PHENOBARBITAL

This package insert contains information for the use of the Abbott Phenobarbital assay on the ARCHITECT *c* Systems. 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.

Read Highlighted Changes: Revised May 2015.

FOR USE WITH
ARCHITECT

en
Phenobarbital
REF **5P07-21**
306704 / R04
B5P070

INTENDED USE

The Phenobarbital assay is for in vitro diagnostic use for the quantitative measurement of phenobarbital in human serum or plasma on the ARCHITECT *c* Systems. The measurements obtained are used in the diagnosis and treatment of phenobarbital overdose and in monitoring levels of phenobarbital to help ensure appropriate therapy.

SUMMARY AND EXPLANATION OF TEST

Phenobarbital was introduced in 1912 for the treatment of epilepsy, particularly for controlling focal motor or sensory seizures and grand mal seizures.[1] Phenobarbital is bound to both plasma and tissue proteins.[2] Monitoring serum concentrations of phenobarbital has been shown to improve patient therapy by providing physicians with a tool for adjusting dosage.[3] In addition, because of the narrow therapeutic index and wide inter-individual variability in the rate of phenobarbital metabolism and clearance, the determination of blood levels of phenobarbital for patients receiving therapy is important.[4]

PRINCIPLES OF PROCEDURE

The Phenobarbital assay is a homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) used for the analysis of phenobarbital in serum or plasma. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the phenobarbital antibody reagent. The phenobarbital-coated microparticle reagent is rapidly agglutinated in the presence of the anti-phenobarbital antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically, and is directly proportional to the rate of agglutination of the particles. When a sample containing phenobarbital is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained, with maximum rate of agglutination at the lowest phenobarbital concentration and the lowest agglutination rate at the highest phenobarbital concentration.

Methodology: Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)

REAGENTS

Reagent Kit

REF 5P07-21 Phenobarbital is supplied as a liquid, ready-to-use, two-reagent kit which contains:

- R1 3 x 23 mL
- R2 3 x 8 mL

Estimated tests per kit: 300

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

Reactive Ingredients		Concentration
R1	Anti-phenobarbital monoclonal antibodies (mouse)	< 2.0%
R2	Phenobarbital-coated microparticles	< 1.0%

Nonreactive Ingredients: R1 and R2 contain human sourced material and sodium azide (< 0.09%). R1 contains animal sourced material and TRIS buffer.

REAGENT HANDLING AND STORAGE

Reagent Handling

- R1 Ready for use.
- R2 Ready for use.
- Before use, invert several times, avoiding the formation of bubbles. Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent 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 the bubbles.

  CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration that could impact results.

Reagent Storage

- Reagent stability is 40 days (960 hours) if the reagent is open and onboard.
- Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Indications of Deterioration

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

WARNINGS AND PRECAUTIONS

Precautions for Users

- IVD
- For *In Vitro* Diagnostic Use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- **CAUTION:** This product contains human sourced and/or potentially infectious components. For a specific listing, refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens.[5] Biosafety Level 2[6] or other appropriate biosafety practices[7,8] should be used for materials that contain or are suspected of containing infectious agents.

  The human sourced material used in R1 and R2 is nonreactive for HBsAg, anti HCV, anti-HIV-1/HIV-2, and HIV-1 RNA or HIV-1 Ag.
- The following warning and precaution apply to R1 and R2:
  Contains sodium azide.
  EUH032 Contact with acids liberates very toxic gas.
  These materials and their containers must be disposed of in a safe way.
  NOTE: Refer to *Section 8* of the **ARCHITECT System Operations Manual** for proper handling and disposal of reagents containing sodium azide.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum and plasma are acceptable specimens. Some gel separation tubes may not be suitable for use with therapeutic drug monitoring assays; refer to information provided by the tube manufacturer.[9]

- **Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place. Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum from blood cells.

  Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting process. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier), sodium heparin, potassium EDTA, sodium citrate, and sodium fluoride/potassium oxalate. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.

Some sample dilution may occur when samples are collected in tubes containing citrate anticoagulant. The amount of dilution and the possible need to correct for it should be considered when interpreting assay results for these samples.

For total sample volume requirements, refer to the ASSAY PARAMETERS section of this package insert and *Section 5* of the **ARCHITECT System Operations Manual**.

