PHENYTOIN

FOR USE WITH
ARCHITECT

en
Phenytoin
REF 5P08-21
306702 / R04
B5P080

This package insert contains information for the use of the Abbott Phenytoin 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.

INTENDED USE

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

SUMMARY AND EXPLANATION OF TEST

Monitoring phenytoin concentrations, along with careful clinical assessment, is the most effective means of improving seizure control, reducing the risk of toxicity, and minimizing the need for additional anticonvulsant medication for the following reasons:[1,2]

- Phenytoin concentrations correlate better with pharmacologic activity than does dosage because of individual differences in absorption, metabolism, disease states, concomitant medication, and compliance. Concentration monitoring helps physicians individualize dosage regimens.
- The hepatic enzyme system for metabolizing phenytoin can become saturated within the drug's therapeutic range. When this occurs, small dosage alterations can lead to unexpected drug accumulation and clinical toxicity.
- Phenytoin is safe and effective only in a narrow range of concentrations.

PRINCIPLES OF PROCEDURE

The Phenytoin assay is a liquid ready-to-use, homogeneous enzyme immunoassay. The method uses specific antibodies to detect phenytoin in the sample, with minimal cross-reactivity to various over-the-counter, structurally related compounds. The method is based on the competition for a fixed amount of specific antibody binding sites between enzyme [glucose-6-phosphate dehydrogenase (G6PDH)]-labeled phenytoin, and phenytoin contained in the sample.

In the absence of phenytoin from the sample, the specific antibody binds the G6PDH-labeled phenytoin and causes a decrease in enzyme activity. If phenytoin is present in the sample, it occupies the antibody binding sites, which allows the G6PDH-labeled phenytoin to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between the phenytoin concentration in sample and enzyme activity. By measuring the enzyme's ability to convert nicotinamide adenine dinucleotide (NAD) to NADH, its activity is determined spectrophotometrically at 340 nm.

Methodology: Enzyme Immunoassay

REAGENTS

Reagent Kit

REF 5P08-21 Phenytoin is supplied as a liquid, ready-to-use, two-reagent kit which contains:

R1 3 x 26 mL

R2 3 x 10 mL

Estimated tests per kit: 300

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

Reactive Ingredients		Concentration
R1	Anti-phenytoin monoclonal antibodies (mouse)	< 1.0%
R2	Phenytoin-labeled glucose-6-phosphate dehydrogenase	< 1.0%

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

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 requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.[3] Biosafety Level 2[4] or other appropriate biosafety practices[5,6] should be used for materials that contain or are suspected of containing infectious agents.
- 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.[7]

- **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	≤ 2 days	8
2 to 8˚C	≤ 1 month	8, 9
-20˚C	≤ 5 months	8

Guder et al.[8] 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 5P08 Phenytoin 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 phenytoin values exceeding 40.0 µg/mL (158.4 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 7 days (168 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 Phenytoin 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 phenytoin 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 phenytoin 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.[1,2]

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.

EXPECTED VALUES

Serum and Plasma

The Phenytoin assay accurately quantitates phenytoin concentrations in human serum or plasma containing up to 40 µg/mL (158.4 µmol/L). Most patients achieve a satisfactory therapeutic response in the serum concentration range of 10 to 20 µg/mL (40 to 79 µmol/L). Peak concentrations above 20 µg/mL (79 µmol/L) are often associated with toxicity.[10]

NOTE: To convert results from µg/mL to µmol/L, multiply µg/mL by 3.96.[11]

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 Phenytoin assay measures the total (protein-bound plus unbound) phenytoin 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 15 µg/mL phenytoin.

Compound	Conc. Tested (µg/mL)
Acetaminophen	1,000
Acetylsalicylic acid (aspirin)	1,000
Amitriptyline	50
Amobarbital	100
Carbamazepine	600
Carbamazepine-10,11-epoxide	500
Chlordiazepoxide	100
Chlorpromazine	20
Clorazepate	500
Diazepam	60
Ethosuximide	600
Ethotoin	200
5-ethyl-5-phenylhydantoin (Nirvanol)	250
Glutethimide	15
5-(*p*-hydroxyphenyl)-5-phenylhydantoin	25
Imipramine	10
Mephenytoin	75
Methsuximide	200
Nortriptyline	10
Oxaprozin	230
Pentobarbital	100
Phenobarbital	500
2-phenyl-2-ethyl-malondiamide (PEMA)	500
Phensuximide	600
Primidone	200
Promethazine	30
Secobarbital	50
Valproic acid (2-propyl-pentanoic acid)	1,000

NOTE: The compound fosphenytoin, at a level of 60 µg/mL, caused a 41.1% change in drug concentration when tested in the presence of 15 µg/mL phenytoin.

Measuring Interval

The measuring interval of Phenytoin serum/plasma is 1.8 to 40.0 µg/mL (7.1 to 158.4 µmol/L).

