GammaCoeur™ ELISA

IUO

REF GCEK001

INTENDED USE

The gamma-prime Fibrinogen ELISA Test System is intended to be used as part of a risk assessment in adults suspected of/at risk for cardiovascular disease (CVD), for example, adults with hypertension, increased BMI, diabetes, history of smoking, or family history of CVD. It is a quantitative ELISA assay intended to measure the amount of Gamma-prime fibrinogen in human plasma samples and is for investigational use only.

SIGNIFICANCE AND BACKGROUND

Fibrinogen is a heterogeneous mixture of isoforms with varying relative proportions. Alternative mRNA processing and posttranslational modifications give rise to several different fibrinogen isoforms with widely varying characteristics. In addition, because fibrinogen is a 6-chain molecule containing 2 copies each of the Aα, Bβ, and γ chains, various combinations of altered chains can be assembled, particularly in fibrinogens resulting from heterozygous polymorphisms or mutations. The fibrinogen γ chain has 2 isoforms, the gamma A (γA or simply γ) isoform and the gamma-prime (or γB) isoform. The gamma-prime isoform arises from alternative mRNA processing that results in the substitution of the carboxyl terminal 4 amino acids with a different 20-amino acid sequence. The gamma-prime chain is usually paired with the more common γA chain. Gamma-prime fibrinogen typically constitutes approximately 7% of total fibrinogen in plasma, although this percentage can vary among individuals.

Gamma-prime fibrinogen has several biochemical and biophysical properties that distinguish it from the more common γA isoform. Clots made from fibrinogen containing gamma-prime chains in the presence of factor XIII are highly resistant to fibrinolysis. In addition, the gamma-prime chain contains a binding site for thrombin, and clots made from gamma-prime fibrinogen have been reported to have an altered clot architecture.

Possibly as a result of these properties, recent studies suggest that gamma-prime fibrinogen is a risk factor for cardiovascular disease (1) (2) (3). An association has been found between gamma-prime fibrinogen concentrations and prevalent coronary artery disease (4), myocardial infarction (5), stroke (3), and inflammation (6).

PRINCIPLE OF THE ASSAY

The GammaCoeur™ assay is a two-site sandwich immunoassay that measures the gamma-prime fibrinogen isoform in human plasma samples. Gamma-prime fibrinogen in the sample binds to a monoclonal capture antibody coated on the assay plate microwells. After incubation, excess sample (including unbound *non*-gamma-prime fibrinogen [i.e. gammaA/gammaA fibrinogen] and other plasma components) are removed by washing. Enzyme-labeled polyclonal anti-fibrinogen detection antibody is added, which binds to the captured gamma-prime fibrinogen, forming a "capture antibody/analyte/detection antibody" sandwich. After another incubation, excess detection antibody is removed by washing. Finally, a substrate for the enzyme-labeled detector is added to generate a colored product. After a last incubation, a stop solution is added to each well and the absorbance of the colored end-product is read on a spectrophotometer. The amount of colored reaction product formed is proportional to the amount of enzyme-labeled antibody bound to analyte, which is in turn proportional to the amount of gamma-prime fibrinogen present in the sample. All reagents required are provided in the GammaCoeur Test Kit.

TEST SYSTEM COMPONENTS

Materials Provided:

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on the packaging label.

