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ADVIA® Chemistry XPT
Systems

Triglycerides_2 (TRIG_2)

Current Revision and Date[a]	Rev. D, 2016-09	
Product Name	ADVIA® Chemistry Triglycerides_2 (TRIG_2) Reagent	REF 10335892
Systems	ADVIA Chemistry XPT System	
Materials Required but Not Provided	Siemens Chemistry Calibrator Reagent container adapters Commercially available controls	REF 09784096 (T03-1291-62)
Specimen Types	Human serum, plasma (lithium heparin, potassium EDTA)	
Assay Principle	GPO-Trinder without serum blank	
Assay Range	Serum: 10–550 mg/dL (0.11–6.22 mmol/L) Plasma: 10–550 mg/dL (0.11–6.22 mmol/L)	
Reagent Storage	2–8°C	
Reagent On-System Stability	60 days	
Reagent Code	74082	

[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 measurement of triglycerides in human serum and plasma on ADVIA® Chemistry XPT systems. Measurements of triglycerides are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

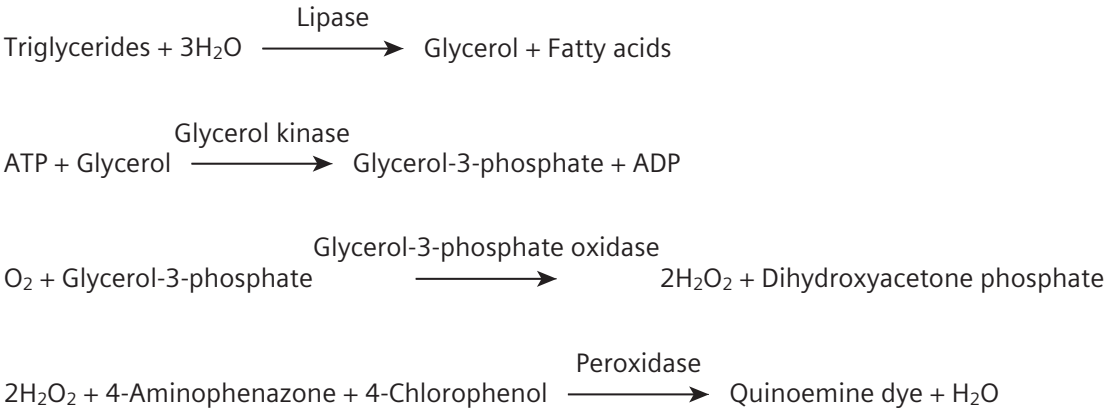
Summary and Explanation

The ADVIA Chemistry Triglycerides_2 (TRIG_2) assay is based on the Fossati three-step enzymatic reaction with a Trinder endpoint. The single-reagent procedure quantitates the total triglycerides including the mono- and diglycerides and the free glycerol fractions.[1,2]

Principles of the Procedure

The triglycerides are converted to glycerol and free fatty acids by lipase. The glycerol is then converted to glycerol-3-phosphate by glycerol kinase followed by its conversion by glycerol-3-phosphate oxidase to hydrogen peroxide. A colored complex is formed from hydrogen peroxide, 4-aminophenazone and 4-chlorophenol under the catalytic influence of peroxidase. The absorbance of the complex is measured as an endpoint reaction at 505/694 nm.

Reaction Equation



Reagents

Reagent	Description	Storage	Reagent Stability
REF 10335892	**ADVIA Chemistry Triglycerides_2 (TRIG_2) Reagent**		
Triglycerides_2 Reagent 1 TRIG_2 R1	38.0 mL in 40-mL containers 4-Chlorophenol (5.5 mmol/L) Peroxidase (≥ 0.5 U/mL) Glycerol kinase (≥ 0.4 U/mL) Glycerol-3-phosphate oxidase (≥ 1.5 U/mL) 4-Aminophenazone (0.25 mmol/L) Lipase (≥ 10 U/mL) NaN_3 (0.05%)	2–8°C	**Unopened:** Stable until the expiration date on product. **On-system:** 60 days

Warnings and Precautions

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

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

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.

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.

Specimen Collection and Handling

Siemens Healthcare Diagnostics has validated serum and plasma (lithium heparin and potassium EDTA) for the ADVIA Chemistry TRIG_2 assay.

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.

Collecting the Specimen

Follow these guidelines for specimens used for this assay:

- Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture.[3] Follow the instructions provided with your specimen collection device for use and processing.[4]
- Complete clot formation should take place before centrifugation for serum specimens.
- 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.[5]
- Specimens should be free of particulate matter.
- Specimens should be as fresh as possible.

Storing the Specimen

Specimens may be stored for up to 7 days at 2–8°C.[6]

Procedure

Materials Provided

The following materials are provided:

Item	Contents	Number of Tests
REF 10335892	Reagent 1: 4 × 40-mL containers	4 × 362

Materials Required but Not Provided

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

Item	Description
REF 09784096 (T03-1291-62)	Siemens Chemistry Calibrator
REF 10719152	40-mL reagent container adapter for 70-mL slot
	Commercially available control materials

Assay Procedure

Sampling, reagent delivery, mixing, and processing are automatically performed by the ADVIA Chemistry XPT 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 TRIG_2 reagent is stable on the system for 60 days.