Specimen Storage

Serum and Plasma

Temperature	Maximum Storage	Bibliographic Reference
20 to 25˚C	≤ 7 days	*
2 to 8˚C	≤ 6 months	10, 11
-20˚C	≤ 6 months	11

* Internal study showed that samples can be stored at room temperature (20 to 25˚C) for up to 7 days.

Guder et al.[10] suggest storage of frozen specimens at -20˚C for no longer than the time interval cited above.

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

PROCEDURE

Materials Provided

REF 5P07 Phenobarbital Reagent Kit

Materials Required but not Provided

- REF 5P04 TDM Multiconstituent Calibrator
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

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

Specimen Dilution Procedures

The ARCHITECT *c* Systems have an automatic dilution feature; refer to *Section 2* of the **ARCHITECT System Operations Manual** for additional information.

Serum and Plasma: Specimens with phenobarbital values exceeding 80.0 µg/mL (344.8 µmol/L) or the highest calibrator are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Manual Dilution Procedure

- Use saline (0.85% to 0.90% NaCl) or CAL 1 to dilute the sample.
- The operator must enter the manual 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 multiplied by the appropriate manual dilution factor before reporting the result.

NOTE: If a diluted sample 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 *Section 5* of the **ARCHITECT System Operations Manual**.

CALIBRATION

Calibration is stable for 14 days (336 hours). A full calibration is required with each change in reagent lot number. Verify calibration curve 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 a detailed description of how to calibrate an assay, refer to *Section 6* of the **ARCHITECT System Operations Manual**.

For information on calibrator standardization, refer to the REF 5P04 TDM Multiconstituent Calibrator package insert.

QUALITY CONTROL

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

- A minimum of two levels of controls spanning the medical decision range are to be run every 24 hours.
- Run both levels of quality control with each cartridge change.
- 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

Factors that can influence the relationship between phenobarbital serum or plasma concentrations and clinical response include the type and severity of seizures, age, general state of health, and use of other drugs.

The concentration of phenobarbital in serum or plasma depends on the time of the last drug dose; mode of administration; concomitant drug therapy; sample condition; time of sample collection; and individual variations in absorption, distribution, biotransformation, and excretion. These parameters must be considered when interpreting results.[12,13]

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

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

LIMITATIONS OF THE PROCEDURE

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

The following assay REF 3L79 Calcium is affected by the REF 5P07 Phenobarbital assay and requires configuration of SmartWash parameters to avoid interference due to reagent carryover.

Configure REF	COMPONENT	REAGENT / ASSAY	WASH	VOL	REP
CaC	3L79	R1	PHNO9	0.5% Acid Wash	345	2
CaCU	3L79	R1	PHNO9	0.5% Acid Wash	345	2

EXPECTED VALUES

Serum and Plasma

The desired therapeutic effect is usually achieved in the serum concentration range of 15 to 40 µg/mL (65 to 172 µmol/L).[14] Concentrations of 35 to 80 µg/mL (151 to 345 µmol/L) are associated with slowness, ataxia, and nystagmus. Concentrations of 65 to 117 µg/mL (280 to 504 µmol/L) are associated with coma with reflexes. Concentrations > 100 µg/mL (> 430 µmol/L) are associated with coma without reflexes.[14]

NOTE: To convert results from µg/mL to µmol/L, multiply µg/mL by 4.31.[15]

For effective treatment, some patients may require serum levels outside these ranges. Therefore, the expected range is provided only as a guide, and individual patient results should be interpreted in light of other clinical signs and symptoms. Refer to the RESULTS section of this package insert.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are given in this section. Results obtained in individual laboratories may vary.

Specificity

The Phenobarbital assay measures the total (protein-bound plus unbound) phenobarbital concentration in serum and plasma. Compounds whose chemical structure or concurrent therapeutic use would suggest possible cross-reactivity have been tested. Levels tested were at or above maximum physiological or pharmacological concentrations.

The compounds listed in the table below caused ≤ 10% change in drug concentration when tested in the presence of 13 and 30 µg/mL phenobarbital.

