

Lipid Profile (total cholesterol, HDL-cholesterol, triglyceride, calculated LDL)

These assays are run at the Clinical Chemistry Laboratory at Fletcher Allen Health Care, an affiliate of the University of Vermont. The Ortho Vitros Clinical Chemistry System 950IRC instrument (Johnson & Johnson Clinical Diagnostics, Rochester, NY), which uses thin film technology, is used to quantitatively measure lipid levels via a colorimetric reaction.

Cholesterol is measured using a colorimetric reflectance spectrophotometric method. Normal ranges for adults are Desirable : < 200 mg/dL; Borderline: 200 – 239 mg/dL; High: => 240 mg/dL. The reportable range for this assay is 50-325mg/dl. The expected CV of this assay is <2%.

Direct HDL Cholesterol is assayed by colorimetric reflectance spectrophotometry after samples are treated with phosphitungstic acid/magnesium chloride to precipitate HDLs and non-HDLs. Normal ranges for adults are Highly Desirable: > 60 mg/dL; Desirable: 35-60 mg/dL; High Risk: <40 mg/dL. The reportable range for this assay is 5.0-110.0 mg/dL. The expected CV of this assay is approximately 7%.

LDL Cholesterol is calculated: Total Cholesterol – {HDL + (Triglycerides/5)}. Normal ranges for adults are Desirable: < 130 mg/dL; Borderline: 130-159 mg/dL; High Risk: >= 160 mg/dL.

Triglyceride is measured by colorimetric reflectance spectrophotometry. Normal ranges for adults are Normal:<150 mg/dL; Borderline High: 150-199 mg/dL; High; Very High: >=150mg/dL . The reportable range for this assay is 10.0-525.0 mg/dL. The expected CV of this assay is <2%.

INSTRUCTIONS FOR USE

VITROS Chemistry Products TRIG Slides

TRIG

Triglyceride

REF 133 6544
832 9930

Intended Use

For *in vitro* diagnostic use only.

VITROS TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma.

Summary and Explanation of the Test

Triglycerides, fatty acid esters of glycerol, represent the major form of fat found in the body; their primary function is to store and provide cellular energy. The concentration of triglycerides in the plasma at any given time is a balance between the rates of entry and removal. Triglyceride concentrations in the plasma vary with age and gender. Moderate increases occur during growth and development. Triglycerides are used for the evaluation of hyperlipidemias; high concentrations may occur with hypothyroidism, nephrotic syndrome, glycogen storage diseases, and diabetes mellitus. Extremely high triglyceride concentrations are common in acute pancreatitis.¹

Principles of the Procedure

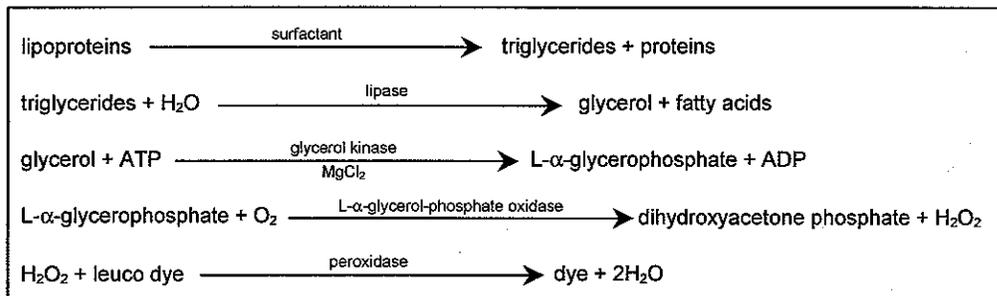
The VITROS TRIG Slide method is performed using the VITROS TRIG Slides and the VITROS Chemistry Products Calibrator Kit 2 on VITROS Chemistry Systems.

