SIEMENS Healthineers

Phenobarbital (Phnb)

Current Revision and Date[a]	Rev. 02, 2019-11	
Product Name	Atellica CH Phenobarbital (Phnb)	REF 11097514 (400 tests)
Abbreviated Product Name	Atellica CH Phnb	
Test Name/ID	Phnb	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH DRUG CAL	REF 11099336
Specimen Types	Serum, plasma (lithium heparin)	
Sample Volume	5 µL	
Measuring Interval	3.0–80.0 µg/mL (12.9–344.8 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 Phenobartibal (Phnb) assay is for *in vitro* diagnostic use for the quantitative measurement of phenobarbital, an anti-epileptic drug and sedative-hypnotic drug, in human serum and plasma (lithium heparin) on the Atellica® CH Analyzer. Phnb test results are used in monitoring levels of phenobarbital to ensure appropriate therapy and in the diagnosis and treatment of phenobarbital overdose.

Summary and Explanation

The phenobarbital assay is based on a particle-enhanced turbidimetric inhibition immunoassay (PETINIA) technique.

Principles of the Procedure

The phenobarbital assay is a homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a synthetic particle-phenobarbital reagent (PR) and phenobarbital-specific monoclonal antibody (Ab). Phenobarbital 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 phenobarbital in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 545/694 nm.

Reaction Equation

Phenobarbital + PR + Ab ⟶ PR-Ab complex + Phenobarbital-Ab
(scatters light at 545 nm)

Reagents

Material Description	Storage	Stability[a]
Atellica CH Phnb	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)

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.[1]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[2]
- Follow the instructions provided with your specimen collection device for use and processing.[3]
- Allow blood specimens to clot completely before centrifugation.[4]
- Keep tubes capped at all times.[4]

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.[5]

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 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.[4]

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
11097514	**Pack 1 (P1)** Well 1 (W1) 10.0 mL of Atellica CH Phnb Reagent 1 Well 2 (W2) 10.0 mL of Atellica CH Phnb Reagent 3 **Pack 2 (P2)** Well 1 (W1) 10.0 mL of Atellica CH Phnb 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]	
11099336	Atellica CH DRUG CAL (calibrator)	2 x 3.0 mL calibrator level 1 CAL 1 2 x 3.0 mL calibrator level 2 CAL 2 2 x 3.0 mL calibrator level 3 CAL 3 2 x 3.0 mL calibrator level 4 CAL 4 2 x 3.0 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 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 36.3 µL of Reagent 3 into a reaction cuvette.
3. Dispenses 10 µL of Reagent 1 and 50 µL of special reagent water into a reaction cuvette.
4. Measures the absorbance after Reagent 1 and Reagent 3 addition.
5. Dispenses 5 µL of pre-diluted sample into a reaction cuvette.
6. Dispenses 10 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 Phnb assay, use Atellica CH DRUG CAL. 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 Phnb 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 4.31 = 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 Phnb assay is limited to the detection of phenobarbital in human serum and plasma (lithium heparin).

Expected Values

Therapeutic Interval

Therapeutic phenobarbital concentrations vary significantly depending on the individual patient. A range of 15.0–40.0 µg/mL (64.7–172.4 µmol/L) for peak drug levels indicates effective plasma or serum levels for many patients; however, some individuals are best treated at concentrations outside this range. Concentrations greater than 50.0 µg/mL (215 µmol/L) are often associated with toxic symptoms.[6-8]

Although amobarbital does not interfere in the therapeutic range, a toxic level at 100 µg/mL (440 µmol/L) amobarbital will increase the response of phenobarbital at a concentration of 30.0 µg/mL (130 µmol/L) by 22.0 µg/mL (95.3 µmol/L). Mephobarbital is rapidly metabolized *in vivo* to phenobarbital, its active metabolite.[8]

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 Phnb assay provides results from 3.0–80.0 µg/mL (12.9–344.8 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 160.0 µg/mL (689.6 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.[9] The assay is designed to have a limit of blank (LoB) < limit of detection (LoD) and LoD ≤ 3.0 µg/mL (12.9 µmol/L).

