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ADVIA® 1800
ADVIA® 2400
Chemistry Systems

Theophylline_2 (THEO_2)

Current Revision and Date[a]	Rev. E, 2020-02	
Product Name	ADVIA® Chemistry Theophylline_2 (THEO_2) Reagents	REF 10377503
Systems	ADVIA 1800 Chemistry System ADVIA 2400 Chemistry System	
Materials Required but Not Provided	ADVIA Chemistry Drug Calibrator 1 Reagent container adapters Reagent container insert Commercially available controls	REF 10376770
Specimen Types	Human serum, plasma (lithium heparin, sodium heparin, EDTA, citrate, oxalate/fluoride)	
Assay Principle	Enzyme Multiplied Immunoassay Technique (EMIT)	
Assay Range	Serum: 1.5–40.0 µg/mL (8.3–222.0 µmol/L) Plasma: 1.5–40.0 µg/mL (8.3–222.0 µmol/L)	
Reagent Storage	2–8°C	
Reagent On-System Stability	7 days when you are not using a reagent container insert 28 days when you are using a reagent container insert	
Reagent Code	74729	

[a] In Rev. C or later, a vertical bar in the margin indicates a technical update to the previous version.

Intended Use

For *in vitro* diagnostic use in the quantitative analysis of theophylline in human serum or plasma on ADVIA® Chemistry systems.

Summary and Explanation

Monitoring theophylline concentrations in serum, along with careful clinical assessment, is the most effective means of ensuring adequate therapy for the following reasons.

The physiological effects of the anti-asthmatic drug theophylline correlate better with the drug's 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 serious toxicity.[1–5]

When theophylline is used to treat acute symptoms, monitoring serum concentrations 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 bronchiospastic 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 six months in rapidly growing children, and for twelve months in other patients. Any of the following events signal the need for measuring the patient's serum theophylline concentration: Changes in concurrent drug therapy; variations in drug elimination or the appearance of side effects; uncontrolled symptoms; or altered drug clearance.[1,3]

Techniques historically used to monitor serum theophylline concentrations include gas-liquid chromatography, high-performance liquid chromatography, and immunoassay.[1,5,6]

Principles of the Procedure

The ADVIA Chemistry Theophylline_2 (THEO_2) assay is a homogeneous immunoassay that is used for the quantitative analysis of theophylline (free and protein-bound) in serum or plasma.[7,8] The ADVIA Chemistry THEO_2 assay contains the Syva® Emit ® 2000 Theophylline reagent filled into ADVIA Chemistry containers.

The ADVIA Chemistry THEO_2 assay is based on competition for antibody binding sites between theophylline in the sample and theophylline labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH). Upon binding to the antibody, enzyme activity decreases. As a result, the theophylline concentration in the samples can be measured in terms of enzyme activity.

Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to reduced nicotinamide adenine dinucleotide (NADH), resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme functions only with the bacterial (Leuconostoc mesenteroides) enzyme used in the assay.

Reagents

Reagent	Description	Storage	Reagent Stability
REF 10377503	**ADVIA Chemistry Theophylline_2 (THEO_2) Reagents**		
Theophylline_2 Reagent 1 THEO_2 R1	11.4 mL in 20-mL containers Mouse monoclonal antibodies reactive to Theophylline (57 µg/mL)[a] Glucose-6-Phosphate (G6P) (22 mmol/L) Nicotinamide adenine dinucleotide (18 mmol/L) Bovine serum albumin, preservatives and stabilizers Methylisothiazolinone (MIT) (0.1%)	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** • 7 days when you are not using a reagent container insert • 28 days when you are using a reagent container insert
Theophylline_2 Reagent 2 THEO_2 R2	7.0 mL in 20-mL containers Theophylline labeled with bacterial G6PDH (0.24 U/mL)[a] Tris buffer Bovine serum albumin, preservatives and stabilizers Methylisothiazolinone (0.1%)	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** • 7 days when you are not using a reagent container insert • 28 days when you are using a reagent container insert

[a] The antibody titer and enzyme conjugate activity may vary from lot to lot.

Warnings and Precautions

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare.

Caution

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

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner, and in compliance with prevailing regulatory requirements.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

Before use, gently invert the capped reagent to disrupt bubbles and ensure homogeneity. If bubbles still exist or foam is present, use a clean transfer pipette to aspirate them from the reagent container prior to use.

Storing and Stability

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

Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C.