The VITROS TRIG Slide is a multilayered, analytical element coated on a polyester support. The analysis is based on an enzymatic method as described by Spayd et al.²

A drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. The Triton X-100 surfactant in the spreading layer aids in dissociating the triglycerides from lipoprotein complexes present in the sample. The triglyceride molecules are then hydrolyzed by lipase to yield glycerol and fatty acids. Glycerol diffuses to the reagent layer, where it is phosphorylated by glycerol kinase in the presence of adenosine triphosphate (ATP). In the presence of L- α -glycerol-phosphate oxidase, L- α -glycerophosphate is then oxidized to dihydroxyacetone phosphate and hydrogen peroxide. The final reaction involves the oxidation of a leuco dye by hydrogen peroxide, catalyzed by peroxidase, to produce a dye.

The density of the dye formed is proportional to the triglyceride concentration present in the sample and is measured by reflectance spectrophotometry.

Reaction Sequence



Test Type and Conditions

Test Type and Conditions for TRIG

Test Type	VITROS System	Approximate Incubation Time	Temperature	Wavelength	Sample Drop Volume*
Colorimetric	5, 1 FS, 950, 750, 550, 250	5 minutes	37°C (98.6°F)	540 nm	5.5 μ L

* The sample drop volume depends on the format of the slide and is determined automatically by the analyzer. Slides with coating numbers <3201 require a 10 μ L sample drop volume.

Warnings and Precautions

For *in vitro* diagnostic use only.

Take care when handling materials and samples of human origin. Since no test method can offer complete assurance that infectious agents are absent, consider all clinical specimens, controls, and calibrators potentially infectious. Handle specimens, solid and liquid waste, and test components in accordance with local regulations and NCCLS Guideline M29³ or other published biohazard safety guidelines.

For specific warnings and precautions for calibrators, quality control materials, and other components, refer to the Instructions for Use for the appropriate VITROS product, or to other manufacturer's product literature.

Reagents

Slide Ingredients

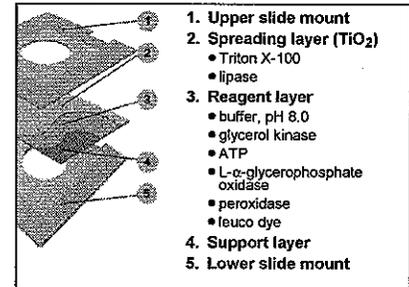
Reactive ingredients per cm²

Lipase (*Candida rugosa*, E.C.3.1.1.3) 0.15 U; peroxidase (horseradish root, E.C.1.11.1.7) 0.52 U; glycerol kinase (*Cellulomonas sp.*, E.C.2.7.1.30) 0.35 U; L- α -glycerophosphate oxidase (*Pediococcus sp.*, E.C.1.1.3.-) 0.19 U; Triton X-100 0.62 mg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl)imidazole (leuco dye) 0.04 mg; and adenosine triphosphate 0.14 mg.

Other ingredients

Pigment, binders, buffer, surfactants, stabilizers, scavenger, enzyme cofactors, dye solubilizer and cross-linking agent.

Slide Diagram



Cartridge Handling

CAUTION: Do not use slide cartridges with damaged or incompletely sealed packaging.

- Inspect the packaging for signs of damage.
- Be careful when opening the outer packaging with a sharp instrument so as to avoid damage to the individual product packaging.

Cartridge Preparation

IMPORTANT: The slide cartridge must reach room temperature, 18°–28°C (64°–82°F), before it is unwrapped and loaded into the slide supply.

1. Remove the slide cartridges from storage.
2. Warm the wrapped cartridge at room temperature for 60 minutes.
3. Unwrap and load the cartridge into the slide supply.

NOTE: Load the cartridges within 24 hours after they reach room temperature, 18°–28°C (64°–82°F).

Slide Storage and Stability

VITROS TRIG Slides are stable until the expiration date on the carton when they are stored and handled as specified.

Slide Storage and Stability for TRIG

Slide Cartridges	Storage Condition		Stability
Unopened	Frozen	≤ 18°C (≤ 0°F)	Until expiration date
Opened	On-analyzer	System turned on	≤ 1 week
	On-analyzer	System turned off	≤ 2 hours

- Verify performance with quality control materials:
 - If the system is turned off for more than 2 hours.
 - After reloading cartridges that have been removed from the slide supply and stored for later use.

