Cancer Antigen CA 19-9

**Principle of the Test**

The ADVIA Centaur® CA 19-9 assay is a two-step sandwich immunoassay using direct chemiluminometric technology which uses a single monoclonal antibody, 1116-NS-19-9, for both the Solid Phase and Lite Reagent. The antibody is covalently coupled to paramagnetic particles in the Solid Phase and the same clone of antibody is labeled with acridinium ester in the Lite Reagent. The sample and Solid Phase are incubated at 37°C for 7.5 minutes followed by a wash step to remove excess unbound antigens. The Lite Reagent is then reacted with the Solid Phase-bound CA 19-9 antigens for an additional 20-minute incubation. Therefore, the high-dose hook effect is eliminated in this assay.

The system automatically performs the following steps:

- dispenses 75 μL of sample into a cuvette
- dispenses 350 μL of Solid Phase and incubates for 7.5 minutes at 37°C
- aspirates, and washes the cuvettes with Wash 1
- resuspends in 100 μL of reagent water
- dispenses 100 μL of Lite Reagent and incubates for 20 minutes at 37°C
- aspirates, and washes the cuvettes with Wash 1 and then with reagent water
- dispenses 300 μL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction
- reports results according to the selected option, as described in the system operating instructions or in the online help system

A direct relationship exists between the concentration of CA 19-9 present in a patient sample and the amount of relative light units (RLUs) detected by the system.

**Clinical Application and Usefulness**

The ADVIA Centaur CA 19-9 Assay is an *in vitro* immunoassay for the quantitative measurement of the CA 19-9 tumor-associated antigen, in human serum, using the ADVIA Centaur System. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

**WARNING:** The concentration of CA 19-9 in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported
by the laboratory to the physician must include the identity of the assay for CA 19-9 used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining serial levels of CA 19-9 is changed, the laboratory must perform additional serial testing to confirm baseline values. The ADVIA Centaur CA 19-9 assay is based on the 1116-NS-19-9 antibody available through agreement with Fujirebio Diagnostics®, Inc. Assays using antibodies other than 1116-NS-19-9 may give different results.

Patients must possess the ability to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen even in the presence of proven malignancy. A patient with a positive genotype for the Lewis antigen may produce varying levels of CA 19-9. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals.

United States federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by, or on the order of a physician.

The ADVIA Centaur CA 19-9 assay is not intended for use on any other system.

**Specimen Collection and Handling**

### Specimen Collection

**BIOHAZARD**

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

- Serum is the recommended sample type for this assay. Gold Top Vacutainer (with SST) is preferred collection tube.
- This assay requires 75 μL of sample for a single determination. Additional volume is required for onboard dilutions. Note: the dead space using the 13x100 mm false bottom tubes is 50 uL.
- Allow samples to clot adequately before centrifugation.
- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

### Specimen Storage and Stability

- Keep tubes covered and upright at all times.
- Do not use samples that have been stored at room temperature for longer than 8 hours.
- Tightly cover and refrigerate specimens at 2 to 8°C if the assay is not completed within 8 hours.
- Freeze samples at or below -20°C if the sample is not assayed within 48 hours.
- Freeze samples only once and mix thoroughly after thawing.
Reagents

Storage and Stability
• Store the reagents upright at 2–8 °C.
• Primary reagents stable until the expiration date on the pack label, or for 28 days onboard the system.
• Wash stable until the expiration date on the bottle label, or for 14 days onboard the system.
• Diluent stable until the expiration date on the pack label, or for 14 consecutive days after accessing the ancillary reagent pack.

CAUTION:
• Discard the primary reagent packs at the end of the onboard stability interval.
• Do not use reagents beyond the expiration date.