Linearity

Phenytoin is linear from 1.8 to 40.0 µg/mL (7.1 to 158.4 µmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol EP6-A.[12]

Sensitivity

The ARCHITECT *c* System Phenytoin assay is designed to have a Limit of Quantitation (LoQ) of ≤ 1.8 µg/mL (7.1 µmol/L). A study to determine LoQ was performed based on guidance from CLSI protocol EP17-A2.[13] The LoQ is the lowest concentration which results in inter-assay precision at 7% CV or 0.7 µg/mL (2.7 µmol/L) SD and bias to be within 10% or 1.0 µg/mL (3.96 µmol/L) that has been measured over an extended period. The results demonstrate that the LoQ is 1.8 µg/mL (7.1 µmol/L).

Spike Recovery

The Phenytoin 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 Phenytoin assay on one instrument, and the resulting bias was calculated.

Target (µg/mL)	Mean Recovery (µg/mL)	Bias
2.5	2.28	-0.22 µg/mL
15.0	14.06	-6.27%
35.0	36.24	3.54%

Interfering Substances

Interference studies were conducted using an acceptance criteria of ± 10% deviation from the target value. Phenytoin 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)	14.66	101.8
Bilirubin, unconjugated	66 mg/dL	(1,129 µmol/L)	14.03	102.4
Hemoglobin	800 mg/dL	(8 g/L)	14.66	108.3
Human anti-mouse antibodies (HAMA)	400 ng/mL	(1,444 mmol/L)	15.07	101.3
Human serum albumin	7.5 g/dL	(75 g/L)	14.66	96.6
IgG	12 g/dL	(120 g/L)	14.66	97.9
Rheumatoid factor	1,166 IU/mL	(1,166 KIU/L)	13.77	99.9
Triglyceride	1,250 mg/dL	(12.83 mmol/L)	13.77	97.2

Precision

Precision was determined as described in CLSI protocol EP5-A2.[14] A tri-level human serum based commercial control containing phenytoin 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	6.37	0.13	2.1	0.16	2.5
Control 2	15.83	0.31	1.90	0.32	2.0
Control 3	31.72	0.69	2.2	0.80	2.5
Patient 1	3.86	0.13	3.3	0.16	4.1
Patient 2	12.58	0.30	2.4	0.33	2.6
Patient 3	14.40	0.31	2.1	0.36	2.5
Patient 4	17.83	0.44	2.5	0.52	2.9
Patient 5	25.66	0.44	1.7	0.77	3.0
Patient 6	36.11	0.58	1.6	0.83	2.3

Method Comparison

Correlation studies were performed based on guidance from CLSI protocol EP9-A2.[15]

Serum results from the REF 5P08 Phenytoin assay were compared with those from the REF 1E07 Phenytoin assay on an ARCHITECT *c* System.

	REF 5P08 vs. REF 1E07
N	100
Slope	1.108
Y - Intercept	0.118
Correlation Coefficient	0.9919
Range (µg/mL)	1.9 to 34.1

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TRADEMARKS

Phenytoin Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **PHNY** Type: **Photometric** Version: †
Number: **2885** 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:	**340** /	*	Main: **20 – 23**
Last required read:	**23**		Flex: ___ – ___
Absorbance range:	**-0.1000 - 3.2000**		Color correction: ___ – ___

Sample blank type: **None**

O Reaction definition ● Reagent / Sample O Validity checks

		R1	R2
Reagent:	**PHNY9**	Reagent volume:	**210**	**70**
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 :	**5.0**	___	___	___	=	**1:1.00**	●
Dil 1 :	**25.0**	**5.0**	**75**	___	=	**1:4.00**	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: **PHNY** 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: **TDMMCC**

Calibrator level		Sample	Diluted sample	Diluent	Water
Blank:	**TDMMCC1**	**5.0**	___	___	___
Cal 1:	**TDMMCC2**	**5.0**	___	___	___
Cal 2:	**TDMMCC3**	**5.0**	___	___	___
Cal 3:	**TDMMCC4**	**5.0**	___	___	___
Cal 4:	**TDMMCC5**	**5.0**	___	___	___
Cal 5:	**TDMMCC6**	**5.0**	___	___	___
Cal 6:	**None**				

O Calibrators O Volumes ● Intervals O Validity checks

Calibration intervals:
Full interval: **168** (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: **PHNY**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	**PHNY9**	**10% Detergent B**	**345**	**1**
R1	**MG000**	**0.5% Acid Wash**	**345**	**1**
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	**PHNY9**	**10% Detergent B**	**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**

Phenytoin Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **PHNY** Assay number: **2885**
Dilution default range: Result units: **ug/mL**
Low-Linearity: **1.8**
High-Linearity: **40.0**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**10.0 – 20.0**	

Configure result units

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

Phenytoin Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **PHNY** Assay number: **2885**
Dilution default range: Result units: **umol/L**
Low-Linearity: **7.1**
High-Linearity: **158.4**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**40.0 – 79.0**	

Configure result units

Assay: **PHNY**
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.
* The *c*8000 Secondary Wavelength is 412 nm; the *c*4000 and *c*16000 Secondary Wavelength is 416 nm.
‡ 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
	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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