Specimen Requirements

WARNING: Handle specimens as biohazardous material.

Specimens Recommended

- Serum
- Plasma: Heparin
- Serum is the specimen of choice because it is the basis for the US National Institutes of Health recommendations relating lipid levels with cardiac risk. Heparin plasma results have been reported as being within 1% of serum results.⁴

IMPORTANT: Certain collection devices have been reported to affect other analytes and tests.⁵
Confirm that your collection devices are compatible with this test.

Specimens Not Recommended

- Plasma: EDTA⁴

Serum and Plasma

Specimen Collection and Preparation

Collect specimens using standard laboratory procedures.^{6,7}

NOTE: For details on minimum fill volume requirements, refer to the operating instructions for your VITROS Chemistry System.

Patient Preparation

- Collect specimens from patients fasting for at least 12 hours.⁸

Special Precautions

- Equipment must be soap-free and glycerol-free.
- Do not use collection tubes with glycerol-lubricated stoppers.
- Centrifuge specimens and remove the serum or plasma from the cellular material within 4 hours of collection.⁹

Specimen Handling and Storage

WARNING: Handle specimens as biohazardous material.

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18°–28°C (64°–82°F), prior to analysis.

Specimen Storage and Stability for TRIG: Serum and Plasma⁹

Storage	Temperature	Stability
Room temperature	18°–28°C (64°–82°F)	≤3 days
Refrigerated	2°–8°C (36°–46°F)	≤7 days
Frozen	≤-18°C (≤0°F)	≤6 months

IMPORTANT: Avoid repeated freeze-thaw cycles.

Testing Procedure

Materials Provided

- VITROS Chemistry Products TRIG Slides

Materials Required But Not Provided

- VITROS Chemistry Products Calibrator Kit 2
- Quality control materials, such as VITROS Chemistry Products Performance Verifier I and II
- VITROS Chemistry Products 7% BSA
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for on-analyzer dilution)

TRIG

Triglyceride

INSTRUCTIONS FOR USE

Calibration

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned workload.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

IMPORTANT: *Bring all fluids and samples to room temperature, 18°–28°C (64°–82°F), prior to analysis.*

Sample Dilution

Serum and Plasma

If samples are grossly lipemic or show triglyceride concentrations that exceed the system's reportable (dynamic) range:

Manual Sample Dilution

1. Dilute the sample with VITROS 7% BSA.
2. Reanalyze.
3. Multiply the results by the dilution factor to obtain an estimate of the original sample's triglyceride concentration.

On-Analyzer Sample Dilution (VITROS 5,1 FS and VITROS 250 only)

Refer to the VITROS Chemistry System operating instructions for more information on the On-Analyzer Dilution Procedure. For VITROS 5,1 FS, use VITROS Chemistry Products FS Diluent Pack 2 for the dilution.

Calibration

Required Calibrators

VITROS Chemistry Products Calibrator Kit 2

Calibrator Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Calibrator Kit 2.

Calibration Procedure

Refer to the operating instructions for your VITROS Chemistry System.

When to Calibrate

Calibrate:

- When the slide lot number changes.
- When critical system parts are replaced due to service or maintenance.
- When government regulations require.
 - For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months.

The VITROS TRIG test may also need to be calibrated:

- If quality control results are consistently outside acceptable range.
- After certain service procedures have been performed.

For additional information, refer to the operating instructions for your VITROS Chemistry System.

Calculations

Reflectance from the slide is measured at 540 nm after the fixed incubation time. Once a calibration has been performed for each slide lot, triglyceride concentration in unknown samples can be determined using the software-resident endpoint colorimetric math model and the response obtained from each unknown test slide.