Specimen Collection and Handling

Siemens Healthcare Diagnostics validated serum and plasma (lithium heparin, sodium heparin, EDTA, citrate or oxalate/fluoride anticoagulants) for the ADVIA Chemistry THEO_2 assay.

Collecting the Specimen

Follow these guidelines for specimens used for this assay:

- Do not use whole blood for this assay.
- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[9] Follow the instructions provided with your specimen collection device for use and processing.[10]
- Complete clot formation should take place before centrifugation.
- Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection.[11]
- Some sample dilution may occur when samples are collected in tubes that contain citrate anticoagulant. Consider the amount of dilution and the need to correct for the dilution when interpreting method results for these samples.
- Pharmacokinetic factors influence the correct time of sample collection after the last drug dose. These factors include dosage form, mode of administration, concomitant drug therapy, and biological variations affecting drug disposition.[1-5] Patient intake of caffeinated beverages does not need to be restricted.
- Handle all human serum and plasma samples as potentially infectious. Handle and dispose of human samples in accordance with established good laboratory practices and in compliance with all local and regulatory requirements.[12-14]

- Specimens should be free of particulate matter.
- Specimens should be as fresh as possible.

The purpose of handling and storage information is to provide guidance to users. 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.

Storing the Specimen

Store the serum and plasma refrigerated at 2–8°C.

Samples can be stored refrigerated at 2–8°C for 1 week, or stored frozen at -20°C for up to 2 months.[15]

Transporting the Specimen

When transporting specimens, maintain the temperature at 2–8°C.

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 10377503	Reagent 1: 4 × 20-mL containers Reagent 2: 4 × 20-mL containers	4 × 100

Materials Required but Not Provided

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

Item	Description
REF 10376770	ADVIA Chemistry Drug Calibrator 1
REF 02404085	20-mL reagent container adapter for 40-mL slot (ADVIA 1800)
REF 00771668	20-mL reagent container adapter for 70-mL slot (ADVIA 2400)
	Commercially available control materials

Optional Materials

The following materials may be used to perform this assay, but are not provided:

Item	Description
REF 02991886	Reagent container insert

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry system.

For detailed information on performing the procedure, refer to the system operating instructions.

Preparing the System

For detailed information on preparing the system, refer to the system operating instructions.

Preparing the Samples

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

On-System Stability

The ADVIA Chemistry THEO_2 reagents are stable on the system for 7 days when you are not using a reagent container insert, and for 28 days when you are using a reagent container insert.

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry THEO_2 assay, use ADVIA Chemistry Drug Calibrator 1, REF 10376770.

Enter the lot-specific calibrator values that are provided with each lot of calibrator. Perform the calibration as described in the calibrator instructions for use.

Calibration Frequency

Calibrate the assay every 7 days when you are not using a reagent container insert. Calibrate the assay every 28 days when you are using a reagent container insert.

Calibrate the assay after the following events:

- When the reagent lot number changes
- When a reagent pack is replaced by a new reagent pack with the same lot number, and the previous reagent pack was recalibrated during use
- When a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run on the previous reagent pack during use (For IFUs that require more frequent blanks than calibrations, put this bullet under RBL)
- After replacing critical optical or hydraulic components
- When indicated by quality control procedures

Individual laboratory quality control programs and procedures may require more frequent calibration.

Reagent Blank (RBL) Frequency

The ADVIA Chemistry system measures the RBL during assay calibration.

Run an RBL every day.

Run an additional RBL when a reagent pack is replaced by a new reagent pack with the same lot number, and an additional reagent blank was run during use.

Note Use deionized water or ADVIA Chemistry Drug Calibrator 1 - Level 1 as the sample for the RBL in the ADVIA Chemistry THEO_2 assay.

For more information on running daily reagent blanks for multiple standard methods on the ADVIA Chemistry systems, refer to the Customer Bulletin entitled: *Performing Reagent Blank (RBL) on Multi Standard (MSTD) Assays* (PN 073D0483, latest revision).

Performing Quality Control

Follow government regulations or accreditation requirements for quality control frequency.

At least once each day of use, analyze 2 levels (low and high) of a commercially available quality control (QC) material with known theophylline concentrations.

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.

The actual frequency of control in a laboratory is based on many factors, such as workflow, system experience, and government regulation. Each laboratory should evaluate the controls based on the frequency established by their laboratory guidelines.

Also, assay controls under the following conditions:

- Whenever you use a new reagent lot
- Following any system maintenance, cleaning, or troubleshooting procedure
- After performing a new calibration or an additional reagent blank

Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.