PLATE		1. Plate: 96 wells configured in twelve, 1 x 8-well, strips coated with mouse anti-human gamma-prime fibrinogen monoclonal antibody (2.G2.H9–15ng/well), blocked and dried. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
DETEC		2. Detector Concentrate: 1000X HRP-labeled anti-human fibrinogen detection antibody (goat polyclonal). 100uL in a 0.5mL screw cap tube.
DIL	DETEC	3. Detector Diluent. One 15ml bottle for diluting concentrated HRP-detector
CONTROL	I	4. Control I: (Approximately 25 – 40 mg/dL of gamma-prime fibrinogen in Human Plasma): One **green**-capped vial containing four lyophilized pellets.
CONTROL	II	5. Control II: (Approximately 40 – 60 mg/dL of gamma- prime fibrinogen in Human Plasma): One **red**-capped vial containing four lyophilized pellets.
CAL	A	6. Calibrator A: 0 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **white**-capped vial containing one lyophilized pellet.
CAL	B	7. Calibrator B: 10 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **yellow**-capped vial containing one lyophilized pellet.
CAL	C	8. Calibrator C: 20 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **orange**-capped vial containing one lyophilized pellet.
CAL	D	9. Calibrator D: 30 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **blue**-capped vial containing one lyophilized pellet.
CAL	E	10. Calibrator E: 40 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **clear**-capped vial containing one lyophilized pellet.
CAL	F	11. Calibrator F: 80 mg/dL (purified gamma-prime fibrinogen in calibrator diluent): One **purple**-capped vial containing one lyophilized pellet.
DIL	SPE	12. Analyte Diluent (HEPES [pH 7.4 ± 0.2], BSA, Tween-20, 0.05% Proclin 300). One 100ml bottle. Ready to use
SOLN	TMB	13. TMB: One, 15mL, amber-capped, amber bottle containing 3, 3', 5, 5' - tetramethylbenzidine (TMB). Ready to use.
SOLN	STOP	14. Stop Solution: One, 15mL, red-capped, bottle containing 1M H_2SO_4, 0.7M HCl. Ready to use.
WASHBUF	10X	15. Wash Buffer Concentrate (10X): Dilute 1 part concentrate + 9 parts deionized or distilled water. One, 100mL, clear-capped, bottle containing a 10X concentrated phosphate-buffered-saline and Tween-20 solution. **NOTE: 1X solution will have a pH of 7.2 ± 0.2.**

NOTES:

1. **The assay calibrators and controls are provided in a sealed foil pouch. Open the foil pouch on the day of use.**
2. **The Stop Solution, TMB Substrate and Wash Buffer are not test system/lot number dependent and may be used interchangeably with any of the ZEUS ELISA™ Test Systems.**
3. **Test System also contains:**
   a. **Component Label containing lot specific information inside the Test System box.**
   b. **Package Insert providing instructions for use.**

PRECAUTIONS

1. For investigational diagnostic use only.

2. Normal precautions for handling laboratory reagents should be followed.
   a. If contact with eyes occurs, rinse eyes immediately with plenty of water and seek medical advice.
   b. Wear suitable protective clothing, gloves, and eye/face protection.
   c. Do not breathe vapors.
   d. Dispose of waste observing all local, state, and federal laws.
3. The wells of the coated plates/strips should be considered **potentially biohazardous materials** and should be handled accordingly.
4. Human plasma controls are **potentially biohazardous materials** and should be handled accordingly. According to their manufacturers, source materials used to prepare the controls were tested and found negative for HIV-1 antigen, HBsAg, and for antibodies against HCV and HIV by approved test methods. However, no test can offer complete assurance that infectious agents are absent. Handle these products at Biosafety Level 2 as recommended for any potentially infectious human blood or plasma specimen in the NIH manual "Biosafety in Microbiological and Biomedical Laboratories" (7), and in accordance with OSHA's Bloodborne Pathogens rules (8).
5. Adherence to specified incubation times and temperatures is essential for accurate results. **All reagents, including microwell plates/strips must be at room temperature (20-25°C) before use**. Return any unused reagents to refrigerated conditions immediately after use.
6. Improper washing could cause falsely low or high assay results. Be sure to minimize the amount of residual wash solution (by blotting or by aspiration) before adding Analyte, Conjugate or Substrate. Do no allow wells to dry out between incubations.
7. The Sample Diluent contains sodium azide at a concentration of 0.1% (v/v). Sodium azide has been reported to form lead or copper azides in laboratory plumbing, which may cause explosions. To prevent, rinse sink thoroughly with water after disposing of solutions containing sodium azide.
8. The Stop Solution is TOXIC. Causes burns. Toxic by inhalation, in contact with skin and if swallowed. In case of accident or if you feel unwell, seek medical advice immediately.
9. The Chromogen solution is HARMFUL. Irritating to eyes, respiratory system and skin.
10. The Wash Buffer is an IRRITANT. Irritating to eyes, respiratory system and skin.
11. Wipe bottom of plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may give erroneous assay results.
13. Reagents from other sources or manufacturers should not be used.
14. Chromogen Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of Chromogen with conjugate or other oxidants will cause the solution to change color prematurely. Do not use the Chromogen if it is noticeably blue in color.
15. Never pipette samples or reagents by mouth. Avoid contact of reagents with skin and mucous membranes.
16. Microbial contamination or cross-contamination of reagents could cause erroneous results.
17. Cross contamination of reagents and/or samples could cause erroneous assay result.
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing of reagents or generating aerosols.
20. Do not expose reagents to strong light during storage or incubation.
21. Allowing the microwell plates/strips to come to room temperature before opening the protective packaging will protect wells from condensation.
22. Wash solution should be collected in a disposal basin. Treat the waste solution with 10% household bleach (0.5% sodium hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Liquid waste at acid pH should be neutralized before adding to bleach solution.
24. **DO NOT USE** a plate/strips if the desiccant strip on the package has turned from blue to pink.
25. Do not allow the conjugate to come in contact with containers or instruments that may have previously contained a solution using sodium azide as a preservative. Residual amounts of sodium azide may destroy the conjugate's enzymatic activity.
26. Do not expose any of the active reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the active reagents in this kit.
27. It has been reported that blood samples from individuals who have undergone therapy or diagnostic procedures that include administration of mouse monoclonal antibodies may produce erroneous results in immunoassays using mouse antibodies. These individuals have developed antibodies to mouse protein (HAMA, heterophilic anti-mouse antibodies), and the HAMA interfere with the antigen-antibody reaction in the immunoassay. Although the GammaCoeur assay contains non-specific mouse IgG to minimize these effects, results from the GammaCoeur assay for such patients should be used in conjunction with results from another diagnostic procedure and with the patient's clinical history and evaluation.

