SIEMENS Healthineers

Valproic Acid (VPA)

Current Revision and Date[a]	Rev. 04, 2019-05	
Product Name	Atellica CH Valproic Acid (VPA)	REF 11097512 (400 tests)
Abbreviated Product Name	Atellica CH VPA	
Test Name/ID	VPA	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH DRUG CAL II	REF 11099405
Specimen Types	Serum, plasma (lithium heparin)	
Sample Volume	2.5 µL	
Measuring Interval	3.0–150.0 µg/mL (20.8–1040.1 µmol/L)	

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

CE

Intended Use

The Atellica® CH Valproic Acid (VPA) assay is for *in vitro* diagnostic use for the quantitative measurement of valproic acid in human serum and plasma (lithium heparin) using the Atellica® CH Analyzer. VPA test results may be used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure appropriate therapy.

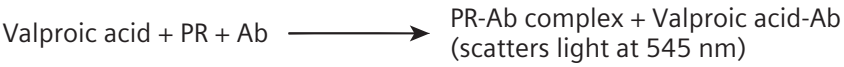
Summary and Explanation

The Atellica CH VPA assay is based on a particle-enhanced turbidimetric inhibition immunoassay (PETINIA) technique which measures the level of valproic acid, an anti-convulsant drug. Valproic acid is used alone or with other anticonvulsants in the prophylactic management of simple and complex absence (petit mal) seizures. The drugs may also be used in conjunction with other anticonvulsants in the management of multiple seizure types which include absence seizures. Valproic acid has been considered by some clinicians to be the drug of choice in the management of myoclonic seizures.[1,2]

Principles of the Procedure

The methodology for VPA involves a homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a synthetic particle-valproic acid conjugate (PR) and valproic acid-specific, monoclonal antibody (Ab). Valproic acid present in the sample competes with the particles for the antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of valproic acid in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 545/694 nm.

Reaction Equation



Reagents

Material Description	Storage	Stability[a]
Atellica CH VPA	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per pack	30 days
Well 1 (W1) Reagent 1 (R1) 10.0 mL Particle reagent (variable by lot)		
Well 2 (W2) Reagent 3 (R3) 10.0 mL Buffer		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 10.0 mL Antibody (mouse monoclonal) (variable by lot)		
Well 2 (W2) Empty		

[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.com/healthineers.

H317 **P280, P272, P302+P352, P333+P313, P363, P501**	**Warning!** May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Dispose of contents and container in accordance with all local, regional, and national regulations. **Contains:** 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (R1, R2, and R3)

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

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

Onboard Stability

Reagents are stable onboard the system for 30 days per pack. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (lithium heparin) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[3]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[4]
- Follow the instructions provided with your specimen collection device for use and processing.[5]
- Allow blood specimens to clot completely before centrifugation.[6]
- Keep tubes capped at all times.[6]

Storing the Specimen

Specimens may be stored for up to 8 hours at 25°C or for up to 2 days at 2–8°C or stored frozen for up to 30 days at -20°C.[7]

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.

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 2.5 µL of sample 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 online help.

Note Do not use specimens with apparent contamination.

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

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[6]

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097512	**Pack 1 (P1)** Well 1 (W1) 10.0 mL of Atellica CH VPA Reagent 1 Well 2 (W2) 10.0 mL of Atellica CH VPA Reagent 3 **Pack 2 (P2)** Well 1 (W1) 10.0 mL of Atellica CH VPA Reagent 2 Well 2 (W2) Empty	4 x 100

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11099405	Atellica CH DRUG CAL II (calibrator)	2 x 5.0 mL calibrator level 1 CAL 1 2 x 5.0 mL calibrator level 2 CAL 2 2 x 5.0 mL calibrator level 3 CAL 3 2 x 5.0 mL calibrator level 4 CAL 4 2 x 5.0 mL calibrator level 5 CAL 5 Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 10 µL of primary sample and 240 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 30 µL of Reagent 3 into a reaction cuvette.
3. Dispenses 15 µL of Reagent 1 and 43.8 µL of special reagent water into a reaction cuvette.
4. Measures the absorbance after Reagent 1 and Reagent 3 addition.
5. Dispenses 2.5 µL of pre-diluted sample into a reaction cuvette.
6. Dispenses 15 µL of Reagent 2 and 10 µL of special reagent water into a reaction cuvette.
7. Mixes and incubates the mixture at 37°C.
8. Measures the absorbance after Reagent 2 addition.
9. Reports results.

