration is determined by calculation using a logit curve fit on a previously stored calibration curve.

Reaction Equation

pyrogallol red-molybdate + protein → PR-MO-protein complex (absorbs at 600 nm)

Reagents

Material Description	Storage	Stability[a]
Atellica CH UCFP assay	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	90 days
Well 1 (W1) Volume: 21.1 mL Pyrogallol red (0.20 mM) in methanol (5%) sodium molybdate (0.35 mM) stabilizers and surfactants.		
Well 2 (W2) Volume: 21.1 mL Pyrogallol red (0.20 mM) in methanol (5%) sodium molybdate (0.35 mM) stabilizers and surfactants.		

[a] Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens-healthineers.com.

H371
P260, P280, P308+P311, P501

Warning!
May cause damage to organs.
Do not breathe vapours. Wear protective gloves/protective clothing/eye protection/face protection. IF exposed or concerned: Call a POISON CENTER or doctor/physician. Dispose of contents and container in accordance with all local, regional, and national regulations.
Contains: Methanol (Atellica CH UCFP assay P1).

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Storage and Stability

Store all reagents in an upright position, away from light and heat. Do not use products beyond the expiration date printed on the product labeling.

For details about product material description, storage, and stability, refer to *Reagents*.

Onboard Stability

Discard products at the end of the onboard stability interval.

For details about product onboard stability, refer to *Reagents*.

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Urine and cerebrospinal fluid (CSF) are the recommended specimen types for this assay.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[2]
- Normal procedures for collecting urine and cerebrospinal fluid may be used for samples to be analyzed by this method.
- Keep tubes capped at all times.[3]
- Avoid hemolyzed samples. Hemolysis increase Atellica CH UCFP assay results at 25 mg/dL hemoglobin.
- Random urine specimens may be used but timed 24-hr specimens are preferred. No preservative is required during 24-hr collection.
- Specimens should not contain blood.[4]
- Collect CSF samples with care to avoid contamination with plasma proteins. Blood present in CSF invalidates the protein values due to contamination with plasma proteins.[4]

Storing the Specimen

- After 24 hours, store urine aliquots at 2–4°C for < 72 hours or frozen at -20°C for up to 1 year.[4-6]
- Specimens must be free of any particulate matter before analysis.
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- For CSF, centrifuge before analysis. Analyze fresh specimens or store at 4°C[7] for less than 72 hours. Frozen specimens are stable at -20°C for 6 months.[7]

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 6.3 µL of urine or CSF for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the system operating instructions.

Do not use samples with apparent contamination.

Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[3]

For a complete list of appropriate sample containers, refer to the system operating instructions.

Before placing samples on the system, ensure they are free of:

- Bubbles or foam.
- Particulate matter.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097543	**Pack 1 (P1)** Well 1 (W1) 21.1 mL of Atellica CH UCFP Reagent 1 Well 2 (W2) 21.1 mL of Atellica CH UCFP Reagent 1	4 x 370

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description	
	Atellica CI Analyzer[a]	
11099339	Atellica CH UCFP CAL	2 x 4.0 mL calibrator level 2 2 x 4.0 mL calibrator level 3 2 x 4.0 mL calibrator level 4 2 x 4.0 mL calibrator level 5 2 x 4.0 mL calibrator level 6
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The Atellica CI Analyzer automatically performs the following steps:

1. For urine or CSF, dispenses 30 µL of primary sample and 35.1 µL of the system diluent into a dilution cuvette.
2. Dispenses 6.3 µL of pre-diluted sample into a reaction cuvette.
3. Dispenses 100 µL of the Atellica CH UCFP Reagent 1 into the same reaction cuvette.
4. Mixes and incubates the mixture at 37°C for 5 minutes.
5. Measures the absorbance.

6. Reports results.

   Test Duration: 5 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Note Do not use reagents that are cloudy, discolored, or contain precipitates.

Preparing the System

For information about loading reagents, refer to the system operating instructions.

Performing Calibration

For calibration of the Atellica CH UCFP assay, use the Atellica CH UCFP CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Calibrate the assay as described in the following table.

Stability Interval	Days
Lot Calibration	60
Pack Calibration	90

In addition, perform a calibration:

- When changing lot numbers of reagents.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service.

Note When loading new reagents, recalibration is not required if there is a valid lot calibration. For information about the calibration interval, refer to the system operating instructions.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

At least once each day of use, analyze two levels of quality control (QC) material with known protein concentration. Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration.
- With use of a new lot of reagent.
- When troubleshooting test results that do not match clinical conditions or symptoms.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system operating instructions.