MATERIALS REQUIRED BUT NOT PROVIDED

1. ELISA microwell reader capable of reading at a wavelength of 450nm.
2. Software capable of computing results using a 4-parameter logistic curve-fitting equation
3. Polypropylene micro dilution tubes (1.5mL).
4. Pipettes capable of accurately delivering 5 – 200µL.
5. Multichannel pipette capable of accurately delivering 50 – 200µL.
6. Reagent reservoirs for multichannel pipettes.
7. Wash bottle or microwell washing system.
8. Distilled or deionized water.
9. One liter graduated cylinder.
10. Serological pipettes.
11. Disposable pipette tips.
12. Paper towels.
13. Laboratory timer to monitor incubation steps.
14. Disposal basin and disinfectant (i.e.: 10% household bleach – 0.5% Sodium Hypochlorite).

STORAGE CONDITIONS

2°C – 8°C	Coated Microwell Strips: Immediately reseal extra strips with desiccant and return to proper storage. After opening – strips are stable for 60 days, as long as the indicator strips on the desiccant pouch remains blue.
	Conjugate – DO NOT FREEZE.
	Unopened Test System, Calibrators, Controls, TMB, Detector Concentrate, Detector Diluent, and Analyte Diluent.
	Reconstituted Controls and Calibrators are stable for 6 days.
2°C – 25°C	Stop Solution: 2 – 25°C Wash Buffer (1X): 20 – 25°C for up to 7 days, 2 – 8°C for 30 days. Wash Buffer (10X): 2 – 25°C

SPECIMEN COLLECTION

1. ZEUS Scientific recommends that the user carry out specimen collection in accordance with CLSI document M29: Protection of Laboratory Workers from Infectious Disease (Current Edition)(9).
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, consider all blood derivatives potentially infectious.
3. Store samples at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, plasma may be stored between 2 - 8°C, for no longer than 48 hours. If a delay in testing is anticipated, store test plasma at -20°C or lower. Avoid multiple freeze/thaw cycles which may cause cause protein degradation and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory (10).
4. Use only freshly drawn and properly refrigerated/frozen **EDTA-plasma** obtained by approved aseptic venipuncture procedures (11, 12). Avoid using hemolyzed, lipemic, or bacterially contaminated plasma.