Taking Corrective Action

If the quality control results do not fall within the expected control range or within the laboratory's established values, do not report results. Take the following actions:

1. Determine and correct the cause of the unacceptable control results:
    a. Verify that the assay was performed according to the instructions for use.
    b. Verify that the materials are not expired.
    c. Verify that required maintenance was performed.
    d. Rerun the assay with fresh quality control samples, and confirm that quality control results are within acceptable limits before running patient samples.
    e. If the quality control results are not within acceptable limits, recalibrate the assay, and repeat the prior step.
    f. If necessary, contact your local technical support provider or distributor for assistance.
2. After corrective action is complete, repeat required testing of patient samples before reporting results.

Perform corrective actions in accordance with your established laboratory protocol.

Results

Calculation of Results

The system calculates and reports results based on the absorbance measurements of the test sample during the test, and of the calibrator(s) from calibration.

The instrument calculates the concentration of theophylline in µg/mL (common units) or µmol/L (SI units).

Conversion factor: µg/mL × 5.55 = µmol/L

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

A number of substances cause physiological changes in serum or plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. Consult the listed reference for specific details on known potential interfering substances.[16]

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Therapeutic Range

The therapeutic range for theophylline is listed in the following table.

Therapeutic Range		
Most patients	10–20 µg/mL (56–111 µmol/L)	Effectively suppresses chronic asthmatic and other bronchospastic symptoms.[2–5]
Neonatal Patients	5–10 µg/mL (28–56 µmol/L)	Controls apneic spells without causing apparent side effects.[2–4]
Toxic Range	> 20 µg/mL (> 111 µmol/L)[2–5]	

The 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 following parameters when considering how to interpret results:[2–5]

- The time of the last drug dose
- The dosage form
- The mode of administration
- Concomitant drug therapy
- Sample condition
- Time of sample collection
- Individual variations in absorption, distribution, biotransformation, and excretion.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Siemens provides this information for reference. As with all *in vitro* diagnostic assays, each laboratory should determine its own reference ranges for the diagnostic evaluation of patient results. Consider these values as a guideline only.

Performance Characteristics

Analytical Measuring Range

The analytical range is from 1.5 µg/mL (8.3 µmol/L) to the ADVIA Chemistry Drug Calibrator 1 - Level 5, 40.0 µg/mL (222.0 µmol/L).

Report the test result as less than 1.5 µg/mL (8.3 µmol/L) when the system reports any of the following:

- A result is less than the low end of the assay range, 1.5 µg/mL (8.3 µmol/L).
- The result is flagged as **L**, **k**, or **RL**.

The system can indicate whether out-of-range results are above or below the analytical range of the method. For further information, refer to the customer bulletin entitled *Configuring Supplemental Flagging for Out-of-Range Results* (073D0499, latest revision).

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay that extends the reportable range to 120.0 µg/mL (666.0 µmol/L). You may configure the system to trigger automatic reruns. Rerun results will be flagged **R**.

All samples that are flagged for a prozone effect should be carefully reviewed by the laboratory and the physician in conjunction with the clinical status of the patient.

Sensitivity

The ADVIA Chemistry THEO_2 assay performance at low levels was evaluated according to CLSI protocol EP17-A, and the limit of blank (LoB) and limit of detection (LoD) were determined.[17]

The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the ADVIA Chemistry THEO_2 assay is 0.6 µg/mL (3.3 µmol/L).

The LoD is the smallest amount that this assay can reliably detect to determine presence or absence of an analyte. The LoD for the ADVIA Chemistry THEO_2 assay is 1.5 µg/mL (8.3 µmol/L).

The LoB and LoD values are determined with proportions of false positives (α) less than 5% and false negatives (β) less than 5%, based on a minimum 80 determinations with a water blank and a low-level sample.

Precision

The precision of the ADVIA Chemistry THEO_2 assay was evaluated according to the CLSI document EP05-A2.[18] Each sample was assayed 2 times per run, 2 runs per day, for at least 20 days.

