THEOPHYLLINE

This package insert contains information for the use of the Abbott Theophylline 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 February 2017.

en

Theophylline

REF 5P06-21

307203/R05

B5P060

FOR USE WITH

ARCHITECT

INTENDED USE

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

SUMMARY AND EXPLANATION OF TEST

The physiological effects of the antiasthmatic drug theophylline correlate better with the drug concentration in serum than with dosage. Since serious toxic effects of theophylline are related to the serum concentration and are not always preceded by minor adverse symptoms, serum theophylline monitoring helps to avoid adverse effects.[1-5]

- When theophylline is used to treat acute symptoms, monitoring serum concentration allows the physician to adjust the dosage regimen to compensate for interpatient variations in the theophylline elimination rate.[1]
- The chronic treatment of asthma and other bronchospastic diseases also requires individualization of the theophylline dosage to maintain serum concentrations within the therapeutic range.[2,3]
- A theophylline dosage generally can be maintained without further monitoring for 6 months in rapidly growing children and for 12 months in other patients. Changes in concurrent drug therapy, variations in drug elimination, or the appearance of side effects, uncontrolled symptoms, or altered drug clearance signal the need for measuring the serum theophylline concentration.[1,3]

PRINCIPLES OF PROCEDURE

The Theophylline assay is a liquid ready-to-use, homogeneous enzyme immunoassay. The method uses specific antibodies to detect theophylline 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 theophylline, and theophylline contained in the sample.

In the absence of theophylline from the sample, the specific antibody binds the G6PDH-labeled theophylline and causes a decrease in enzyme activity. If theophylline is present in the sample, it occupies the antibody binding sites, which allows the G6PDH-labeled theophylline to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between the theophylline 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 5P06-21 Theophylline is supplied as a liquid, ready-to-use, two-reagent kit which contains:

R1 3 x 18 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-theophylline monoclonal antibodies (mouse)	< 1.0%
R2	Theophylline-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 handled in accordance with the OSHA Standard on Bloodborne Pathogens.[6] Biosafety Level 2[7] or other appropriate biosafety practices[8,9] should be used for materials that contain or are suspected of containing infectious agents.
- The following warnings and precautions apply to R1 and R2:
  Contains sodium azide.
  EUH032 Contact with acids liberates very toxic gas.
  P501 Dispose of contents/container in accordance with local regulations.
- Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.
- For a detailed discussion of safety precautions during system operation, refer to the **ARCHITECT System Operations Manual**, *Section 8*.

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.[10]

- **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
2 to 8°C	≤ 3 months	11, 12
-20°C	≤ 3 months	11

Guder et al.[11] 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 5P06-21 Theophylline Reagent Kit

Materials Required but not Provided

- REF 5P04-01 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 theophylline values exceeding 40.0 µg/mL (222.0 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 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 Theophylline 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 theophylline serum or plasma concentrations and clinical response include the type and severity of bronchial constriction, age, smoking, diet, general state of health, and use of other drugs.[2,3]

The concentration of theophylline in serum or plasma depends on the time of the last drug dose; dosage form; 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.[2-5]

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 Theophylline assay accurately quantitates theophylline concentrations in human serum or plasma containing up to 40 µg/mL (222 µmol/L). In most patients, theophylline serum concentrations of 8 to 20 µg/mL (44 to 111 µmol/L) effectively suppress chronic asthmatic and other bronchospastic symptoms. Concentrations above 20 µg/mL (111 µmol/L) are often associated with toxicity.[13]

NOTE: To convert results from µg/mL to µmol/L, multiply µg/mL by 5.55.[14]

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 Theophylline assay measures the total (protein-bound plus unbound) theophylline 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 therapeutic concentrations.

The compounds listed in the table below caused ≤ 10% change in drug concentration when tested in the presence of 15 µg/mL theophylline.

Compound	Conc. Tested (µg/mL)
Acetaminophen	1,000
Acetylsalicylic acid (aspirin)	1,000
Carbamazepine	500
8-chlorotheophylline	60
1,3-dimethyluric acid	100
1,7-dimethylxanthine	100
Dyphylline [7-(2,3-dihydroxypropyl) theophylline]	100
Ephedrine	5
Ethosuximide	500
Hypoxanthine	100
1-methyluric acid	100
3-methyluric acid	200
1-methylxanthine	50
3-methylxanthine	100
7-methylxanthine	100
Paraxanthine	50
Phenobarbital	100
Phenytoin	200
Primidone	200
Promethazine	10
Secobarbital	25
Theobromine (3,7-dimethylxanthine)	100
1,3,7-trimethyluric acid	100
Urea	1,000
Uric acid	200
Valproic acid	500
Xanthine	100

NOTE: The compound caffeine, at a level of 100 µg/mL, caused a 12.3% change in drug concentration when tested in the presence of 15 µg/mL theophylline.

Measuring Interval

The measuring interval of Theophylline serum/plasma is 2.0 to 40.0 µg/mL (11.1 to 222.0 µmol/L).