ASSAY PROCEDURE

1. Remove assay components from the refrigerator and let them come to room temperature (20-25°C) before use.
2. If patient samples have been refrigerated, remove from the refrigerator and let them come to room temperature before use. Mix well before use in case precipitation of proteins has occurred.
3. Determine the number of microwell plates or strips needed to run the assay as outlined below (or similar):
4. Calibrators: 2 wells/calibrator level for each of the calibrators
5. Controls: 2 wells/control, for each control
6. Patient samples: 2 wells per patient

Example Plate Set-up								
	1	2	3	4	5	6	7	8
A	Cal A	Cal A	Patient 1	Patient 1				
B	Cal B	Cal B	Patient 2	Patient 2				
C	Cal C	Cal C	Etc.	Etc.				
D	Cal D	Cal D						
E	Cal E	Cal E						
F	Cal F	Cal F						
G	Con I	Con I						
H	Con II	Con II						

7. **Prepare the 1X Detector Solution**: For each strip being used that day, dilute 1µl of Detector Concentrate into 1ml of Detector Diluent (1:1,000 dilution).
8. **Prepare Calibrators**: Add 1.5ml of Analyte Diluent to each of the six vials containing calibrator lyospheres and gently vortex. *Caution: All vials should be upright and lyospheres visible before opening.* Once prepared, these Calibrators can be used for six days when stored at 2-8°C. Calibrators are ready to use once reconstituted. Calibrators are not diluted like the patient plasma.
9. **Prepare Controls**: Add 0.2ml of DI water to each control vial, gently vortex. Once prepared, these Calibrators can be used for six days when stored at 2-8°C. Controls must be diluted 1:2500 like the patient plasma (see recommended dilution method below):
10. Dilute patient samples and controls 1:2500 using a double dilution technique:
    a. Dispense 490µL Analyte Diluent into microcentrifuge tubes, two for each sample (Dilution 1 and Dilution 2).
    b. Dilute plasma sample (control or patient) 1:50 by pipetting 10µL of sample into its Dilution 1 tube. Mix well.
    c. Dilute 1:50 again by pipetting 10µL from Dilution 1 into the corresponding Dilution 2 tube. Mix well.
    d. Final dilution = 1:2500.
11. Pipette 100µL of each Calibrator, Control and diluted patient plasma into the appropriate wells. Mix by rotating or tapping the plates.
12. Incubate at room temperature (18-25°C) for 30 minutes.
13. Decant/Wash using an automated washer:
    e. Set dispensing volume to 300 - 350µL per well.
    f. Set the wash cycle for 5 washes with no delay between cycles.
    g. When wash cycles are complete, remove the plate/strips from the washer. Depending on the aspiration efficiency of the washer, it may be necessary to invert over a paper towel and tap firmly to remove any residual wash solution from the wells.
14. Pipette 100µL of diluted HRP-Detector into each well at the same rate and in the same order as the specimens were added. Mix by rotating or tapping. Incubate at room temperature (18-25°C) for 30 minutes.
15. Decant/Wash as described at Step 13 above.
16. Pipette 100 µL of TMB into each well at the same rate and in the same order as the specimens were added. Mix by rotating or tapping. Incubate at room temperature (18-25°C) for 10 minutes.
17. Pipette 50 µL of Stop Solution into each well. Mix by rotating or tapping.
18. Read the final reaction at 450nm within 30 minutes of adding Stop solution.
19. Use an automated plate reader to read the wells.
20. Plot the calibration curve using a 4 or 5 parameter logistic curve fitting program;
21. Use average of each set of duplicates to calculate results for the sample.

INTERPRETATION OF RESULTS

Calibration

1. Below are the Nominal concentrations of assay Calibrators when reconstituted in 1.5ml of Analyte Diluent. Nominal concentrations are expressed in mg/deciliter (mg/dL).

Vial Number	Calibrator Concentrations
	Nominal (Dilution corrected) mg/dL
Cal A	0
Cal B	10
Cal C	20
Cal D	30
Cal E	40
Cal F	80

2. To generate a standard curve and calculate results:
   a. Subtract Cal A (background) from all other OD readings
   b. Perform a 4 or 5 parameter logistic curve fit of the Nominal values above (x axis) versus the OD450 readings for Calibrators A thru F (y axis).