Note For information about special reagent water requirements, refer to the online help.

Test Duration: 8 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

Performing Calibration

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

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- 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, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	30
Pack Calibration	7
Reagent Onboard Stability	30

For information about lot calibration and pack calibration intervals, refer to the online help.

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

Performing Quality Control

For quality control of the Atellica CH VPA assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme. 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 online help.

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

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in µg/mL (common units) or µmol/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: µg/mL x 6.934 = µmol/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 Atellica CH VPA assay is limited to the detection of valproic acid in human serum and plasma (lithium heparin).

Expected Values

Therapeutic Interval

Therapeutic valproic acid concentrations vary significantly depending on the individual patient. A therapeutic range of 50–100 µg/mL (346–693 µmol/L) may indicate effective serum concentration for many patients; however, some individuals are best treated at concentrations outside this range. The physician must determine the appropriate therapeutic range for each patient.[1,2,9]

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

Performance Characteristics

Measuring Interval

The Atellica CH VPA assay provides results from 3.0–150.0 µg/mL (20.8–1040.1 µmol/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 300.0 µg/mL (2080.2 µmol/L) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[10] The assay is designed to have a limit of blank (LoB) < limit of detection (LoD) and LoD ≤ 3.0 µg/mL (≤ 20.8 µmol/L).

The LoD corresponds to the lowest concentration of valproic acid that can be detected with a probability of 95%. The LoD for the Atellica CH VPA assay is 1.5 µg/mL (10.4 µmol/L), and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 0.9 µg/mL (6.2 µmol/L).

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

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[11] Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Designed to be ≤	Within-Lab Precision		Designed to be ≤
Sample Type	N	Mean µg/mL (µmol/L)	SD[a] µg/mL (µmol/L)	CV[b] (%)	CV (%)	SD µg/mL (µmol/L)	CV (%)	CV (%)
Serum Pool A	80	24.0 (166.4)	0.42 (2.91)	1.7	5.0	0.70 (4.85)	2.9	6.0
Serum Pool B	80	53.3 (369.6)	0.67 (4.65)	1.2	4.0	0.91 (6.31)	1.7	5.0
Serum Pool C	80	97.5 (676.1)	1.25 (8.67)	1.3	4.0	1.69 (11.72)	1.7	5.0
Plasma Pool	80	139.7 (968.7)	1.65 (11.44)	1.2	5.0	2.43 (16.85)	1.7	6.0

[a] Standard deviation.
[b] Coefficient of variation.

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

Assay Comparison

The Atellica CH VPA assay is designed to have a correlation coefficient of ≥ 0.970 and a slope of 1.0 ± 0.10 compared to Dimension® RxL VALP. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[12] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Dimension RxL VALP	y = 1.01x - 1.4 µg/mL (y = 1.01x - 9.7 µmol/L)	9.6–148.8 µg/mL (66.6–1031.8 µmol/L)	110	0.997

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

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

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[12] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 1.01x - 0.5 µg/mL (y = 1.01x - 3.5 µmol/L)	6.7–125.3 µg/mL (46.5–868.8 µmol/L)	50	0.998

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

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH VPA assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH VPA assay.[13]

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. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration µg/mL (µmol/L)	Percent Bias
Hemoglobin	1000 mg/dL (0.62 mmol/L) 1000 mg/dL (0.62 mmol/L)	4.9 (34.0) 101.0 (700.3)	6 1
Bilirubin, conjugated	80 mg/dL (1368 µmol/L) 80 mg/dL (1368 µmol/L)	5.1 (35.4) 102.2 (708.7)	0 1
Bilirubin, unconjugated	80 mg/dL (1368 µmol/L) 80 mg/dL (1368 µmol/L)	5.0 (34.7) 99.3 (688.5)	0 0
Lipemia (Intralipid®)	1000 mg/dL (11.3 mmol/L) 1000 mg/dL (11.3 mmol/L)	4.6 (31.9) 101.0 (700.3)	4 0

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

Non-Interfering Substances

The following substances do not interfere with the Atellica CH VPA assay when present in human serum and plasma (lithium heparin) at the concentrations indicated in the table below. Bias due to these substances is ≤ 10% at an analyte concentration of 50 µg/mL and 100 µg/mL (346 µmol/L and 693 µmol/L). These data were generated on the Dimension Clinical Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[8]