Compound	Conc. Tested (µg/mL)
Amitriptyline	25
Amobarbital	30
Aprobarbital	100
Barbital	100
Butabarbital	100
Carbamazepine	500
Carbamazepine-10,11-epoxide	500
Chlordiazepoxide	500
Chlorpromazine	60
Clorazepate	500
Diazepam	60
Ethosuximide	500
Ethotoin	200
5-ethyl-5-phenylhydantoin (Nirvanol)	200
Glutethimide	200
p-hydroxyphenobarbital	22
5-(*p*-hydroxyphenyl)-5-phenylhydantoin	100
Imipramine	5
Mephenytoin	200
Methsuximide	150
Nortriptyline	10
2-phenyl-2-ethyl-malondiamide (PEMA)	500
Pentobarbital	100
Phensuximide	500
Phenytoin	200
Primidone	200
Promethazine	30
Secobarbital	50
Thiopental	100
Valproic acid (2-propyl-pentanoic acid)	1,000

Measuring Interval

The measuring interval of Phenobarbital serum/plasma is 2.0 to 80.0 µg/mL (8.6 to 344.8 µmol/L).

Linearity

Phenobarbital is linear from 2.0 to 80.0 µg/mL (8.6 to 344.8 µmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol EP6-A.[16]

Sensitivity

The ARCHITECT *c* System Phenobarbital assay is designed to have a Limit of Quantitation (LoQ) of ≤ 2.0 µg/mL (8.6 µmol/L). A study to determine LoQ was performed based on guidance from CLSI protocol EP17-A2.[17] The LoQ is the lowest concentration which results in inter-assay precision ≤ 7% CV or ≤ 0.7 µg/mL (3.0 µmol/L) SD and bias to be within 10% or 1.0 µg/mL (4.3 µmol/L) that has been measured over an extended period. The results demonstrate that the LoQ is 2.0 µg/mL (8.6 µmol/L).

Spike Recovery

The Phenobarbital assay is designed to have a mean percent recovery of 100 ± 10% or ± 1.0 µg/mL of target concentration for samples across the measuring interval of the assay.

A study was performed with three specimens spiked using National Institute of Standards and Technology (NIST) traceable analyte at levels representing the sub-therapeutic, therapeutic, and toxic range. Each specimen was measured in replicates of 21 using the Phenobarbital assay on one instrument, and the resulting bias was calculated.

Target (µg/mL)	Mean Recovery (µg/mL)	Bias
8.0	8.13	0.13 µg/mL
30.0	31.55	5.17%
72.0	74.21	3.07%

Interfering Substances

Interference studies were conducted using an acceptance criteria of ± 10% deviation from the target value. Phenobarbital is not affected by the presence of the following interferents up to the concentrations indicated below.

Interfering Substance	Concentration	Target (µg/mL)	Observed (% of Target)
Bilirubin, conjugated	30 mg/dL (513 µmol/L)	19.27	102.6
Bilirubin, unconjugated	66 mg/dL (1,129 µmol/L)	18.72	100.1
Cholesterol	500 mg/dL (14.1 mmol/L)	17.53	109.5
Hemoglobin	800 mg/dL (8 g/L)	19.76	100.0
Human anti-mouse antibodies (HAMA)	400 ng/mL (1,444 mmol/L)	19.97	100.7
Human serum albumin	7.5 g/dL (75 g/L)	19.76	99.0
IgG	12 g/dL (120 g/L)	19.76	97.0
Rheumatoid factor	1,166 IU/mL (1,166 KIU/L)	20.00	93.5
Triglyceride	1,500 mg/dL (16.95 mmol/L)	20.00	94.8

Precision

Precision was determined as described in CLSI protocol EP5-A2.[18] A tri-level human serum based commercial control containing phenobarbital and six human serum panels were used in the study. Each sample was assayed in duplicate twice a day for 20 days. Each of the runs per day were separated by at least two hours.

Acceptance criteria ≤ 7% Total CV.

Sample	Mean (µg/mL)	Within Run SD	Within Run %CV	Total Run SD	Total Run %CV
Control 1	9.29	0.11	1.2	0.29	3.2
Control 2	24.02	0.33	1.4	0.52	2.2
Control 3	48.79	0.76	1.6	1.33	2.7
Patient 1	2.51	0.08	3.3	0.12	4.9
Patient 2	4.35	0.09	2.0	0.15	3.5
Patient 3	11.01	0.12	1.1	0.73	6.7
Patient 4	25.93	0.31	1.2	0.79	3.1
Patient 5	47.72	1.01	2.1	1.44	3.0
Patient 6	77.22	1.00	1.3	1.34	1.7

Method Comparison

Correlation studies were performed based on guidance from CLSI protocol EP9-A2.[19]

Serum results from the REF 5P07 Phenobarbital assay were compared with those from the REF 1E08 Phenobarbital assay on an ARCHITECT *c* System. Serum results from the Phenobarbital assay on an ARCHITECT *c* System were compared with HPLC.