Taking Corrective Action

If the quality control results do not fall within the expected control interval, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the system operating instructions.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the system operating instructions. The system reports results in mg/dL (conventional units) or mg/L (SI units [Systèm International d'Unités]), depending on the units defined when setting up the assay.

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

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- The Atellica CH UCFP assay is limited to the detection of protein in urine and CSF.
- Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.
- Samples containing amikacin, gentamicin, kanamycin, and tobramycin should be avoided since these substances falsely increase Atellica CH UCFP assay results.
- Neomycin sulfate at 15 µg/mL increases Atellica CH assay results by 11% and at 7.5 µg/mL the interference is less than 5%.
- As with any chemical reaction, you must be alert to the possible effect of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Expected Values

Reference Interval

The reference interval for protein is 1–14 mg/dL (10–140 mg/L) for urine[4] and 15–45 mg/dL (150–450 mg/L) for CSF.[5] Siemens has verified the transference of reported reference interval for the Atellica CH UCFP assay.[8,9]

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[9] Consider these values as guidance only.

Performance Characteristics

Measuring Interval

The Atellica CH UCFP assay is linear from 6.0–250.0 mg/dL (60–2500 mg/L). The system flags all values that are outside the specified measuring interval.

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 2500 mg/dL (25,000 mg/L). You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ limit of detection (LoD).

The Limit of Detection (LoD) corresponds to the lowest concentration of protein that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ 6.0 mg/dL (≤ 60 mg/L).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of protein in a sample at which the total allowable error is ≤ 35%. The assay is designed to have an LoQ ≤ 6.0 mg/dL (≤ 60 mg/L).

Detection capability was determined in accordance with CLSI Document EP17-A2.[10]

The following results were obtained:

Specimen Type	Detection Capability	Result mg/dL (mg/L)
Urine	LoB	3.0 (30)
	LoD	6.0 (60)
	LoQ	6.0 (60)
CSF	LoB	3.0 (30)
	LoD	6.0 (60)
	LoQ	6.0 (60)

The LoD was determined using 360 determinations, with 180 blank and 180 low-level replicates, and an LoB of 3.0 mg/dL (30 mg/L).

Assay results obtained at individual laboratories may vary from the data presented.

Precision

The Repeatability precision of the Atellica CH UCFP assay is designed to have the following characteristics:

- CV ≤ 6% at 15.0–29.0 mg/dL
- CV ≤ 4% at 30.0–129.0 mg/dL
- CV ≤ 3% at 130.0–250.0 mg/dL

The Within-Laboratory precision of the Atellica CH UCFP assay is designed to have the following characteristics:

- CV ≤ 9% at 15.0–29.0 mg/dL
- CV ≤ 6% at 30.0–129.0 mg/dL
- CV ≤ 6% at 130.0–250.0 mg/dL

Precision was determined in accordance with CLSI Document EP05-A3.[11] Samples were assayed on the Atellica CI Analyzer in duplicate in 2 runs per day for 20 days.

The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Specimen Type	N[a]	Mean mg/dL (mg/L)	SD[b] mg/dL (mg/L)	CV[c] (%)	SD mg/dL (mg/L)	CV (%)
Urine Control 1	80	24.8 (248)	1.07 (10.7)	4.3	1.17 (11.7)	4.7
Urine Control 2	80	69.5 (695)	1.21 (12.1)	1.7	1.27 (12.7)	1.8
Urine Pool 1	80	21.1 (211)	1.07 (10.7)	5.1	1.19 (11.9)	5.6
Urine Pool 2	80	145.8 (1458)	1.33 (13.3)	0.9	1.42 (14.2)	1.0
CSF Control	80	90.9 (909)	1.04 (10.4)	1.1	2.36 (23.6)	2.6
CSF Pool	80	43.7 (437)	1.26 (12.6)	2.9	1.75 (17.5)	4.0

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

Reproducibility

The assay is designed to have the following reproducibility:

- CV ≤ 9% at 15.0–29.0 mg/dL
- CV ≤ 6% at 30.0–129.0 mg/dL
- CV ≤ 6% at 130.0–250.0 mg/dL