Ingredients
Reagent ingredients for the ADVIA Centaur CA 19-9 assay are as follows:

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Volume</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lite Reagent</td>
<td>5.0 mL/ReadyPack</td>
<td>monoclonal mouse anti- CA 19-9 antibody (~0.4 µg/mL) labeled with acridinium ester in buffer with protein stabilizers, sodium azide (&lt; 0.1%), and preservatives</td>
</tr>
<tr>
<td>Solid Phase</td>
<td>17.5 mL/ReadyPack</td>
<td>monoclonal mouse anti- CA 19-9 antibody (~0.02 mg/mL) covalently coupled to paramagnetic particles in buffer with protein stabilizers, sodium azide (&lt; 0.1%), and preservatives</td>
</tr>
<tr>
<td>Wash 1</td>
<td>1500 mL/bottle</td>
<td>phosphate buffered saline with sodium azide (&lt; 0.1%) and surfactant</td>
</tr>
<tr>
<td>CA 19-9 Diluent</td>
<td>5.0 mL/ReadyPack</td>
<td>fetal bovine serum with buffer, sodium azide (&lt; 0.1%), and preservatives</td>
</tr>
</tbody>
</table>

WARNING: Sodium azide can react with copper and lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides, if disposal into a drain is in compliance with federal, state, and local requirements.

BIOHAZARD
All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.
**Reagents Special Preparation**

No special preparation of reagents is required.

**Calibration**

For detailed procedural information about scheduling a calibration, refer to the ADVIA Centaur Reference Manual or to the online help system.

**Two-point Calibration Interval**

Use Calibrator 9 to perform two-point calibrations.

Perform a two-point calibration every 28 days. Additionally, calibrate when the following conditions occur:

- the lot numbers of the primary reagent packs have changed
- system components are repaired or replaced
- quality control results do not fall within established ranges

**Defining Calibrator Values for Two-point Calibration**

1. At the workspace, select **Calibration**.
2. Select **Calibrator Definition**.
3. Select **Scan Data**.
4. Scan the barcodes on the Calibrator Assigned Value Card.
5. Define the LIS field.
6. Review the values on the Calibrator Assigned Value card to ensure that they are correct. Scan again, if required.
7. Select **Save**.

**Master Curve**

Use the barcode reader to enter the Master Curve values from the Master Curve card onto the system. Ensure that the lot number on the Master Curve matches the lot number of the ReadyPack.

**Defining the Master Curve Using the Barcode Scanner**

1. At the workspace, select **Calibration**.
2. Select **Master Curve Definition**.
3. At the Calibration-Master Curve Definition window, select **Scan Data**.
4. Scan the barcodes on the CA 19-9 Master Curve Card.

5. Select Save.

Quality Control (QC)

BioRad Lyphochek Tumor Marker Control, Levels 1 and 2.

Using a Volumetric pipet, reconstitute each vial of control with 2.0 mL of Reagent water.
Allow the controls to stand at room temperature for approximately 15 minutes, swirling occasionally.
After reconstitution, the controls are frozen in 0.4 mL aliquots. The frozen aliquots are stable for 30 days at -20ºC.
See posted QC chart for acceptability limits.

QC Frequency

Analyze all levels of quality control material on each day that samples are analyzed.
Analyze all levels of quality control material each time a two-point calibration is performed.

Troubleshooting Out-of-Range QC Values

A QC run is acceptable when all values fall within the expected ranges.
If the CA 19-9 QC results do not fall within the defined ranges then the run is rejected, and you must take the following corrective action:

• review these instructions to ensure that the assay was performed according to the procedures recommended by Bayer HealthCare
• verify that the materials are not expired
• verify that required maintenance was performed
• if necessary, recalibrate the system and then rerun the quality control samples or contact Bayer HealthCare for more assistance

Instrument Operation and System Description

The ADVIA Centaur system is an automated, random access, direct chemiluminescent immunoassay analyzer that offers no-pause reloading of reagents, samples, and supplies. Comprehensive assay groups are available.

When the sample start button is pressed, the barcode labels on the sample cups are read, sample is aspirated, reagent is dispensed, and the assay process begins. Paramagnetic particles are magnetically separated in the cuvette incubation ring. The addition of hydroxyl groups to complete the flash reaction is accomplished by the addition of Acid and Base. The chemiluminescent reaction occurs in the luminometer. The PMT measures the chemical light reaction that takes place.

Refer to Section 4 in the ADVIA Centaur Reference Manual for detailed procedures that describe how to schedule samples and manage the worklist.
A. System Start Button
There is one (1) main system operation button on the ADVIA Centaur, the Start button. Pressing this button performs the following actions:

• Homes the subsystems.
• Starts specimen sampling.
• If the Start button is pressed while the system is processing samples, it stops sampling additional specimens, however it continues to process the specimens in the incubation ring.