	REF 5P07 vs. REF 1E08	REF 5P07 vs. HPLC
N	118	108
Slope (Passing-Bablok)	0.997	0.933
Y - Intercept	0.421	0.68
Correlation Coefficient	0.9956	0.9887
Range (µg/mL)	5.3 to 79.3	5.6 to 80.0

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TRADEMARKS

ARCHITECT *c* Systems Assay Parameters

Phenobarbital Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **PHNO** Type: **Photometric** Version: †
Number: **2884** Assay availability: **Enabled**
Run controls for onboard reagents by: **Kit**

● Reaction definition O Reagent / Sample O Validity checks

Reaction mode: **Rate up**
Primary Secondary Read times
Wavelength: **700** / None Main: **20 – 33**
Last required read: **33** Flex: ___ – ___
Absorbance range: **-0.1000 – 3.2000** Color correction: ___ – ___
Sample blank type: **None**

O Reaction definition ● Reagent / Sample O Validity checks

		R1	R2
Reagent:	**PHNO9**	Reagent volume:	**180**	**50**
Diluent:	**Saline**	Water volume:	___	___
Diluent dispense mode:	**Type 0**	Dispense mode:	**Type 0**	**Type 0**

Dilution name	Sample	Diluted sample	Diluent	Water		Dilution factor	Default dilution
STANDARD :	**2.0**	___	___	___	=	**1:1.00**	●
Dil 1 :	**25.0**	**4.0**	**75**	___	=	**1:2.02**	O
_____ :	___	___	___	___	=		O

O Reaction definition O Reagent / Sample ● Validity checks

Reaction check: **None**

Rate linearity %: ___

Configure assay parameters — Calibration

O General ● Calibration O SmartWash O Results O Interpretation

Assay: **PHNO** Calibration method: **Spline**

● Calibrators O Volumes O Intervals O Validity checks

Calibrator set: **TDMMCC**
Replicates: **2** [Range 1 – 3]

Calibrator level:	Concentration:
Blank: **TDMMCC1**	0‡
Cal 1: **TDMMCC2**	‡‡
Cal 2: **TDMMCC3**	‡‡
Cal 3: **TDMMCC4**	‡‡
Cal 4: **TDMMCC5**	‡‡
Cal 5: **TDMMCC6**	‡‡
Cal 6: **None**	

O Calibrators ● Volumes O Intervals O Validity checks

Calibrator: **TDMCCC**

Calibrator level		Sample	Diluted sample	Diluent	Water
Blank:	**TDMMCC1**	**2.0**	___	___	___
Cal 1:	**TDMMCC2**	**2.0**	___	___	___
Cal 2:	**TDMMCC3**	**2.0**	___	___	___
Cal 3:	**TDMMCC4**	**2.0**	___	___	___
Cal 4:	**TDMMCC5**	**2.0**	___	___	___
Cal 5:	**TDMMCC6**	**2.0**	___	___	___
Cal 6:	**None**				

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **336** (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: **PHNO**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**DIG00**	**Detergent A**	**345**	**1**
R1	**AMIK9**	**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	**DIG00**	**Detergent A**	**345**	**1**
R2	**AMIK9**	**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**

Phenobarbital Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **PHNO** Assay number: **2884**
Dilution default range: Result units: **ug/mL**
Low-Linearity: **2.0**
High-Linearity: **80.0**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**15.0 – 40.0**	

Configure result units

Assay: **PHNO**
Version: †
Result units: **ug/mL**
Decimal places: **1** [Range 0 – 4]
Correlation factor: **1.0000**
Intercept: **0.0000**

Phenobarbital Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **PHNO** Assay number: **2884**
Dilution default range: Result units: **umol/L**
Low-Linearity: **8.6**
High-Linearity: **344.8**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**65.0 – 172.0**	

Configure result units

Assay: **PHNO**
Version: †
Result units: **umol/L**
Decimal places: **1** [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.

Key to Symbols

CAL 1	Calibrator 1
CONTAINS: AZIDE	Contains sodium azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
EC REP	Authorized Representative in the European Community
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch code/Lot number
PRODUCT OF USA	Product of USA
R1	Reagent 1
R2	Reagent 2
REF	Catalog number/List number
SN	Serial number
	Caution
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date

Customer Service: **Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com.**

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