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		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (µg/mL)					
Serum Control 1	5.1	0.26	5.1	0.34	6.7
Serum Control 2	15.3	0.64	4.2	0.78	5.1
Serum Control 3	25.5	0.89	3.5	1.47	5.8
SI Units (µmol/L)					
Serum Control 1	28.2	1.44	5.1	1.88	6.7
Serum Control 2	84.8	3.57	4.2	4.33	5.1
Serum Control 3	141.2	4.94	3.5	8.17	5.8

[a] SD = standard deviation
[b] CV = coefficient of variation

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		Repeatability (Within-Run)		Within-Lab (Total)	
Specimen Type	**Mean**	**SD[a]**	**CV[b] (%)**	**SD**	**CV (%)**
Common Units (µg/mL)					
Serum Control 1	4.7	0.27	5.8	0.37	7.9
Serum Control 2	14.5	0.60	4.1	0.91	6.3
Serum Control 3	23.2	1.14	4.9	1.57	6.8
SI Units (µmol/L)					
Serum Control 1	26.2	1.51	5.8	2.07	7.9
Serum Control 2	80.6	3.32	4.1	5.04	6.3
Serum Control 3	128.7	6.33	4.9	8.71	6.8

[a] SD = standard deviation
[b] CV = coefficient of variation

Actual results will vary depending on the study design, and on the sample and sample population used. Results obtained at individual laboratories may vary from the data provided.

Accuracy / Method Comparison

The performance of the ADVIA Chemistry THEO_2 assay (y) was compared with the performance of the comparison assay on the indicated system (x).

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Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Serum	Emit 2000 Theophylline (on Hitachi 717)	87	y = 0.98x + 0.58 y = 0.98x + 3.22	1.40 7.77	0.99	2.3–39.8 µg/mL 12.8–220.9 µmol/L
Serum	ADVIA 1650/1800 THEO	88	y = 1.03x - 0.05 y = 1.03x - 0.28	0.94 5.22	0.99	2.2–37.3 µg/mL 12.2–207.0 µmol/L
Serum	Dimension® Theophylline	35	y = 1.01x - 0.30 y = 1.01x - 1.67	0.99 5.49	0.99	3.3–27.5 µg/mL 18.3–152.6 µmol/L
Plasma (Citrate)	ADVIA 1650/1800 (serum)	53	y = 1.00x + 0.11 y = 1.00x + 0.61	1.29 7.16	0.99	2.2–39.7 µg/mL 12.2–220.3 µmol/L
Plasma (EDTA)	ADVIA 1650/1800 (serum)	53	y = 0.98x + 0.39 y = 0.98x + 2.16	1.82 10.10	0.99	2.2–39.7 µg/mL 12.2–220.3 µmol/L
Plasma (Lithium Heparin)	ADVIA 1650/1800 (serum)	52	y = 0.99x + 0.30 y = 0.99x + 1.67	0.88 4.88	0.99	2.2–39.7 µg/mL 12.2–220.3 µmol/L
Plasma (Sodium Heparin)	ADVIA 1650/1800 (serum)	53	y = 0.99x + 0.26 y = 0.99x + 1.44	2.03 11.27	0.99	2.2–39.7 µg/mL 12.2–220.3 µmol/L
Plasma (Oxalate/Fluoride)	ADVIA 1650/1800 (serum)	52	y = 1.01x + 0.17 y = 1.01x + 0.94	1.61 8.94	0.99	2.2–39.7 µg/mL 12.2–220.3 µmol/L

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Specimen Type	Comparison Assay (x)	N	Regression Equation	Sy.x	r	Sample Range
Serum	ADVIA 2400 THEO	89	y = 1.01x + 0.29 y = 1.01x + 1.61	0.68 3.77	0.99	2.4–39.8 µg/mL 13.3–220.9 µmol/L
Serum	ADVIA 1650/1800 THEO_2	88	y = 0.99x - 0.00 y = 0.99x - 0.00	0.94 5.22	0.99	2.4–39.4 µg/mL 13.3–218.7 µmol/L
Plasma (Citrate)	ADVIA 2400 (serum)	41	y = 0.99x + 0.32 y = 0.99x + 1.78	1.97 10.93	0.99	2.7–39.7 µg/mL 15.0–220.3 µmol/L
Plasma (EDTA)	ADVIA 2400 (serum)	42	y = 1.00x - 0.17 y = 1.00x - 0.94	1.50 8.33	0.99	2.7–39.7 µg/mL 15.0–220.3 µmol/L
Plasma (Lithium Heparin)	ADVIA 2400 (serum)	41	y = 1.04x - 0.75 y = 1.04x - 4.16	2.08 11.54	0.99	2.7–39.7 µg/mL 15.0–220.3 µmol/L
Plasma (Sodium Heparin)	ADVIA 2400 (serum)	40	y = 1.00x - 0.23 y = 1.00x - 1.28	2.51 13.93	0.97	2.7–39.7 µg/mL 15.0–220.3 µmol/L
Plasma (Oxalate/Fluoride)	ADVIA 2400 (serum)	43	y = 1.02x - 0.77 y = 1.02x - 4.27	2.36 13.10	0.98	2.7–39.7 µg/mL 15.0–220.3 µmol/L

The correlation of the assay may vary depending on the study design, comparable method, and sample population. Results obtained at individual laboratories may vary from the data provided.