Validity of a Calibration

Calibration parameters are automatically assessed by the VITROS Chemistry System against a set of quality parameters detailed in the Coefficients and Limits screen (for VITROS 5,1 FS, see the Review Assay Data screen). Failure to meet any of the pre-defined quality parameters results in a failed calibration. The calibration report should be used in conjunction with quality control results to determine the validity of a calibration.

Reportable (Dynamic) Range

Reportable (Dynamic) Range for TRIG

Conventional Units (mg/dL)	SI Units (mmol/L)	Alternate Units (g/L)
10.0–525.0	0.11–5.93	0.10–5.25

For out-of-range samples, refer to "Sample Dilution."

Traceability of the Calibration

Values assigned to the VITROS Chemistry Products Calibrator Kit 2 for triglyceride are traceable to the CDC chromotropic acid reference procedure.¹⁰ The Ortho-Clinical Diagnostics (OCD) calibration laboratory uses value assigned human serum pools, from a CDC Reference Network Certified Laboratory, to calibrate a glycerol phosphate oxidase triglyceride spectrophotometric method¹¹ to support triglyceride value assignment for VITROS Calibrator Kit 2.

Quality Control

Procedure Recommendations

WARNING: Handle quality control materials as biohazardous material.

- Choose control levels that check the clinically relevant range.
- Analyze quality control materials in the same manner as patient samples, before or during patient sample processing.
- To verify system performance, analyze control materials:
 - After calibration.
 - According to local regulations or at least once each day that the test is being performed.
 - After specified service procedures are performed. Refer to the operating instructions for your VITROS Chemistry System.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- For general quality control recommendations, refer to *Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline-Second Edition*¹² or other published guidelines.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

Quality Control Material Selection

IMPORTANT: VITROS Performance Verifiers are recommended for use with the VITROS Chemistry System. Evaluate the performance of other commercial control fluids for compatibility with this test before using for quality control.

- Control materials other than VITROS Performance Verifiers may show a difference when compared with other triglyceride methods if they:
 - Depart from a true human matrix.
 - Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives.
- Do not use control materials stabilized with ethylene glycol.

Quality Control Material Preparation and Storage

Refer to the Instructions for Use for VITROS Chemistry Products Performance Verifier I and II or to other manufacturer's product literature.

Expected Values and Reporting Units

Reference Interval

These reference intervals are recommended by NCEP.¹³

Reference Interval for TRIG

Triglycerides Classification	Conv. Units (mg/dL)	SI Units (mmol/L)	Alternate Units (g/L)
Normal	<150	<1.69	<1.50
Borderline High	150–199	1.69–2.25	1.50–1.99
High	200–499	2.26–5.64	2.00–4.99
Very High	≥500	≥5.65	≥5.00

Each laboratory should confirm the validity of these intervals for the population it serves.

Reporting Units and Unit Conversion

The VITROS Chemistry System may be programmed to report TRIG results in conventional, SI, and alternate units.

Reporting Units and Unit Conversion for TRIG

Conventional Units	SI Units	Alternate Units
mg/dL	mmol/L (mg/dL x 0.01129)	g/L (mg/dL x 0.01)

TRIG

Triglyceride

INSTRUCTIONS FOR USE

Limitations of the Procedure

Limitations of the Procedure

Known Interferences

- **Free glycerol**¹⁴
Free (nonesterified) glycerol in serum is measured along with the glycerol from the hydrolysis of triglycerides and diglycerides. Certain clinical conditions (e.g., diabetes mellitus and cardiac ischemia) show high endogenous free glycerol levels. Some drugs used in the treatment of lipemia also produce elevated glycerol levels. Triglyceride results from samples of such patients will not reflect actual serum triglyceride content.
- **Grossly lipemic samples** show a slower rate of color development than do clear serums, which results in a negative bias. These samples often contain triglyceride concentrations greater than the system's reportable (dynamic) range. See "Sample Dilution" for instructions.

For substances that were tested and did not interfere, see "Specificity."