B. Start-up
1. Put the samples racks on the sample entry queue.
2. Press the Start button.

C. Verify Supplies:
While the system is running, you can manage the following supplies without interrupting the run.
• Reagent water supply
• Liquid waste container
• Acid and Base reagents
• Cuvette waste bin
• Sample tip waste bin and tip tray waste area
• Cuvette supply
• Sample tip supply
• Ancillary reagent packs
• Primary reagent packs

D. Scheduling a Run/Entering a Worklist
You can enter a worklist by different methods:

Automated Worklist
You can send the worklist to the ADVIA Centaur from a Lab Information System (LIS). This is done in a unidirectional manner (Dynamic Download) or in a bi-directional manner (Host Query).

Manual (Operator-initiated) Worklist

Scheduling Calibrators
1. At the workspace, select Worklist and then select Schedule.
2. Select the Calibrator box.

3. Select the test you want to schedule for calibration.

4. The reagent lot that is on the system and any defined calibrators are displayed. Select the appropriate reagent and calibrator lot combination.

5. Select Save.

6. Ensure that the lot numbers of reagent and calibrator are available for system use.

**Scheduling Controls**

1. At the workspace, select Worklist and then select Schedule.

2. Select the Control box.

3. Select each test you would like to schedule.

4. Select each control level and lot number you need to run.

5. Select Save.

**Scheduling Patient Samples**

1. At the workspace, select Worklist and then select Schedule.

2. Select the Patient box.

3. Enter a patient sample identification number (SID).

4. Press the Enter key.

5. Select each test, profile, dilution, and/or replicates needed.

6. Select Save.

For detailed operating procedural information, refer to the ADVIA Centaur Reference Manual or to the online help system.

**E. Loading Sample Racks**

**BIOHAZARD**

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

**CAUTION:** Do not load more than one size of sample container in each rack. The rack indicator must be positioned at the correct setting for the size of sample container.

- Gently mix the calibrators and quality controls before dispensing into the sample cups.
• Load the sample cups containing the calibrators, controls, or patient specimen into any Centaur rack.
• Load racks onto the sample entry queue.
• Press the Start button.

F. Loading Ancillary Reagents
Place the ancillary reagent pack on the ancillary entry queue until the green light comes on. The ADVIA Centaur moves the pack into the ancillary queue.

G. Loading Primary Reagents
**CAUTION:** Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. For detailed information about preparing reagents for use, refer to Appendix C, *Handling Reagents*, in your ADVIA Centaur Assay Manual.

1. Gently mix the CA 19-9 ReadyPack before placing it on the reagent shelf for the first time.
2. Load the CA 19-9 ReadyPack by matching the color on the pack to the color-coded reagent shelf.
3. Close the reagent compartment door.

H. Loading STAT Samples in the STAT Entry Queue
1. Press the Start button, if the green Start light is not lit.
2. Place the STAT sample tube or sample cup in the rack.
3. Load the rack in the STAT entry queue until the green STAT light comes on, indicating the system has accepted the rack.

**Performance Characteristics**

**Precision**

Five samples were assayed 4 times with two separate lots of reagents, in 2 runs per day, on 2 systems, over a period of 10 days (n = 180 for each sample per reagent lot). The total %CV had a range of 5.5 to 14.5%. The within-run %CV was under 11.3% for all samples. The following results were obtained:
Specificity