Interferences

Siemens tested the following potential interferents and found the results shown below.

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Interferent	Interferent Level	Theophylline Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	60 mg/dL (1026 µmol/L)	10.1, 19.1 µg/mL (55.8, 105.7 µmol/L)	NSI[a]
Hemolysis (hemoglobin)	1000 mg/dL (10.0 g/L)	9.7, 18.2 µg/mL (53.8, 100.7 µmol/L)	NSI
Lipemia[b] (from Intralipid)	1000 mg/dL (11.3 mmol/L)	8.7, 16.4 µg/mL (48.0, 90.7 µmol/L)	NSI

[a] NSI = No significant interference. A percentage effect ≥ 10% is considered a significant interference.

[b] SI units calculated as triolein

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Interferent	Interferent Level	Theophylline Sample Concentration	Interference
Bilirubin (conjugated and unconjugated)	60 mg/dL (1026 µmol/L)	9.9, 18.9 µg/mL (54.9, 105.0 µmol/L)	NSI[a]
Hemolysis (hemoglobin)	1000 mg/dL (10.0 g/L)	9.5, 18.9 µg/mL (52.8, 104.8 µmol/L)	NSI
Lipemia[b] (from Intralipid)	1000 mg/dL (11.3 mmol/L)	8.9, 16.3 µg/mL (49.6, 90.7 µmol/L)	NSI

[a] NSI = No significant interference. A percentage effect ≥ 10% is considered a significant interference.

[b] SI units calculated as triolein

Note There is poor correlation between turbidity and triglyceride concentration in a lipemic sample.[19]

Actual results will vary depending on the study design, the levels of the potential interferences tested, and the samples used. Results obtained at individual laboratories may vary from the data provided.

Specificity

The ADVIA Chemistry THEO_2 assay measures the total (protein-bound plus unbound) theophylline concentration in serum or plasma. The specificity of the assay was evaluated by testing compounds whose chemical structure or concurrent usage could potentially interfere with the ADVIA Chemistry THEO_2 assay. This data was collected on an automated chemistry system using method parameters equivalent to those used on the ADVIA Chemistry XPT system.[20]

The following compounds did not interfere with the ADVIA Chemistry THEO_2 assay when tested in the presence of 10 µg/mL theophylline. Levels tested were at or above maximum pharmacological concentrations.

Compound Tested	Concentration Tested (µg/mL)
Caffeine	35
8-Chlorotheophylline	25
1,3-Dimethyluric Acid	100

Compound Tested	Concentration Tested (µg/mL)
Dyphylline	100
Ephedrine	5
Hypoxanthine	100
1-Methyluric Acid	100
3-Methyluric Acid	200
1-Methylxanthine	30
3-Methylxanthine	100
7-Methylxanthine	100
Paraxanthine	50
Phenobarbital	100
Theobromine	100
1,3,7-Trimethyluric Acid	100
Urea	1000
Uric Acid	200
Xanthine	100

The compound 3-isobutyl-1-methylxanthine interferes in this method. The compound is not a naturally occurring xanthine or known metabolite, but some laboratories use it as an internal standard in chromatographic procedures.[21]

Standardization

The ADVIA Chemistry THEO_2 assay is traceable to an internal standard manufactured using United States Pharmacopoeia (USP) material. Assigned values of ADVIA Chemistry Drug Calibrator 1 are traceable to this standardization.

Technical Assistance

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

siemens.com/healthcare

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Definition	Symbol	Definition
IVD	*In vitro* diagnostic medical device	REF REF	Catalog number
	Legal manufacturer	EC REP	Authorized Representative in the European Community
CE	CE Mark	CE 0088	CE Mark with identification number of notified body
	Consult instructions for use		Biological risk
	Keep away from sunlight and heat		Temperature limitation
	Lower limit of temperature		Upper limit of temperature
	Do not freeze (> 0°C)		Up
	Use by	Σ (n)	Contains sufficient for (n) tests
	Recycle	PRINTED WITH SOY INK	Printed with soy ink
Rev.	Revision	YYYY-MM-DD	Date format (year-month-day)
LOT	Batch code	**RxOnly**	Prescription Device (US only)

Trademarks

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