Reproducibility was determined in accordance with CLSI Document EP05-A3.[11] Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mg/dL (mg/L)	SD[b] mg/dL (mg/L)	CV[c] (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)
Urine 1	225	22.9 (229)	0.88 (8.8)	3.8	0.96 (9.6)	4.2	0.45 (4.5)	2.0	0.48 (4.8)	2.1	1.46 (14.6)	6.4
Urine 2	225	150.8 (1508)	0.84 (8.4)	0.6	1.63 (16.3)	1.1	0.77 (7.7)	0.5	0.97 (9.7)	0.6	2.21 (22.1)	1.5
Urine QC 1	225	31.3 (313)	0.58 (5.8)	1.9	0.80 (8.0)	2.6	0.35 (3.5)	1.1	0.22 (2.2)	0.7	1.07 (10.7)	3.4

			Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
Sample	N[a]	Mean mg/dL (mg/L)	SD[b] mg/dL (mg/L)	CV[c] (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)	SD mg/dL (mg/L)	CV (%)
Urine QC 2	225	75.7 (757)	0.63 (6.3)	0.8	0.96 (9.6)	1.3	0.69 (6.9)	0.9	0.38 (3.8)	0.5	1.39 (13.9)	1.8
CSF QC 1	225	42.3 (423)	0.53 (5.3)	1.3	1.59 (15.9)	3.8	0.73 (7.3)	1.7	0.27 (2.7)	0.6	1.85 (18.5)	4.4
CSF QC 2	225	91.5 (915)	0.71 (7.1)	0.8	1.03 (10.3)	1.1	0.84 (8.4)	0.9	0.42 (4.2)	0.5	1.56 (15.6)	1.7

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

Assay Comparison

The performance of the Atellica CH UCFP assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.10 for Urine, and a slope of 1.00 ± 0.10 for CSF. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.[12] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Urine	Dimension® RxL UCFP on Dimension® RxL Analyzer	y = 0.97x + 1.9 mg/dL (y = 0.97x + 19 mg/L)	6.3–233.0 mg/dL (63–2330 mg/L)	100	0.992
CSF	Dimension® RxL UCFP on Dimension® RxL Analyzer	y = 0.98x + 0.5 mg/dL (y = 0.98x + 5 mg/L)	8.4–250.0 mg/dL (84–2500 mg/L)	103	0.998
Urine	Atellica CH UCFP on Atellica CH Analyzer	y = 0.93x + 1.9 mg/dL (y = 0.93x + 19 mg/L)	7.0–224.0 mg/dL (70–2240 mg/L)	100	0.997
CSF	Atellica CH UCFP on Atellica CH Analyzer	y = 0.97x + 0.9 mg/dL (y = 0.97x + 9 mg/L)	9.1–246.6 mg/dL (91–2466 mg/L)	103	0.998

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the assays may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

These data were generated on the Atellica CH Analyzer with assay reaction conditions that are equivalent to those on the Atellica CI Analyzer.

Non-Interfering Substances

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. The Atellica CH UCFP assay is designed to have < 10% interference from substances tested at analyte concentrations of 10–20 mg/dL (100–200 mg/L) for urine and 40–50 mg/dL (400–500 mg/L) for CSF.

The following substances do not interfere with Atellica CH UCFP assay when present in urine and CFS at the concentrations indicated in the tables below. Bias due to these substances is ≤ 10% at an analyte concentration of indicated in the tables below.

Interference testing was performed in accordance with CLSI Document EP07-A2.[13] The following results were obtained.