Other Limitations

Certain drugs and clinical conditions are known to alter triglyceride concentration *in vivo*. For additional information, refer to one of the published summaries.^{15,16}

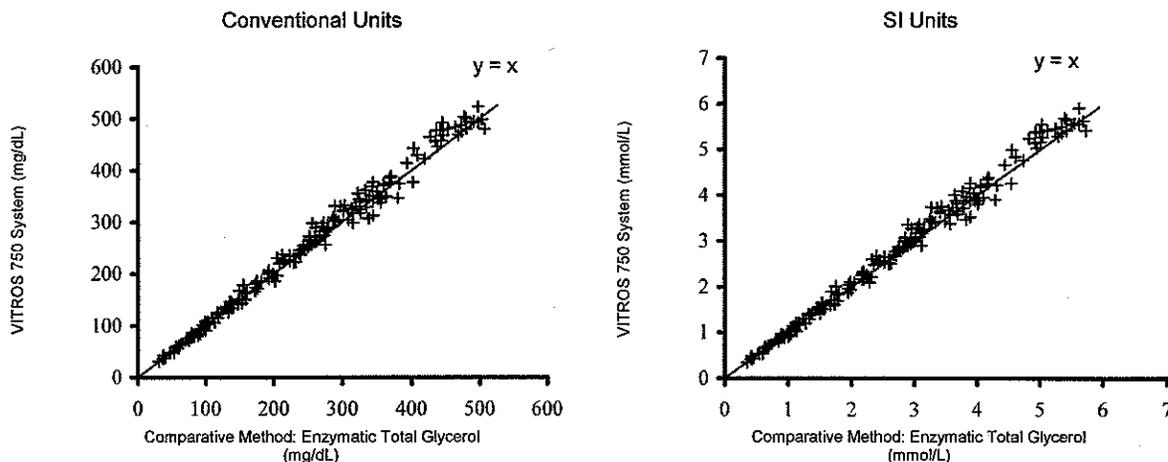
Performance Characteristics

Method Comparison

The plot and table show the results of a comparison of samples analyzed on the VITROS 750 System with those analyzed using the enzymatic total glycerol comparative method.¹¹ Testing followed NCCLS Protocol EP9.¹⁷

The table also shows the results of comparisons of the VITROS 250 and 950 Systems with the VITROS 750 System, and comparisons of the 5,1 FS System with the 950 System.

Method Comparison for TRIG: Serum



Method Comparison for TRIG: Serum

	n	Slope	Correlation Coefficient	Conventional Units (mg/dL)			SI Units (mmol/L)		
				Range of Sample Conc.	Intercept	Sy.x	Range of Sample Conc.	Intercept	Sy.x
750 System vs. comparative method	197	1.03	0.995	31–507	-1.09	13.09	0.35–5.72	-0.01	0.15
250 System vs. 750 System	77	1.02	1.000	41–520	-2.68	3.94	0.47–5.87	-0.03	0.04
950 System vs. 750 System	117	0.99	0.999	44–510	+2.07	2.36	0.50–5.76	+0.02	0.03
5,1 FS System vs. 950 System	128	0.98	0.999	48–495	+2.05	4.48	0.54–5.59	+0.02	0.05

Precision

Precision was evaluated with quality control materials on VITROS 250, 750, 950, and 5,1 FS Systems following NCCLS Protocol EP5.¹⁸

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

Precision for TRIG: Serum

System	Conventional Units (mg/dL)			SI Units (mmol/L)			Within Lab CV%**	No. Observ.	No. Days
	Mean Conc.	Within Day SD*	Within Lab SD**	Mean Conc.	Within Day SD*	Within Lab SD**			
VITROS 250	116	1.0	1.7	1.30	0.01	0.02	1.5	80	20
	225	2.0	3.6	2.54	0.02	0.04	1.6	80	20
VITROS 750	108	0.9	1.4	1.22	0.01	0.02	1.3	91	23
	189	1.4	2.7	2.13	0.02	0.03	1.4	92	23
	230	1.8	3.4	2.60	0.02	0.04	1.5	91	23
VITROS 950	110	0.8	1.6	1.24	0.01	0.02	1.4	85	23
	232	1.7	3.6	2.62	0.02	0.04	1.6	85	23
VITROS 5,1 FS	120	0.8	1.7	1.35	0.01	0.02	1.4	88	22
	249	1.2	2.2	2.81	0.01	0.03	0.9	89	22

* Within Day precision was determined using two runs/day with two to three replications.

