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 phosphotungstic 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

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-glycerophosphate 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

- lipoproteins
  - surfactant
  - triglycerides + proteins
- triglycerides + H₂O
  - lipase
  - glycerol + fatty acids
- glycerol + ATP
  - glycerol kinase
  - MgCl₂
  - L-α-glycerophosphate + ADP
- L-α-glycerophosphate + O₂
  - L-α-glycerophosphate oxidase
  - dihydroxyacetone phosphate + H₂O₂
- H₂O₂ + leuco dye
  - peroxidase
  - dye + 2H₂O

Test Type and Conditions

<table>
<thead>
<tr>
<th>Test Type</th>
<th>VITROS System</th>
<th>Approximate Incubation Time</th>
<th>Temperature</th>
<th>Wavelength</th>
<th>Sample Drop Volume*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorimetric</td>
<td>5.1 FS, 950, 750, 550, 250</td>
<td>5 minutes</td>
<td>37°C (98.6°F)</td>
<td>540 nm</td>
<td>5.5 μL</td>
</tr>
</tbody>
</table>

* 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 μL 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 M292 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 0.02 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.

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

<table>
<thead>
<tr>
<th>Slide Cartridges</th>
<th>Storage Condition</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>Frozen</td>
<td>≤-18°C (≤0°F)</td>
</tr>
<tr>
<td>Opened</td>
<td>On-analyzer</td>
<td>System turned on</td>
</tr>
<tr>
<td></td>
<td>On-analyzer</td>
<td>System turned off</td>
</tr>
</tbody>
</table>

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

Specimens Not Recommended

- **Plasma:** EDTA

Serum and Plasma

**Specimen Collection and Preparation**
Collect specimens using standard laboratory procedures.  

**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.

**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.

**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°C–28°C (64°F–82°F), prior to analysis.

**Specimen Storage and Stability for TRIG: Serum and Plasma**

<table>
<thead>
<tr>
<th>Storage</th>
<th>Temperature</th>
<th>Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room temperature</td>
<td>18°C–28°C (64°F–82°F)</td>
<td>≤3 days</td>
</tr>
<tr>
<td>Refrigerated</td>
<td>2°C–8°C (36°F–46°F)</td>
<td>≤7 days</td>
</tr>
<tr>
<td>Frozen</td>
<td>≤-18°C (≤0°F)</td>
<td>≤6 months</td>
</tr>
</tbody>
</table>

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)
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 259 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**

<table>
<thead>
<tr>
<th>Conventional Units (mg/dL)</th>
<th>SI Units (mmol/L)</th>
<th>Alternate Units (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0–525.0</td>
<td>0.11–5.93</td>
<td>0.10–5.25</td>
</tr>
</tbody>
</table>

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. 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 method to support triglyceride value assignment for VITROS Calibrator Kit 2.

Quality Control

Procedure Recommendations

- 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 or other published guidelines.
- For additional information, refer to the operating instructions for your VITROS Chemistry System.

Quality Control Material Selection

- 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.

Reference Interval for TRIG

<table>
<thead>
<tr>
<th>Triglycerides Classification</th>
<th>Conv. Units (mg/dL)</th>
<th>SI Units (mmol/L)</th>
<th>Alternate Units (g/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;150</td>
<td>&lt;1.69</td>
<td>&lt;1.50</td>
</tr>
<tr>
<td>Borderline High</td>
<td>150–199</td>
<td>1.69–2.25</td>
<td>1.50–1.99</td>
</tr>
<tr>
<td>High</td>
<td>200–499</td>
<td>2.26–5.64</td>
<td>2.00–4.99</td>
</tr>
<tr>
<td>Very High</td>
<td>≥500</td>
<td>≥5.65</td>
<td>≥5.00</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Conventional Units</th>
<th>SI Units</th>
<th>Alternate Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/dL</td>
<td>mmol/L (mg/dL x 0.01129)</td>
<td>g/L (mg/dL x 0.01)</td>
</tr>
</tbody>
</table>
Limitations of the Procedure

Known Interferences
- Free glycerol:
  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 hyperlipidemia also produce elevated glycerol levels. Triglyceride results from samples of such patients will not reflect actual serum triglyceride content.
- Grossly hyper lipidemic samples show a slower rate of color development than do clear sera, 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. 