The LoD corresponds to the lowest concentration of phenobarbital that can be detected with a probability of 95%. The LoD for the Atellica CH Phnb assay is 2.0 µg/mL (8.6 µmol/L), and was determined using 120 determinations, with 60 blank and 60 low level replicates, and a LoB of 1.5 µg/mL (6.5 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.[10] 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		Within-Lab Precision	
Sample Type	**N**	**Mean µg/mL (µmol/L)**	**SD[a] µg/mL (µmol/L)**	**CV[b] (%)**	**SD µg/mL (µmol/L)**	**CV (%)**
Serum Pool	80	14.1 (60.8)	0.20 (0.86)	1.4	0.39 (1.68)	2.8
Plasma Pool	80	32.0 (137.9)	0.38 (1.64)	1.2	0.59 (2.54)	1.8
Serum Pool	80	47.0 (202.6)	0.46 (1.98)	1.0	0.73 (3.17)	1.6
Serum Pool	80	67.6 (291.4)	0.61 (2.63)	0.9	1.53 (6.59)	2.3

[a] Standard deviation.

[b] Coefficient of variation.

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

Assay Comparison

The Phnb assay is designed to have a correlation coefficient of ≥ 0.980 and a slope of 1.0 ± 0.05 compared to Dimension® PHNO. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[11] The following results were obtained:

Specimen	**Comparative Assay (x)**	**Regression Equation**	**Sample Interval**	**N[a]**	**r[b]**
Serum	Dimension PHNO	y = 0.92x + 0.7 µg/mL (y = 0.92x + 3.0 µmol/L)	4.1–74.5 µg/mL (17.7–321.1 µmol/L)	106	0.994

[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.[11] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 0.99x + 0.28 µg/mL (y = 0.99x + 1.2 µmol/L)	3.9–70.7 µg/mL (16.8–304.7 µmol/L)	53	0.996

[a] Number of samples tested.

[b] Correlation coefficient.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Phnb 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 Phnb assay.[12]

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	500 mg/dL (0.31 mmol/L) 500 mg/dL (0.31 mmol/L)	5.2 (22.4) 42.6 (183.6)	3 5
Bilirubin, conjugated	80 mg/dL (1368 µmol/L) 80 mg/dL (1368 µmol/L)	5.0 (21.6) 41.4 (178.4)	6 0
Bilirubin, unconjugated	80 mg/dL (1368 µmol/L) 80 mg/dL (1368 µmol/L)	5.6 (24.1) 40.6 (175.0)	2 0
Lipemia (Intralipid®)	200 mg/dL (2.26 mmol/L) 200 mg/dL (2.26 mmol/L)	4.7 (20.3) 41.5 (178.9)	10 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 Phnb assay when present in serum and plasma at the concentrations indicated in the table below. Bias due to these substances is ≤ 10% at an analyte concentration of 30.0 µg/mL (130 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.[13]

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Acetaminophen	200 µg/mL (1323 µmol/L)	≤ 10%
Acetylsalicylic Acid	500 µg/mL (1665 µmol/L)	≤ 10%
Amikacin	150 µg/mL (256 µmol/L)	≤ 10%