** Within Lab precision was determined using a single lot of slides and calibrating weekly.

Specificity

Substances That Do Not Interfere

The substances listed in the table were tested with VITROS TRIG Slides and found not to interfere, bias <12 mg/dL (<0.14 mmol/L), at the concentration shown.

Substances That Do Not Interfere With TRIG

Compound	Concentration	
Acetaminophen	5 mg/dL	331 µmol/L
Acetylsalicylic acid	30 mg/dL	1665 µmol/L
Para-Aminosalicylic acid	23 mg/dL	1718 µmol/L
Ascorbic acid	3 mg/dL	170 µmol/L
Bilirubin	27 mg/dL	462 µmol/L
Cholesterol	500 mg/dL	12.9 mmol/L
Chlorothiazide	3 mg/dL	101 µmol/L
Dextran	1000 mg/dL	250 µmol/L
Ethanol	300 mg/dL	65 mmol/L
Gentisic acid	0.5 mg/dL	32 µmol/L
Glutathione	1 mg/dL	33 µmol/L
Hemoglobin	1000 mg/dL	10 g/L

Compound	Concentration	
Hypaque	500 mg/dL	8.2 mmol/L
Iodide	2 meq/L	2 meq/L
Isoniazid	0.4 mg/dL	29 µmol/L
Lactic acid	15 mg/dL	1665 µmol/L
L-dopa	0.6 mg/dL	30 µmol/L
6-Mercaptopurine	1.50 mg/dL	99 µmol/L
Phospholipids	400 mg/dL	4 g/L
Sulfathiazole	6 mg/dL	235 µmol/L
Total protein	10 g/dL	100 g/L
Tyrosine	24 mg/dL	1325 µmol/L
Urea nitrogen	100 mg/dL	36 mmol/L

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Glossary of Symbols

The following symbols may have been used in the labeling of this product.

	Do Not Reuse		Upper Limit of Temperature		This end up
	Use by or Expiration Date (Year-Month-Day)		Lower Limit of Temperature		SI Units
	Lot Number		Temperature Limitation		Conventional Units
	Serial Number		Consult Instructions for Use		Value
	Catalog Number or Product Code		Irritant		Range
	Attention: See Instructions for Use		Harmful		Range of Means
	Manufacturer		Toxic		Midpoint
	Authorized Representative in the European Community		Fragile, Handle with Care		Revised
	Contains Sufficient for "n" Tests		Keep Dry		Supersedes
	In vitro Diagnostic Medical Device		Der Grüne Punkt (the Green Dot). Manu- facturer follows certain packaging material waste disposal management regulations		Estimate within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
2006-01-09	5.0	<ul style="list-style-type: none"> Quality Control Material Preparation and Storage – added section
2005-03-31	4.0	<ul style="list-style-type: none"> Sample Dilution – added information about grossly lipemic samples Limitations of the Procedure – added information about grossly lipemic samples
2004-09-13	3.0	<ul style="list-style-type: none"> Added VITROS 5,1 FS Chemistry System Specimen Requirements, Special Precautions – wording update Specificity – updated Bilirubin, Hemoglobin Glossary of Symbols – updated data
2003-06-30	2.0	<ul style="list-style-type: none"> New organization and sections consistent with IVD Directive Sample Dilution and Limitations of the Procedure – Remove statements regarding grossly lipemic samples Reference Interval – minor correction References – added 3, 5, 10, 14
2002APR19	1.0 – English only	New format, technically equivalent to 2001OCT18.

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.	
<hr/> Signature	<hr/> Obsolete Date

TRIG

Triglyceride

INSTRUCTIONS FOR USE



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