AutoGenomics

# INFINITI® CYP450 2C19PLUS Assay

***Directional Package Insert (DPI)***

**For *In Vitro* Diagnostic Use**

CE

**FOR EXPORT ONLY**

**USING the INFINITI PLUS® ANALYZER**

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**INTENDED USE**

The INFINITI CYP450 2C19PLUS Assay is an *in vitro* diagnostic test for the identification of a patient's CYP450 2C19 genotype from genomic deoxyribonucleic acid (DNA) obtained from whole blood samples. The INFINITI CYP450 2C19PLUS Assay is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

The INFINITI CYP450 2C19PLUS Assay is indicated for use as an aid to clinicians in determining therapeutic strategy and treatment dose for therapeutics that are metabolized by the CYP2C19 gene product.

The information provided from this test may supplement decision making and should only be used in conjunction with routine monitoring by a physician. Because of the variability in the knowledge of clinical utility with specific drugs that are metabolized by CYP2C19, clinicians should use professional judgment in the interpretation of results from this test. Results from this type of assay should not be used in predicting a patient's response to drugs for which the drug metabolizing enzyme activity of the allele, or the drug metabolic pathway, has not been clearly established.

**BACKGROUND INFORMATION**

Cytochrome P450 (CYP450) 2C19 is a member of the hepatic microsomal enzymes which is involved in the xenobiotics metabolism. CYP450 2C19 (CYP2C19) is a highly polymorphic liver enzyme of the liver and is involved in the metabolism and elimination of many commonly prescribed drugs including antidepressants, antiepileptics, barbiturates and proton pump inhibitors.

Genetic polymorphisms in CYP2C19 are common and can affect therapeutic response to drugs. The enzyme activity is expressed at highly variable levels. Three phenotypes are identified: poor metabolizers (PM), intermediate metabolizers (IM) and normal metabolizers (NM).

CYP2C19 acts on 5-10% of drugs in current clinical use. About 2-6% of individuals of European origin (Caucasians), 15-20% of Japanese, and 10-20% of Africans have a slow acting, poor metabolizer form of this enzyme. However there is wide variability among populations. For example, the percent of Polynesians who are poor metabolizers ranges from 38-79% depending on location.

Detecting genetic variations in drug-metabolizing enzymes is useful for identifying individuals who may experience adverse drug reactions with conventional doses of certain medications. Individuals who possess CYP2C19 poor metabolizer variants may exhibit different pharmacokinetics (drug levels) than normal individuals. As a result, such individuals may require non-conventional doses of medications that require CYP2C19 activity for biotransformation. Conversely, medications that do not require CYP2C19 biotransformation may be preferentially selected for patients with potentially impaired CYP2C19 metabolic capacity to avoid adverse drug reactions.

Adjustment of drug dosage could be beneficial based upon knowledge of these differences in metabolism, particularly for individuals possessing the poor metabolizer phenotype. Data is available in literature that supports phenotypic determinations for drugs that are metabolized by CYP2C19. The following table lists some clinically relevant drugs that are known substrates of CYP2C19 enzymes.

| Antifungals | Cardiovascular | Gastroenterology | Neurology & Psychiatry |
|---|---|---|---|
| Voriconazole | Clopidogrel | Dexlansoprazole | Citalopram |
| | Prasugrel | Esomeprazole | Clobazam |
| | Ticagrelor | Lansoprazole | Diazepam |
| | | Omeprazole | |
| | | Pantoprazole | |
| | | Rabeprazole | |

The **INFINITI CYP450 2C19PLUS Assay** detects mutations in nine CYP2C19 alleles:

*2, *3, *4, *5, *6, *7, *8, *9, *10, *17

The CYP2C19 allelic variants detected in this genotyping test provide greater than 98% coverage of the variant alleles found for this gene.

The most common poor metabolizer phenotypes have been identified as CYP2C19*2 and CYP2C19*3. The allele frequency of CYP2C19*2 has been reported to be as high as 75-85% in Asians and approximately 15% in Europeans and African Americans. The allele frequency of CYP2C19*3 has been reported to be as high as 6-10% in Asians and is rare in Europeans and African Americans.

Other poor metabolizer phenotypes include *4, *5, *6, *7 and *8 which have all been shown to have a non-functional response. *9 and *10 are very similar (poor metabolizer phenotypes) but have a decreased enzymatic activity response. *17 is the one phenotype that has an opposite effect. It has been shown to increase CYP2C19 expression and displays an increased enzymatic activity.

Clinicians should use caution in predicting phenotype and adjusting treatment strategy for patients who express alleles that have not been investigated for activity in metabolizing a specific drug.