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. Testing followed NCCLS Protocol EP9.  
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

<table>
<thead>
<tr>
<th>System Comparison</th>
<th>n</th>
<th>Slope</th>
<th>Correlation Coefficient</th>
<th>Conventional Units (mg/dL) Range of Sample Conc.</th>
<th>SI Units (mmol/L) Range of Sample Conc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>750 System vs. comparative method</td>
<td>197</td>
<td>1.03</td>
<td>0.995</td>
<td>31–507</td>
<td>-1.09</td>
</tr>
<tr>
<td>250 System vs. 750 System</td>
<td>77</td>
<td>1.02</td>
<td>1.000</td>
<td>41–520</td>
<td>-2.88</td>
</tr>
<tr>
<td>950 System vs. 750 System</td>
<td>117</td>
<td>0.99</td>
<td>0.999</td>
<td>44–510</td>
<td>+2.07</td>
</tr>
<tr>
<td>5.1 FS System vs. 950 System</td>
<td>128</td>
<td>0.98</td>
<td>0.999</td>
<td>48–495</td>
<td>+2.05</td>
</tr>
</tbody>
</table>
Precision

Precision was evaluated with quality control materials on VITROS 250, 750, 950, and 5.1 FS Systems following NCCLS Protocol EP5.13 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

<table>
<thead>
<tr>
<th>System</th>
<th>Conventional Units (mg/dL)</th>
<th>SI Units (mmol/L)</th>
<th>Within Lab CV%**</th>
<th>No. Observ.</th>
<th>No. Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean Conc.</td>
<td>Within Day SD*</td>
<td>Within Lab SD**</td>
<td>Mean Conc.</td>
<td>Within Day SD*</td>
</tr>
<tr>
<td>VITROS 250</td>
<td>118</td>
<td>1.0</td>
<td>1.7</td>
<td>1.30</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>225</td>
<td>2.0</td>
<td>3.6</td>
<td>2.54</td>
<td>0.02</td>
</tr>
<tr>
<td>VITROS 750</td>
<td>108</td>
<td>0.9</td>
<td>1.4</td>
<td>1.22</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>189</td>
<td>1.4</td>
<td>2.7</td>
<td>2.13</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>232</td>
<td>1.8</td>
<td>3.4</td>
<td>2.60</td>
<td>0.02</td>
</tr>
<tr>
<td>VITROS 950</td>
<td>110</td>
<td>0.8</td>
<td>1.6</td>
<td>1.24</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>232</td>
<td>1.7</td>
<td>3.6</td>
<td>2.62</td>
<td>0.02</td>
</tr>
<tr>
<td>VITROS 5.1 FS</td>
<td>120</td>
<td>0.8</td>
<td>1.7</td>
<td>1.35</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>243</td>
<td>1.2</td>
<td>2.2</td>
<td>2.61</td>
<td>0.01</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>5 mg/dL</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>30 mg/dL</td>
</tr>
<tr>
<td>Para-Aminosalicylic acid</td>
<td>23 mg/dL</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>3 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>27 mg/dL</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Chlorothiazide</td>
<td>3 mg/dL</td>
</tr>
<tr>
<td>Dextran</td>
<td>1000 mg/dL</td>
</tr>
<tr>
<td>Ethanol</td>
<td>300 mg/dL</td>
</tr>
<tr>
<td>Gentisic acid</td>
<td>0.5 mg/dL</td>
</tr>
<tr>
<td>Glutathione</td>
<td>1 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 mg/dL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypaque</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Iodide</td>
<td>2 meq/L</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>0.4 mg/dL</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>15 mg/dL</td>
</tr>
<tr>
<td>L-Dopa</td>
<td>0.6 mg/dL</td>
</tr>
<tr>
<td>6-Mercaptopurine</td>
<td>1.50 mg/dL</td>
</tr>
<tr>
<td>Phospholipids</td>
<td>400 mg/dL</td>
</tr>
<tr>
<td>Sulfathiazole</td>
<td>6 mg/dL</td>
</tr>
<tr>
<td>Total protein</td>
<td>10 g/dL</td>
</tr>
<tr>
<td>Tyrosine</td>
<td>24 mg/dL</td>
</tr>
<tr>
<td>Urea nitrogen</td>
<td>100 mg/dL</td>
</tr>
</tbody>
</table>
References

8. NCEP. Recommendations for improving cholesterol measurement. A report from the Laboratory Standardization Panel of the National Cholesterol Education Program. NIH publication no. 90-2964:29–29; 1990.

Glossary of Symbols

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

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

<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Version</th>
<th>Description of Technical Changes*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-01-09</td>
<td>5.0</td>
<td>• Quality Control Material Preparation and Storage – added section</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Dilution – added information about grossly lipemic samples</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Limitations of the Procedure – added information about grossly lipemic samples</td>
</tr>
<tr>
<td>2004-09-13</td>
<td>3.0</td>
<td>• Added VITROS 5,1 FS Chemistry System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specimen Requirements, Special Precautions – wording update</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity – updated Bilirubin, Hemoglobin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Glossary of Symbols – updated data</td>
</tr>
<tr>
<td>2003-06-30</td>
<td>2.0</td>
<td>• New organization and sections consistent with IVD Directive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sample Dilution and Limitations of the Procedure – Remove statements regarding grossly lipemic samples</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reference Interval – minor correction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• References – added 3, 5, 10, 14</td>
</tr>
<tr>
<td>2002APR19</td>
<td>1.0 – English only</td>
<td>New format, technically equivalent to 2001OCT18.</td>
</tr>
</tbody>
</table>

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

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When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

______________________________   ________________
Signature                          Obsolete Date