There are no known cross-reactants for CA 19-9.
The potential interference of chemotherapeutic agents, therapeutic drugs, and other tumor marker antigens was tested by adding these substances to serum pools containing CA 19-9 ranging from 38.4 to 235 U/mL. The level of CA 19-9 in each of these pools was then determined and normalized to the level without the respective drugs or antigens.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Amount Added</th>
<th>Mean % Recovery (Spike/control x 100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinoembryonic antigen (CEA)</td>
<td>1 µg/mL</td>
<td>101.7</td>
</tr>
<tr>
<td>PSA</td>
<td>100 ng/mL</td>
<td>98.2</td>
</tr>
<tr>
<td>CA 15-3</td>
<td>100 U/mL</td>
<td>103.2</td>
</tr>
<tr>
<td>CA 125</td>
<td>1000 U/mL</td>
<td>105.2</td>
</tr>
<tr>
<td>Serum alpha-fetoprotein (AFP)</td>
<td>300 ng/mL</td>
<td>98.5</td>
</tr>
<tr>
<td>Rheumatoid factor 1</td>
<td>29 U/mL</td>
<td>98.9</td>
</tr>
<tr>
<td>Rheumatoid factor 2</td>
<td>29 U/mL</td>
<td>95.7</td>
</tr>
<tr>
<td>Rheumatoid factor 3</td>
<td>129 U/mL</td>
<td>102.3</td>
</tr>
<tr>
<td>HAMA</td>
<td>1.70E-03 mg/mL</td>
<td>96.2</td>
</tr>
<tr>
<td>5-fluorouracil / Adrucil</td>
<td>1 mg/mL</td>
<td>100.8</td>
</tr>
<tr>
<td>Acetaminophen / Tylenol</td>
<td>0.2 mg/mL</td>
<td>99.4</td>
</tr>
<tr>
<td>Acetylsalicylic acid / aspirin</td>
<td>0.5 mg/mL</td>
<td>99.1</td>
</tr>
<tr>
<td>Adriamycin / Doxorubicin-HCL</td>
<td>0.1 mg/mL</td>
<td>101.5</td>
</tr>
<tr>
<td>Methotrexate-hydrate. Methotrexate</td>
<td>4.5 mg/mL</td>
<td>108.0</td>
</tr>
<tr>
<td>Amikacin / Amikin-sulfate salt</td>
<td>0.15 mg/mL</td>
<td>100.6</td>
</tr>
<tr>
<td>Caffeine</td>
<td>0.1 mg/mL</td>
<td>99.2</td>
</tr>
<tr>
<td>cisplatin-dichloride</td>
<td>1 mg/mL</td>
<td>99.2</td>
</tr>
<tr>
<td>Cortisol / hydrocortisone disodium salt</td>
<td>1 mg/mL</td>
<td>98.3</td>
</tr>
<tr>
<td>Coumarin / 3-(a-acetonybenzyl)-4-hydroxybenzamid / sodium salt</td>
<td>0.14 mg/mL</td>
<td>100.1</td>
</tr>
<tr>
<td>Cyclophosphamide / Cytoxan</td>
<td>0.25 mg/mL</td>
<td>101.9</td>
</tr>
<tr>
<td>Cyclosporin A</td>
<td>2.97E-05 mg/mL</td>
<td>103.3</td>
</tr>
<tr>
<td>Digoxin</td>
<td>5.00E-05 mg/mL</td>
<td>100.7</td>
</tr>
<tr>
<td>Gentamicin-sulfate</td>
<td>0.12 mg/mL</td>
<td>105.0</td>
</tr>
<tr>
<td>Heparin</td>
<td>500 U/mL</td>
<td>101.7</td>
</tr>
</tbody>
</table>
**Analytical Sensitivity**

The ADVIA Centaur CA 19-9 assay has an analytical sensitivity of 1.2 U/mL.

Analytical sensitivity is defined as the concentration of CA 19-9 that corresponds to the RLU's that are two standard deviations more than the mean RLU's of replicate determinations of the CA 19-9 zero standard. This response is an estimate of the minimum detectable concentration with 95% confidence.

**Analytical Measuring Range (AMR)**

The analytical measuring range of the ADVIA Centaur CA 19-9 assay is 1.2 to 700 U/mL.

**Reporting Results**

**Reportable Range**

Values below 2 U/mL are reported as <2 U/mL. Values above 700 U/mL are run on dilution until an answer is achieved.