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Amobarbital	15 µg/mL (66 µmol/L)	≤ 10%
Ampicillin	50 µg/mL (143 µmol/L)	≤ 10%
Ascorbic Acid	30 µg/mL (170 µmol/L)	≤ 10%
Butabarbital	250 µg/mL (1180 µmol/L)	≤ 10%
Caffeine	100 µg/mL (515 µmol/L)	≤ 10%
Calcium	20 mg/dL (5 mmol/L)	≤ 10%
Carbamazepine	500 µg/mL (2117 µmol/L)	≤ 10%
Chloramphenicol	250 µg/mL (774 µmol/L)	≤ 10%
Chlordiazepoxide	1000 µg/mL (3350 µmol/L)	≤ 10%
Chlorpromazine	1000 µg/mL (3140 µmol/L)	≤ 10%
Cimetidine	100 µg/mL (396 µmol/L)	≤ 10%
Codeine	100 ng/mL (334 nmol/L)	≤ 10%
Creatinine	30 mg/dL (2652 µmol/L)	≤ 10%
Dextran 75	2500 µg/mL (33 µmol/L)	≤ 10%
Diazepam	1000 µg/dL (3500 µmol/L)	≤ 10%
Digoxin	3 ng/mL (3.8 nmol/L)	≤ 10%
Erythromycin	200 µg/mL (273 µmol/L)	≤ 10%
Ethanol	350 mg/dL (76 mmol/L)	≤ 10%
Ethosuximide	500 µg/mL (3542 µmol/L)	≤ 10%
Ethotoin	1000 µg/mL (4902 µmol/L)	≤ 10%
Fluoride	10 µg/mL (526 µmol/L)	≤ 10%
Furosimide	20 µg/mL (61 µmol/L)	≤ 10%
Gentamicin	120 µg/mL (221 µmol/L)	≤ 10%
Glucose	1200 mg/dL (66 mmol/L)	≤ 10%
p-Hydroxyphenobarbital	1000 µg/mL (4029 µmol/L)	≤ 10%
Hydroxyphenyl-phenyl-hydantoin (HPPH)	200 µg/mL (747 µmol/L)	≤ 10%
Ibuprofen	400 µg/mL (1939 µmol/L)	≤ 10%
Lidocaine	60 µg/mL (256 µmol/L)	≤ 10%
Lithium	5 mEq/L (5.04 mmol/L)	≤ 10%
Magnesium	12 mg/dL (4.93 mmol/L)	≤ 10%
Mephobarbital	50 µg/mL (203 µmol/L)	≤ 10%
Methsuximide	1000 µg/mL (4920 µmol/L)	≤ 10%
Nicotine	20 µg/mL (123 µmol/L)	≤ 10%

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Penicillin	800 µg/mL (2247 µmol/L)	≤ 10%
Pentobarbital	1000 µg/mL (4420 µmol/L)	≤ 10%
Phenytoin	100 µg/mL (396 µmol/L)	≤ 10%
Primidone	100 µg/mL (458 µmol/L)	≤ 10%
Propoxyphene	4 µg/mL (12 µmol/L)	≤ 10%
Protein	12 g/dL (120 g/L)	≤ 10%
Rheumatoid factor	750 IU/L (750 IU/L)	≤ 10%
Salicylic Acid	500 µg/mL (3620 µmol/L)	≤ 10%
Secobarbital	300 µg/mL (1260 µmol/L)	≤ 10%
Theophylline	250 µg/mL (1388 µmol/L)	≤ 10%
Urea	500 mg/dL (83.3 mmol/L)	≤ 10%
Uric Acid	20 mg/dL (1.2 mmol/L)	≤ 10%
Valproic Acid	500 µg/mL (3467 µmol/L)	≤ 10%

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

Standardization

The Atellica CH Phnb assay is traceable to USP Phenobarbital Standard.

Assigned values for calibrators are traceable to this standardization.[13]

Technical Assistance

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

siemens.com/healthineers

References

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4. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
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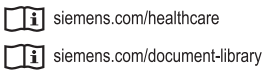
8. Baselt RC, Cravey RH. *Disposition of Toxic Drugs and Chemicals in Man.* 3rd ed. Chicago, IL: Year Book Medical Publishers, Inc.; 1989.
9. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
10. 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.
11. 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.
12. 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.
13. Data on file at Siemens Healthcare Diagnostics.

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
Rev. REVISION	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

Symbol	Symbol Title and Description
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	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.

Symbol	Symbol Title and Description
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units
	International System of Units
	Material
	Unique material identification number
	Name of control
	Type of control

Legal Information

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