Urine

Substance	Substance Concentration	Analyte Concentration mg/dL (mg/L)	Bias %
Acetaminophen	25 mg/dL (1.65 mmol/L)	16.0 (160)	-3.1
Ampicillin	5 mg/dL (0.13 mmol/L)	15.3 (153)	-3.3
Ascorbic Acid	200 mg/dL (11.36 mmol/L)	15.1 (151)	1.3
Boric Acid	500 mg/dL (80.91 mmol/L)	14.4 (144)	-0.7
Caffeine	10 mg/dL (0.51 mmol/L)	16.0 (160)	-6.3
Carbamazepine	12 mg/dL (0.51 mmol/L)	16.0 (160)	-9.4
Chloroamphenicol	25 mg/dL (0.77 mmol/L)	14.4 (144)	5.6
Chlordiazepoxide	2 mg/dL (0.07 mmol/L)	16.1 (161)	-1.2
Chlorpromazine	4 mg/dL (0.13 mmol/L)	16.0 (160)	2.5
Cimetidine	10 mg/dL (0.40 mmol/L)	19.3 (193)	1.0
Citric Acid	25 mg/dL (1.30 mmol/L)	14.4 (144)	-9.0
Diazepam	2 mg/dL (0.07 mmol/L)	16.1 (161)	-6.2
Digoxin	3 ng/mL (0.04 nmol/L)	15.7 (157)	-5.1
Erythromycin	20 mg/dL (0.27 mmol/L)	14.4 (144)	4.9
Ethanol	350 mg/dL (87.28 mmol/L)	16.0 (160)	3.1
Ethosuximide	30 mg/dL (2.12 mmol/L)	14.4 (144)	-1.4
Furosemide	2 mg/dL (0.06 mmol/L)	14.4 (144)	-5.6
Glucose	5000 mg/dL (277.47 mmol/L)	19.0 (190)	-1.6
Ibuprofen	40 mg/dL (1.94 mmol/L)	16.0 (160)	9.4
Lidocaine	6 mg/dL (0.26 mmol/L)	14.4 (144)	-6.3
Lithium	3.5 mg/dL (0.83 mmol/L)	15.4 (154)	-1.3
Nicotine	2 mg/dL (0.12 mmol/L)	15.3 (153)	2.0
Penicillin V	80 mg/dL (2.28 mmol/L)	15.4 (154)	1.9
Pentobarbital	10 mg/dL (0.44 mmol/L)	14.4 (144)	-6.9
Phenobarbital	15 mg/dL (0.65 mmol/L)	12.7 (127)	-5.5
Phenytoin	100 µg/mL (3.96 µmol/L)	15.3 (153)	3.9
Primidone	10 mg/dL (0.46 mmol/L)	15.3 (153)	-0.7
Propoxyphene	0.4 mg/dL (0.01 mmol/L)	16.3 (163)	6.1

Substance	Substance Concentration	Analyte Concentration mg/dL (mg/L)	Bias %
Salicylic Acid	50 mg/dL (3.62 mmol/L)	16.0 (160)	5.0
Theophylline	250 µg/mL (13.87 µmol/L)	16.0 (160)	2.5
Thymol	150 mg/dL (9.99 mmol/L)	16.3 (163)	8.6
Toluene	1.5% v/v (1.5% v/v)	15.4 (154)	1.9
Urea	500 mg/dL (83.19 mmol/L)	14.4 (144)	-2.1
Uric Acid	7.5 mg/dL (0.45 mmol/L)	14.4 (144)	-2.1

CSF

Substance	Substance Concentration	Analyte Concentration mg/dL (mg/L)	Bias %
Acetaminophen	25 mg/dL (1.65 mmol/L)	47.8 (478)	-2.9
Ampicillin	5 mg/dL (0.13 mmol/L)	49.4 (494)	-3.4
Ascorbic Acid	200 mg/dL (11.36 mmol/L)	43.7 (437)	-6.2
Boric Acid	500 mg/dL (80.91 mmol/L)	43.7 (437)	-2.1
Caffeine	10 mg/dL (0.51 mmol/L)	47.8 (478)	-2.9
Carbamazepine	12 mg/dL (0.51 mmol/L)	47.8 (478)	-1.0
Chloroamphenicol	25 mg/dL (0.77 mmol/L)	43.7 (437)	-1.6
Chlordiazepoxide	2 mg/dL (0.07 mmol/L)	49.5 (495)	-2.4
Chlorpromazine	4 mg/dL (0.13 mmol/L)	47.8 (478)	0.4
Cimetidine	10 mg/dL (0.40 mmol/L)	47.4 (474)	1.5
Citric Acid	25 mg/dL (1.30 mmol/L)	43.7 (437)	-4.1
Diazepam	2 mg/dL (0.07 mmol/L)	47.4 (474)	1.5
Digoxin	3 ng/mL (0.04 nmol/L)	49.9 (499)	-2.4
Erythromycin	20 mg/dL (0.27 mmol/L)	43.7 (437)	-0.7
Ethanol	350 mg/dL (87.28 mmol/L)	49.6 (496)	0.4
Ethosuximide	30 mg/dL (2.12 mmol/L)	43.7 (437)	-1.4
Furosemide	2 mg/dL (0.06 mmol/L)	43.7 (437)	-2.1
Glucose	5000 mg/dL (277.47 mmol/L)	45.0 (450)	0.9
Ibuprofen	40 mg/dL (1.94 mmol/L)	47.8 (478)	2.9
Lidocaine	6 mg/dL (0.26 mmol/L)	43.7 (437)	0.0
Lithium	3.5 mg/dL (0.83 mmol/L)	47.6 (476)	-1.5
Nicotine	2 mg/dL (0.12 mmol/L)	47.3 (473)	1.5
Penicillin V	80 mg/dL (2.28 mmol/L)	49.6 (496)	0.6
Pentobarbital	10 mg/dL (0.44 mmol/L)	43.7 (437)	-1.1