**Dilutions**

- Serum samples with levels of CA 19-9 greater than 700 U/mL must be diluted and retested to obtain accurate results.
- Patient samples can be automatically diluted by the system or prepared manually.
- The Centaur is programmed to rerun samples that exceed 700 U/mL on a 1:100 instrument performed dilution. You will need to place the sample rack back onto the loading queue and press start (unless green light is on). Note: the Centaur will report a value that has already been corrected for the dilution.
- If the 1:100 dilution is not high enough, order a 1:200 onboard dilution. Note: the Centaur will report a value that has already been corrected for the dilution.
- If the 1:200 dilution is not high enough, then manually perform a dilution using CA 19-9 diluent until an answer is achieved. **Important**: you will need to mathematically correct for the manual dilution you performed to report out the diluted result.
- For automatic dilutions, ensure that ADVIA Centaur CA 19-9 Diluent is loaded and set the system parameters as follows:
  - Dilution point: ≤ 1000 U/mL
  - Dilution factor: 10, 100, 200
For detailed information about automatic dilutions, refer to the system operating instructions or to the online help system.

**UCSF Clinical Labs Reference Interval**

less than 36 U/mL.

**Units for Reporting Results**

The system reports serum CA 19-9 results in U/mL. Units are user-defined in the system software.

**Expected Results**

To establish the performance characteristics of the ADVIA Centaur CA 19-9 assay, serum samples from 427 apparently healthy subjects, comprised of 203 females and 224 males, were tested. The Upper Limit of Normal (ULN) for this group, defined as the 97.5th percentile of the observed results, was 35 U/mL. Additional data were generated on the patient populations as shown below. These data show the percent of samples whose levels of CA 19-9 are elevated above the ULN.

<table>
<thead>
<tr>
<th>Sample Category</th>
<th>N</th>
<th>Median (U/mL)</th>
<th>Mean (U/mL)</th>
<th>% &gt; ULN</th>
<th>Range (U/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Benign Diseases</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI Tract</td>
<td>99</td>
<td>11.0</td>
<td>13.8</td>
<td>4.0</td>
<td>4.5 – 51.8</td>
</tr>
<tr>
<td>Pancreas</td>
<td>100</td>
<td>13.9</td>
<td>16.7</td>
<td>8.0</td>
<td>3.9 – 50.6</td>
</tr>
<tr>
<td>Chronic Heart Disease/Hypertension</td>
<td>100</td>
<td>10.4</td>
<td>12.5</td>
<td>5.0</td>
<td>3.6 – 38.8</td>
</tr>
<tr>
<td>Urogenital Tract</td>
<td>132</td>
<td>11.4</td>
<td>13.8</td>
<td>4.5</td>
<td>3.1 – 48.1</td>
</tr>
<tr>
<td><strong>Malignant Diseases (Treated)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung/Liver</td>
<td>89</td>
<td>15.1</td>
<td>204.9</td>
<td>25.8</td>
<td>4.4 – 14618</td>
</tr>
<tr>
<td>Breast/Ovarian/Cervical</td>
<td>87</td>
<td>14.8</td>
<td>53.6</td>
<td>25.3</td>
<td>3.5 – 883.3</td>
</tr>
<tr>
<td>Gall Bladder/Biliary</td>
<td>41</td>
<td>169.3</td>
<td>1681.8</td>
<td>61.0</td>
<td>4.1 – 23333</td>
</tr>
<tr>
<td>Pancreatic</td>
<td>31</td>
<td>145.6</td>
<td>3466.8</td>
<td>67.7</td>
<td>5.9 – 56240</td>
</tr>
<tr>
<td>Colorectal</td>
<td>183</td>
<td>22.5</td>
<td>395.8</td>
<td>44.3</td>
<td>2.6 – 20.049</td>
</tr>
<tr>
<td>Other</td>
<td>43</td>
<td>9.2</td>
<td>18.7</td>
<td>9.3</td>
<td>3.5 – 209.6</td>
</tr>
</tbody>
</table>

As with all diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results. The clinical utility of ADVIA Centaur CA 19-9 Assay in monitoring the disease status in those patients having confirmed pancreatic cancer was evaluated using retrospective serum samples. CA 19-9 values were measured in 59 patients with histologically confirmed pancreatic cancer. The median total time in the study was 309 days (10 months). These results were separated into groups that either demonstrated CA 19-9 values that paralleled the clinical course of disease, or CA 19-9 values that did not parallel the clinical course of disease. Serial measurements were
analyzed on a per-patient basis as well as visit-to-visit basis. For each pair of serial measurements, an increase of greater than 15% on the ADVIA Centaur CA 19-9 was considered to indicate progression, and an increase of less than or equal to 15% was considered to indicate a lack of progression. The following two tables show the overall correspondence of the serial CA 19-9 change with changes in clinical status.