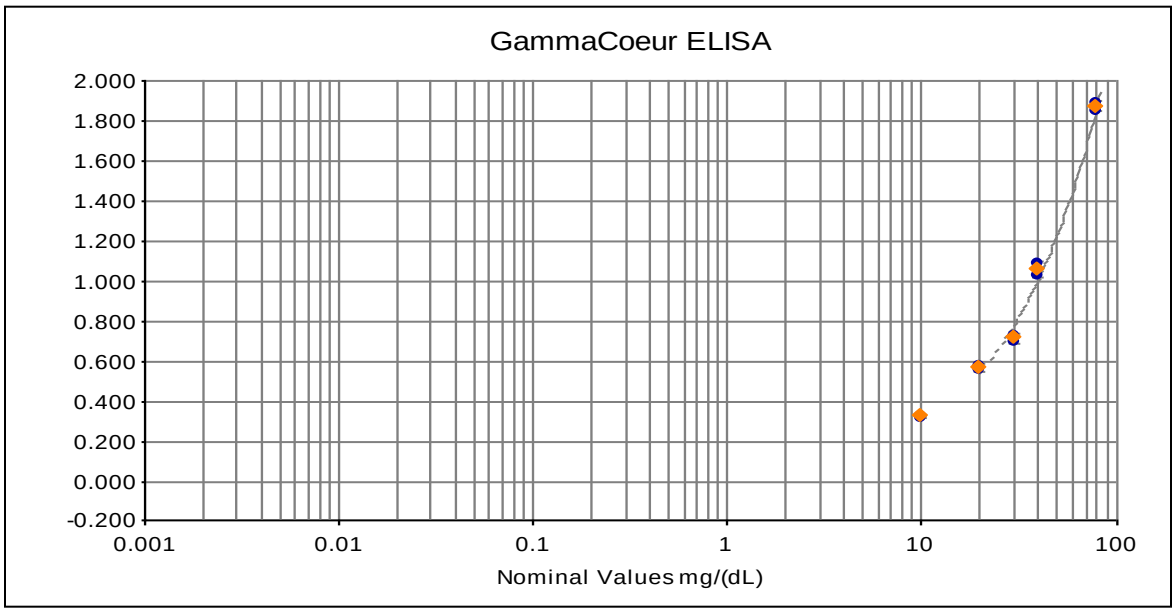
c. Back calculate values of calibrators, controls and unknowns using either the ELISA system's software or a commercial off-the-shelf curve-fitting/data analysis software package.

d. Verify that the observed values for calibrators and controls are within the parameters listed on the lot specification label.

e. **Expected Linearity of Calibration Curve**: R > 0.99 (4P or 5P logistic equation)

Sample Calibration Curve:

Blank = 0.160 OD
R = 0.996



QUALITY CONTROL

Target OD of highest calibrator (80mg/dL) should be approximately equal to 1.5 to 2 OD (wider range should give acceptable results). The mean values and ranges printed on the specification label packaged with the controls were derived from replicate testing on multiple vials that were representative of the entire lot of each control solution. The mean and range values listed on the specification sheet should serve as guidelines in assessing the accuracy of the GammaCoeur ELISA until the laboratory has established its own mean and range through repeated testing (it is considered good laboratory practice for each laboratory to establish its own mean and range for the control solutions and test methods it uses).

If a control gives an unacceptable result, the results for the plate are considered invalid and the patient results may not be reported. Troubleshooting may include:

- Inspect all equipment to ensure it is operating correctly.
- Check the expiration date of the GammaCoeur ELISA kit and of the control materials to ensure they are not expired.
- Repeat the assay using freshly diluted patient and control samples.
- If the retest still gives unacceptable results, contact Technical Services.

Results

Control and patient results will be automatically calculated by the ELISA software, using the calibration curve generated, and averaging the results from the duplicate wells will give a single numeric assay result for each sample tested.