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Acetaminophen	20 mg/dL (1323 µmol/L)	≤ 10
Amikacin	15 mg/dL (256 µmol/L)	≤ 10
Ampicillin	5 mg/dL (143 µmol/L)	≤ 10
Ascorbic acid[a]	5 mg/dL (284 µmol/L)	≤ 10
Caffeine	10 mg/dL (515 µmol/L)	≤ 10
Carbamazepine	12 mg/dL (508 µmol/L)	≤ 10
Chloramphenicol	25 mg/dL (774 µmol/L)	≤ 10
Chlordiazepoxide	2 mg/dL (67 µmol/L)	≤ 10
Chlorpromazine	5 mg/dL (157 µmol/L)	≤ 10
Cholesterol	500 mg/dL (12932 µmol/L)	≤ 10
Cimetidine	5 mg/dL (198 µmol/L)	≤ 10
Creatinine	30 mg/dL (2652 µmol/L)	≤ 10

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Dextran 40[a]	6000 mg/dL (1500 µmol/L)	≤ 10
Dextran 75	2500 mg/dL (333 µmol/L)	≤ 10
Diazepam	2 mg/dL (70.2 µmol/L)	≤ 10
Digoxin	5 ng/mL (6.4 nmol/L)	≤ 10
Erythromycin	20 mg/dL (273 µmol/L)	≤ 10
Ethanol	350 mg/dL (76 mmol/L)	≤ 10
Ethosuximide	30 mg/dL (2125 µmol/L)	≤ 10
Furosemide	2 mg/dL (60 µmol/L)	≤ 10
Gentamicin	12 mg/dL (257 µmol/L)	≤ 10
Heparin (Porcine)	8 U/mL (8000 U/L)	≤ 10
Ibuprofen	40 mg/dL (1939 µmol/L)	≤ 10
Lidocaine	6 mg/dL (256 µmol/L)	≤ 10
Lithium	3.5 mg/dL (5.04 mmol/L)	≤ 10
Nicotine	2 mg/dL (123 µmol/L)	≤ 10
Penicillin G	25 U/mL (25000 U/L)	≤ 10
Pentobarbital	10 mg/dL (442 µmol/L)	≤ 10
Phenobarbital	15 mg/dL (646 µmol/L)	≤ 10
Phenytoin	10 mg/dL (396 µmol/L)	≤ 10
Primidone	10 mg/dL (458 µmol/L)	≤ 10
Propoxyphene	0.4 mg/dL (12 µmol/L)	≤ 10
Protein - Albumin	6 g/dL (60 g/L)	≤ 10
Protein - IgG	6 g/dL (60 g/L)	≤ 10
Protein - Total	12 g/dL (120 g/L)	≤ 10
Rheumatoid factor	750 IU/mL (750 IU/mL)	≤ 10
Salicylic acid	50 mg/dL (3.62 mmol/L)	≤ 10
Theophylline	25 mg/dL (1388 µmol/L)	≤ 10
Urea	500 mg/dL (83.3 mmol/L)	≤ 10
Uric acid	20 mg/dL (1.2 mmol/L)	≤ 10

[a] Ascorbic Acid and Dextran 40 were only tested at a valproic acid concentration of 50 µg/mL (346 µmol/L).

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

Cross-Reactivity

The following structurally related compounds exhibited cross-reactivity at a valproic acid concentration of 100 µg/mL (693 µmol/L).

These data were generated on the Dimension Clinical Chemistry system with assay reaction conditions that are equivalent to those on the Atellica CH Analyzer.[8]

Substance Tested	Concentration Tested	% Cross-Reactivity
3-Keto valproic acid	100 µg/mL (633 µmol/L)	< 5
3-Hydroxy valproic acid	100 µg/mL (625 µmol/L)	< 8
4-Hydroxy valproic acid	100 µg/mL (625 µmol/L)	< 8
2-Propyl glutaric acid	500 µg/mL (2874 µmol/L)	< 8
5-Hydroxy valproic acid	100 µg/mL (625 µmol/L)	28
4-Ene valproic acid[a]	100 µg/mL (704 µmol/L)	47

[a] Metabolite not present in plasma

Standardization

The VPA assay standardization is traceable to an internal standard manufactured using USP-grade (United States Pharmacopeia-grade) material.

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

Technical Assistance

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

siemens.com/healthineers

References

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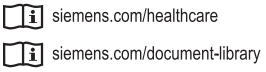
11. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
12. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
13. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable

Symbol	Symbol Title and Description
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer

Symbol	Symbol Title and Description
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
CE 0088	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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