Substance	Substance Concentration	Analyte Concentration mg/dL (mg/L)	Bias %
Phenobarbital	15 mg/dL (0.65 mmol/L)	42.9 (429)	-0.9
Phenytoin	100 µg/mL (3.96 µmol/L)	49.4 (494)	-1.6
Primidone	10 mg/dL (0.46 mmol/L)	49.4 (494)	-1.0
Propoxyphene	0.4 mg/dL (0.01 mmol/L)	48.6 (486)	1.0
Salicylic Acid	50 mg/dL (3.62 mmol/L)	47.8 (478)	-2.5
Theophylline	250 µg/mL (13.87 µmol/L)	47.8 (478)	0.4
Thymol	150 mg/dL (9.99 mmol/L)	49.5 (495)	-3.2
Toluene	1.5% v/v (1.5% v/v)	49.9 (499)	-0.2
Urea	500 mg/dL (83.19 mmol/L)	43.7 (437)	0.7
Uric Acid	7.5 mg/dL (0.45 mmol/L)	43.7 (437)	-0.5

Assay results obtained at individual laboratories may vary from the data presented.

Linearity

The Atellica CH UCFP assay is designed to be linear across the measuring interval 6.0–250.0 mg/dL (60–2500 mg/L).

The linear interval of Atellica CH UCFP assay was established based on CLSI Document EP06-ED2[14] using the Atellica CI Analyzer.

Linearity was evaluated using a sample that contained a high level of protein, which was mixed in various proportions with a sample at a low level of protein. The resulting sample mixtures (9 combinations) were assayed for protein.

The Atellica CH UCFP assay is linear from 6.0–250.0 mg/dL (60–2500 mg/L).

Onboard Dilution

Human urine and CSF samples were diluted onboard the Atellica CI Analyzer with saline. The following results were obtained:

Sample	Dilution	Expected mg/dL (mg/L)	Observed mg/dL (mg/L)	Recovery %
1 (Urine)	1:10	255.9 (2559)	253.7 (2537)	99
2 (Urine)	1:10	448.2 (4482)	460.0 (4600)	103
3 (Urine)	1:10	745.0 (7450)	765.2 (7652)	103
4 (Urine)	1:10	1234.2 (12342)	1260.1 (12601)	102
5 (Urine)	1:10	1776.1 (17761)	1839.7 (18397)	104
1 (CSF)	1:10	481.2 (4812)	485.1 (4851)	101
2 (CSF)	1:10	693.0 (6930)	673.5 (6735)	97
3 (CSF)	1:10	1077.7 (10777)	1078.8 (10788)	100
4 (CSF)	1:10	1468.3 (14683)	1462.8 (14628)	100
5 (CSF)	1:10	2127.8 (21278)	2128.9 (21289)	100

Assay results obtained at individual laboratories may vary from the data presented.

Standardization

The Atellica CH UCFP assay standardization is traceable to a reference method, which uses National Institute of Standards and Technology Standard (NIST) Reference Material NIST-SRM 927.

Assigned values for calibrators are traceable to this standardization.[8]

Technical Assistance

For customer support, contact your local technical support provider or distributor.

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Symbol	Symbol Title
	Manufacturer		Authorized representative in the European Community
	Use-by date		Authorized representative in Switzerland
	Catalog number		Batch code
	Consult Instructions for Use		Contains sufficient for <n> tests
 <…/eifu>	Internet URL address to access the electronic instructions for use		Version of Instructions for Use
	*In vitro* diagnostic medical device		Revision
RxOnly	Prescription device (US only)		Unique Device Identifier
	CE Marking with Notified Body		CE Marking
	Temperature limit		Keep away from sunlight
	Upper limit of temperature		Lower limit of temperature
	Do not re-use		Do not freeze
	Recycle		This way up
	Biological risks		Caution
	Common Units		International System of Units
YYYY-MM-DD	Date format (year-month-day)	**YYYY-MM**	Date format (year-month)
	Document face up[a]		Handheld barcode scanner
	Target		Mixing of substances
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.		Interval

Symbol	Symbol Title	Symbol	Symbol Title
MATERIAL ID	Unique material identification number	MATERIAL	Material
CONTROL TYPE	Type of control	CONTROL NAME	Name of control
CONTROL LOT VAL	Quality control lot value	CAL LOT VAL	Calibrator lot value

[a] Indicates Assay-eNote

Legal Information

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