Do not use reagents beyond the expiration date.

Performing Calibration

To calibrate the ADVIA Chemistry TRIG_2 assay, use the Siemens Chemistry Calibrator, REF 09784096 (T03-1291-62).

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 60 days.

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
- 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 XPT system measures the RBL during assay calibration.

Run an additional RBL on the same reagent pack every 14 days thereafter.

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 as the sample for the RBL in the ADVIA Chemistry TRIG_2 assay.

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 triglycerides 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 triglycerides in mg/dL (common units) or mmol/L (SI units).

Conversion factor: mg/dL × 0.0113 = mmol/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.[7]

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.

Note Siemens has determined that there is a possibility for certain ADVIA Chemistry reagents to interact with the ADVIA Chemistry TRIG_2 assay when run on the same system. To mitigate these carryover events, the ADVIA Chemistry system software provides a Contamination Avoidance process. For further information and instructions to establish this process on your systems, refer to the Customer Bulletin entitled: *Consolidated Directory of Contamination Avoidance Settings for ADVIA Chemistry XPT Systems* (PN 10815606, latest revision).

Venipuncture should occur prior to N-Acetyl Cysteine (NAC) or Metamizole (Sulpyrine) administration due to the potential for falsely depressed results.

Expected Values

The reference range for triglycerides for serum and plasma is listed in the following table.[6]

Sample Type	Reference Range
Normal	< 150 mg/dL (< 1.70 mmol/L)
Borderline high	150–199 mg/dL (1.70–2.25 mmol/L)
High	200–499 mg/dL (2.26–5.64 mmol/L)
Very High	≥ 500 mg/dL (≥ 5.65 mmol/L)

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

This assay is linear from 10–550 mg/dL (0.11–6.22 mmol/L).

Results that are below the low end of the assay range are flagged **< Conc Range**. You should report the test result as < 10 mg/dL (< 0.11 mmol/L).

Results that are above the high end of the assay range are flagged **> Conc Range**.

Extended Measuring Range

Siemens has validated an automatic rerun condition for this assay that extends the reportable range to 1100 mg/dL (12.43 mmol/L). You may configure the system to trigger automatic reruns. Rerun results will be flagged **Autorepeat**.

Sensitivity

The ADVIA Chemistry TRIG_2 assay performance at low levels was analyzed as described in CLSI protocol EP17-A2, and the limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) were determined.[8]

The LoB is the highest measurement result that is likely to be observed on a blank sample. The LoB for the ADVIA Chemistry TRIG_2 assay is 5 mg/dL (0.06 mmol/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 TRIG_2 assay is 8 mg/dL (0.09 mmol/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 180 determinations with 120 blank and 60 low-level sample replicates.

The LoQ is 10 mg/dL (0.11 mmol/L).

Precision

The precision of the ADVIA Chemistry TRIG_2 assay was analyzed as described in CLSI protocol EP5-A2.[9] Each sample was assayed 2 times per run, 2 runs per day, for at least 20 days.

Precision: Common Units

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
Specimen Type	N	Mean (mg/dL)	SD[a] (mg/dL)	CV[b] (%)	SD[a] (mg/dL)	CV[b] (%)	SD[a] (mg/dL)	CV[b] (%)	SD[a] (mg/dL)	CV[b] (%)
Serum Control 1	120	177	1.5	0.8	0.0	0.0	0.7	0.4	1.6	0.9
Serum Control 2	120	88	0.7	0.8	0.3	0.3	0.6	0.7	0.9	1.1
Serum Pool 1	120	112	0.9	0.8	0.8	0.7	1.0	0.9	1.5	1.4
Serum Pool 2	120	152	1.1	0.7	1.4	0.9	1.3	0.9	2.2	1.5
Serum Pool 3	120	256	1.5	0.6	2.5	1.0	1.0	0.4	3.1	1.2
Serum Pool 4	120	501	3.1	0.6	2.3	0.5	1.3	0.3	4.0	0.8

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

Precision: SI Units

			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Lab (Total)	
Specimen Type	N	Mean (mmol/L)	SD[a] (mmol/L)	CV[b] (%)	SD[a] (mmol/L)	CV[b] (%)	SD[a] (mmol/L)	CV[b] (%)	SD[a] (mmol/L)	CV[b] (%)
Serum Control 1	120	2.00	0.017	0.8	0.000	0.0	0.008	0.4	0.018	0.9
Serum Control 2	120	0.99	0.008	0.8	0.003	0.3	0.007	0.7	0.010	1.1
Serum Pool 1	120	1.27	0.010	0.8	0.009	0.7	0.011	0.9	0.017	1.4
Serum Pool 2	120	1.72	0.012	0.7	0.016	0.9	0.015	0.9	0.025	1.5
Serum Pool 3	120	2.89	0.017	0.6	0.028	1.0	0.011	0.4	0.035	1.2
Serum Pool 4	120	5.66	0.035	0.6	0.026	0.5	0.015	0.3	0.045	0.8

[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 TRIG_2 assay (y) was compared with the performance of the comparison assay on the indicated system (x).