LIMITATIONS OF THE ASSAY

1. Diagnosis of cardiovascular disease (CVD) should not be made on the basis of the GammaCoeur assay result alone. Results should be interpreted in conjunction with other diagnostics procedures, patient history, etc.
2. Reproducible and reliable ELISA results are highly dependent on adhering to incubation times and temperatures, as well as thorough washing of wells and thorough mixing of all reagents.
3. Hemolytic, lipemic, and icteric samples may interfere with this assay. Avoid use of these sample types if possible. See Performance Characteristics/Interfering Substances below.

EXPECTED RESULTS

Using samples from normal, healthy individuals and disease-state samples, the manufacturer has established the following guidelines to interpret patient results:

Refererence range (central 95%): 8.9 – 55.1 mg/dL
Cut-off for increased risk of CVD: > ~30 mg/dL

Values that fall above the cut-off value (> ~30 mg/dL) may be indicative of increased risk of cardiovascular disease and may require further testing for CVD. Accurate diagnosis of a patient's CVD status and risk should not depend on the GammaCoeur result alone, but should be used in conjunction with other diagnostic tests and clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

1. **Reportable Range**
   The GammaCoeur ELISA assay can measure gamma-prime fibrinogen concentrations in the range of 10 mg/dL to 80 mg/dL (highest calibrator). Results lower than 10 mg/dL should be reported as "< 10 mg/dL". Results greater than 80mg/dL should be reported as "> 80 mg/dL".
2. **Cutoff Value**
   A defined threshold value has not been established for the present immunoassay format. A previous assay system yielding a median normal gamma-prime concentration of 23.4 mg/dL gave a cutoff value of **30mg/dL** based on the inflection point of the ROC curve.
3. **Functional Sensitivity (Limit of Quantification)** Functional sensitivity is defined as that concentration of analyte with an inter-assay CV of 20%. A precision profile for the GammaCoeur assay was constructed by testing each of TBD plasma pools five times per run, 3 times a day, for 3 days. The mean gamma-prime fibrinogen level measured in each of the pools was plotted vs. the within-run precision for each pool. The functional sensitivity of the GammaCoeur assay is ~1.0mg/dL.

4. **Lower Limit of Detection**
   Using "OD of blank + 2X StDev of blank" = ~1.5 mg/dL with a CV of 11%.
5. **Specificity**
   Cross-Reactivity (Specificity of the monoclonal antibody for gamma-prime fibrinogen)
   Cross-reactivity of the GammaCoeur capture antibody for total fibrinogen was measured using serial dilutions of capture antibody reacted against purified gamma-A/gamma-A fibrinogen or gamma-A/gamma-prime fibrinogen. The dilutions ranged from 1:5 to 1:100,000 (samples are tested in the GammaCoeur assay at 1:2500 dilution, so 1:100,000 represents a 40-fold dilution of an assay sample). The GammaCoeur capture antibody showed no measurable reactivity against gamma-A/gamma-A fibrinogen even at the lowest dilutions (1:5).
6. **Reproducibility**
   a. **Intra-assay (Repeatability):**
   Acceptance criteria for the %CV of the study was less than or equal to 7.5% and the criteria was met for all instruments.

	Hamilton A318, A421		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	21.7	29.5	47.4
Standard Deviation	1.1	1.5	3.6
% CV	4.9	5.1	7.5

	Hamilton A415, A590		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	22.2	31.3	53.9
Standard Deviation	1.5	1.6	3.1
% CV	6.7	5.2	5.7

	Hamilton A415, A610		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	23.1	30.3	49.6
Standard Deviation	1.3	1.4	3.3
% CV	5.7	4.7	6.8

   b. **Inter-assay (Reproducibility) and Inter-instrument, Inter-assay Precision Study:**
   Acceptance criteria for the %CV of the study was less than or equal to 10%.

	Hamilton A318, A421		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	21.2	29.1	48.9
Standard Deviation	1.5	2.2	3.1
% CV	7.3	7.4	6.3

	Hamilton A415, A590		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	25.3	17.0	8.9
Standard Deviation	1.2	1.0	0.7
% CV	4.6	6.4	8.3

	Hamilton A415, A610		
	Level 1 Results	Level 2 Results	Level 3 Results
Mean (mg/dL)	26.0	19.1	9.6
Standard Deviation	2.0	1.2	0.7
% CV	7.3	6.4	6.9

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