**Procedure Notes**

**Calculations**
For detailed information about how the system calculates results, refer to the ADVIA Centaur Reference Manual or to the online help system.

**High Dose Hook Effect**
In the ADVIA Centaur CA 19-9 assay, patient samples with levels of CA 19-9 as high as 5,800,000 U/mL do not demonstrate a paradoxical decrease in the relative light units (RLUs).

**Interchangeability of Assay Values**
The concentration of CA 19-9 in a given specimen can vary due to differences in assay methods and reagent specificity. Do not use values obtained with different CA 19-9 assay methods interchangeably.

**Disposal**
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 all federal, state, and local requirements.

**Method Limitations**

**NOTE:** Do not interpret serum levels of CA 19-9 as absolute evidence of the presence or the absence of malignant disease. Before treatment, patients with confirmed carcinoma frequently have levels of CA 19-9 within the range observed in healthy individuals. Furthermore, patients known to be genetically negative for the Lewis blood group antigens will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotype positive for the Lewis antigen may produce varying levels of CA 19-9 as the result of gene dosage effect. Additionally, elevated levels of CA 19-9 can be observed in patients with nonmalignant diseases. Measurements of CA 19-9 should always be used in conjunction with other diagnostic procedures, including information from the patient’s clinical evaluation.

**WARNING:** This device is not indicated for screening or the early detection of pancreatic cancer or as a diagnostic tool to confirm the presence or absence of malignant pancreatic disease. Do not predict disease recurrence solely on levels of ADVIA Centaur CA 19-9. Normal levels of ADVIA Centaur CA 19-9 do not always preclude the presence of disease.
The concentration of CA 19-9 in a given specimen determined with assays from different manufacturers can vary because of differences in assay methods, calibration, and reagent specificity. CA 19-9 determined with different manufacturers’ assays will vary depending on the method of standardization and antibody specificity. Therefore, it is important to use assay-specific values to evaluate quality control results.

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with \textit{in vitro} immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

Endogenous interfering substances, such as high concentrations of hemoglobin, triglycerides, protein (human serum albumin) and bilirubin, have no effect beyond the limits of random within-run variations. Recoveries were within 10\% of the control level for all interfering substances tested.

\begin{tabular}{|l|l|}
\hline
\textbf{Serum specimens that are . . .} & \textbf{Demonstrate \(\leq 10.0\%\) change in results up to . . .} \\
\hline
Hemolyzed & 1200 mg/dL of hemoglobin \\
Lipemic & 3500 mg/dL of triglycerides \\
Icteric & 60 mg/dL of bilirubin \\
Proteinemic & 14 g/dL of protein \\
\hline
\end{tabular}

If there is an interferant (hemolysis, lipemia and icterus), run the sample undiluted and send the corresponding ETC Code:

- TUR “Specimen turbid, result may be invalid”
- ICTRQ “Specimen icteric, result may be invalid”
- HEMRQ “Specimen hemolyzed, result may be invalid”

For additional information on performance characteristics including cross reactivity and dilution recovery, see the product information in the ADVIA Centaur Assay Manual.

\textbf{Equipment and Supplies}

- ADVIA Centaur CA 19-9 ReadyPack
- ADVIA Centaur Calibrator 9
- ADVIA Centaur Wash 1
- ADVIA Centaur CA 19-9 Diluent
- ADVIA Centaur Sample Cups and Caps
- ADVIA Centaur Cuvettes
- ADVIA Centaur Tips
• ADVIA Centaur Cleaning Solution Concentrate
• ADVIA Centaur Acid Reagent (0.5% H$_2$O$_2$, 0.1N HNO$_3$)
• ADVIA Centaur Base Reagent (0.25N NaOH and surfactant)
• Reagent Water

References
1. Bayer HealthCare ADVIA Centaur CA 19-9 product insert, Revision E.
2. Bayer Diagnostics ADVIA Centaur Reference Manual, Revision D.

Technical Assistance
Bayer HealthCare Technical Care Center: 1-877-229-3711
Customer Service: 1-800-255-3232
Serial Number: IRL80600727
Customer Account Number: 139214