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sy.x	Sample Range
Serum	ADVIA 2400 TRIG_2	101	0.999	y = 0.97x + 2.4 mg/dL y = 0.97x + 0.027 mmol/L	6.1 mg/dL 0.069 mmol/L	30–530 mg/dL 0.34–5.99 mmol/L
Serum	ADVIA 1800 TRIG_2	101	0.999	y = 0.97x + 1.4 mg/dL y = 0.97x + 0.016 mmol/L	5.8 mg/dL 0.066 mmol/L	33–531 mg/dL 0.37–6.00 mmol/L
Plasma (Lithium Heparin)	ADVIA 1800 TRIG_2	58	1.000	y = 0.99x + 1.0 mg/dL y = 0.99x + 0.011 mmol/L	3.3 mg/dL 0.037 mmol/L	35–543 mg/dL 0.40–6.14 mmol/L
Plasma[a] (Lithium Heparin) ADVIA 1650/1800	ADVIA 1650/1800 TRIG_2 - Serum	59	0.999	y = 1.01x - 2.6 mg/dL y = 1.01x - 0.03 mmol/L	7.8 mg/dL 0.09 mmol/L	34–509 mg/dL 0.38–5.75 mmol/L
Plasma (Potassium EDTA)	ADVIA 1800 TRIG_2	55	1.000	y = 1.00x - 0.2 mg/dL y = 1.00x - 0.002 mmol/L	3.4 mg/dL 0.038 mmol/L	47–497 mg/dL 0.53–5.62 mmol/L
Plasma[a] (Potassium EDTA) ADVIA 1650/1800	ADVIA 1650/1800 TRIG_2 - Serum	60	0.999	y = 1.02x - 7.5 mg/dL y = 1.02x - 0.08 mmol/L	6.4 mg/dL 0.07 mmol/L	34–509 mg/dL 0.38–5.75 mmol/L

[a] Matrix comparison. Correlations between serum and plasma samples on ADVIA 1650/1800 Chemistry systems are provided for reference.

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. Interfering substances at the levels indicated in the table below were tested using the ADVIA Chemistry TRIG_2 assay as described in CLSI protocol EP7-A2.[10]

Interferent	Interferent Level	Triglycerides Sample Concentration	Interference
Bilirubin (conjugated)	15 mg/dL (256.5 µmol/L)	102 mg/dL (1.15 mmol/L)	NSI[a]
	22.5 mg/dL (384.8 µmol/L)	102 mg/dL (1.15 mmol/L)	-13.7%
	7.5 mg/dL (128.3 µmol/L)	159 mg/dL (1.80 mmol/L)	NSI
	15 mg/dL (256.5 µmol/L)	159 mg/dL (1.80 mmol/L)	-10.1%
	30 mg/dL (513 µmol/L)	511 mg/dL (5.77 mmol/L)	NSI

Interferent	Interferent Level	Triglycerides Sample Concentration	Interference
Bilirubin (unconjugated)	7.5 mg/dL (128.3 µmol/L)	103 mg/dL (1.16 mmol/L)	NSI
	15 mg/dL (256.5 µmol/L)	103 mg/dL (1.16 mmol/L)	+16.5%
	15 mg/dL (256.5 µmol/L)	158 mg/dL (1.79 mmol/L)	NSI
	22.5 mg/dL (384.8 µmol/L)	158 mg/dL (1.79 mmol/L)	+13.3%
	30 mg/dL (513 µmol/L)	510 mg/dL (5.76 mmol/L)	NSI
Hemolysis (hemoglobin)	250 mg/dL (2.5 g/L)	97 mg/dL (1.10 mmol/L)	NSI
	500 mg/dL (5 g/L)	97 mg/dL (1.10 mmol/L)	+14.4%
	500 mg/dL (5 g/L)	152 mg/dL (1.72 mmol/L)	NSI
	750 mg/dL (7.5 g/L)	152 mg/dL (1.72 mmol/L)	+12.5%
	1000 mg/dL (10 g/L)	493 mg/dL (5.57 mmol/L)	NSI
Ascorbic Acid[b]	3 mg/dL (170 µmol/L)	142 mg/dL (1.60 mmol/L)	NSI
	6 mg/dL (341 µmol/L)	142 mg/dL (1.60 mmol/L)	-13.0%
	12 mg/dL (682 µmol/L)	483 mg/dL (5.46 mmol/L)	NSI

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

[b] Results are from the ADVIA 2400 Chemistry system using the same reagent, with assay conditions identical to those on the ADVIA Chemistry XPT system.

Note There is poor correlation between turbidity and triglyceride concentration in a lipemic sample.[11]

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.

Standardization

The ADVIA Chemistry TRIG_2 assay measures total glycerols. The assay is traceable to reference material SRM909c from the National Institute of Standards and Technology (NIST). Assigned values of Siemens Chemistry Calibrator are traceable to this standardization.

Technical Assistance

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

siemens.com/healthcare

References

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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		

Trademarks

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