Linearity

Theophylline is linear from 2.0 to 40.0 µg/mL (11.1 to 222.0 µmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol EP6-A.[15]

Sensitivity

The ARCHITECT *c* System Theophylline assay is designed to have a Limit of Quantitation (LoQ) of ≤ 2.0 µg/mL (11.1 µmol/L). A study to determine LoQ was performed based on guidance from CLSI protocol EP17-A2.[16] The LoQ is the lowest concentration which results in inter-assay precision at 7% CV or 0.7 µg/mL (3.9 µmol/L) SD and bias to be within 10% or 1.0 µg/mL (5.6 µmol/L) that has been measured over an extended period. The results demonstrate that the LoQ is 2.0 µg/mL (11.1 µmol/L).

Spike Recovery

The Theophylline assay is designed to have a mean percent recovery of 100 ± 10% or ± 0.6 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 Theophylline assay on one instrument, and the resulting bias was calculated.

Target (µg/mL)	Mean Recovery (µg/mL)	Bias
2.5	2.45	-0.05 µg/mL
15.0	15.54	3.60%
35.0	35.03	0.09%

Interfering Substances

Interference studies were conducted using an acceptance criteria of ± 10% deviation from the target value. Theophylline 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)	14.19	102.4
Bilirubin, unconjugated	66 mg/dL	(1,129 µmol/L)	14.06	99.0
Hemoglobin	800 mg/dL	(8 g/L)	14.19	98.8
Human anti-mouse antibodies (HAMA)	400 ng/mL	(1,444 mmol/L)	14.82	100.3
Human serum albumin	7.5 g/dL	(75 g/L)	14.19	97.4
IgG	12 g/dL	(120 g/L)	14.19	95.7
Rheumatoid factor	1,166 IU/mL	(1,166 KIU/L)	17.73	95.3
Sulfapyridine	300 mg/L	(1204.8 µmol/L)	12.19	100.5
Sulfasalazine	300 mg/L	(753.8 µmol/L)	12.19	103.4
Temozolomide	20 mg/L	(103.1 µmol/L)	6.9	97.9
Triglyceride	1,000 mg/dL	(11.30 mmol/L)	17.73	98.0

Precision

Precision was determined as described in CLSI protocol EP5-A2.[17] A tri-level human serum based commercial control containing theophylline 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	4.81	0.11	2.3	0.14	2.9
Control 2	12.46	0.17	1.4	0.31	2.5
Control 3	25.97	0.40	1.5	0.50	1.9
Patient 1	3.50	0.08	2.2	0.11	3.3
Patient 2	12.55	0.20	1.6	0.35	2.8
Patient 3	13.70	0.22	1.6	0.34	2.5
Patient 4	17.15	0.29	1.7	0.50	2.9
Patient 5	24.48	0.43	1.8	0.77	3.1
Patient 6	37.03	0.54	1.5	1.08	2.9

Method Comparison

Correlation studies were performed based on guidance from CLSI protocol EP9-A2.[18]

Serum results from the 5P06 Theophylline assay were compared with those from the 1E09 Theophylline assay on an ARCHITECT *c* System.

	5P06 vs. 1E09
N	103
Slope (Passing-Bablok)	1.07
Y - Intercept	-0.071
Correlation Coefficient	0.9985
Range (µg/mL)	2.5 to 36.9

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TRADEMARKS

The ARCHITECT *c* System family of instruments consists of *c* 4000, *c* 8000, and *c* 16000 instruments.

ARCHITECT *c* Systems Assay Parameters

Theophylline Serum/Plasma—Conventional and SI Units

Configure assay parameters — General

● General O Calibration O SmartWash O Results O Interpretation

Assay: **THEOP** Type: **Photometric** Version: †
Number: **2883** 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:	**THEOP**				Reagent volume:	**141**	**47**
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 :	**6.7**	___	___	___ =	**1:1.00**		●
Dil 1 :	**25.0**	**6.7**	**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: **THEOP** 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**	**6.7**	___	___	___
Cal 1: **TDMMCC2**	**6.7**	___	___	___
Cal 2: **TDMMCC3**	**6.7**	___	___	___
Cal 3: **TDMMCC4**	**6.7**	___	___	___
Cal 4: **TDMMCC5**	**6.7**	___	___	___
Cal 5: **TDMMCC6**	**6.7**	___	___	___
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: **THEOP**

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates

Theophylline Serum/Plasma—Conventional Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **THEOP** Assay number: **2883**
Dilution default range: Result units: **ug/mL**
Low-Linearity: **2.0**
High-Linearity: **40.0**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**8.0 – 20.0**	

Configure result units

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

Theophylline Serum/Plasma—SI Units

Configure assay parameters — Results

O General O Calibration O SmartWash ● Results O Interpretation

Assay: **THEOP** Assay number: **2883**
Dilution default range: Result units: **umol/L**
Low-Linearity: **11.1**
High-Linearity: **222.0**
Gender and age specific ranges

GENDER	AGE (UNITS)	NORMAL	EXTREME
Either	**0 – 130 (Y)**	**44.0 – 111.0**	

Configure result units

Assay: **THEOP**
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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