**TEST PRINCIPLE/ASSAY OVERVIEW**

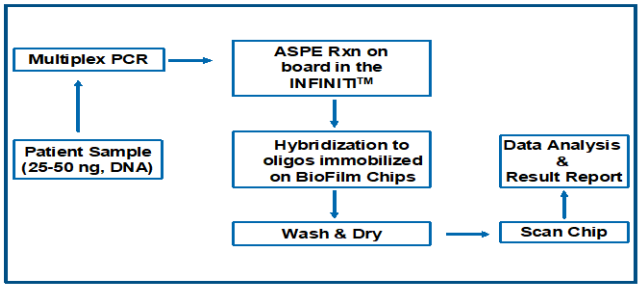
The INFINITI CYP450 2C19PLUS Assay is an *in vitro* diagnostic test for the multiplex detection of the genotypes of CYP2C19 in deoxyribonucleic acid (DNA) obtained from human blood samples.

The INFINITI CYP450 2C19PLUS Assay is based on the following processes:

a) DNA extraction from human blood sample.
b) PCR amplification of purified DNA.
c) Fluorescent label incorporation using analyte specific primer extension (ASPE).
d) Hybridization of the ASPE primers to a microarray followed by washing.
e) Scanning of the microarray.
f) Signal detection and analysis.

Steps (c) through (f) are automated by the CE-marked INFINITI PLUS Analyzer.

A schematic overview of the assay is shown below.



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## DEVICE DESCRIPTION

The INFINITI CYP450 2C19PLUS Assay is an *in vitro* diagnostic device which utilizes AutoGenomics' proprietary film-based microarray technology combined with process automation, reagent management and software technology for the detection and genotyping of the CYP2C19 allelic variants in genomic deoxyribonucleic acid (DNA) obtained from whole blood samples.

The INFINITI CYP450 2C19PLUS Assay is comprised of the BioFilmChip® Microarray and the Intellipac® Reagent Module.

The **BioFilmChip Microarray** consists of a polyester film coated with proprietary multi-layer components designed for DNA analysis. The layers have been designed to provide a versatile surface to enhance test performance. The microarrays are designed to be assay specific. The INFINITI CYP450 2C19PLUS Assay uses a microarray chip (R-Chip) which contains unused capture probes which could potentially be used for certain specific assays. Therefore, multiple assays can be developed using the same microarray.

The **Intellipac Reagent Module** which acts as a communication link contains up to four reservoirs that house the test reagents and has an integrated memory chip. Information on the reagent such as lot number, expiration date and number of tests is archived in the memory chip.

The INFINITI CYP450 2C19PLUS Assay should be run using the AutoGenomics **INFINITI PLUS® Analyzer**. The INFINITI PLUS is an instrument used for clinical multiplex systems intended to measure and sort multiple signals from a clinical sample. The INFINITI PLUS is designed to measure fluorescence signals of labeled DNA target hybridized to BioFilmChip microarrays. The INFINITI PLUS automates the CYP450 2C19PLUS Assay and integrates all the discrete processes of sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. The assay is processed automatically and the spots are read by the built-in confocal microscope. Results are analyzed and presented as genotype calls.

The INFINITI PLUS Analyzer are CE-marked.

Instructions on how to use the INFINITI PLUS is provided in the INFINITI PLUS® Analyzer Operator's Manual.

## WARNINGS AND PRECAUTIONS

### Handling Requirements

- **For *in vitro* diagnostic use. To be used by qualified laboratory personnel.**
- All patient specimens are potentially hazardous and care should be taken when handling materials of human origin. No test method can offer complete assurance that HCV, HIV or other infectious agents are absent.
  **Follow the CLSI Guidelines (Molecular Diagnostics Methods for Infectious Diseases; Approved Guidelines; MM3-A).**
- Upon receipt of samples, visually inspect sample condition. Specifically, look for abnormal signs that indicate that sample integrity has been compromised (e.g., evaporation, decrease in volume, precipitation, spills, discoloration, sedimentation, separation, turbidity, etc.). If you observe or suspect any sample abnormality, do not perform any test.
- Samples should be handled with extreme caution to prevent contamination, spillage, sample mix-up. Sample containers should be labeled clearly to prevent mix-up.
- Store samples at the specified conditions.
- To minimize the risk of cross contamination, sample preparation, PCR reaction set up and PCR product analysis should be performed according to approved guidelines such as CLSI (Molecular Diagnostic Methods for Genetic Diseases: Approved Guideline).
- Do not pool/mix reagents from different lots.

- Do not use a kit or reagent past its expiration date.
- Store kits and reagents according to the product label.

**Laboratory Procedures**

- Follow normal precautions for handling laboratory reagents.
- Follow safe laboratory procedures: do not pipette by mouth; wear protective clothing (e.g., disposable gloves laboratory coats) and eye protection; do not eat, drink or smoke in the laboratory work areas; wash hands thoroughly after handling samples and reagents.

**Waste Handling**

- Dispose of unused reagents, specimens and waste according to applicable country, federal, state and local regulations.
- Safety data Sheets (SDS) are available upon request from AutoGenomics Customer Service.

**Sample Preparation**

- Refer to the safety instructions in the package insert provided with the DNA extraction kit used.
- It is critical to perform the PCR properly, ensuring proper pipetting of reagents. In addition, proper sealing of the PCR tubes should be ensured by pressing down on the lid.
- The thermocycler used for PCR should be properly calibrated.
- Visually inspect each PCR product for indication of evaporation, e.g., low volume or discoloration.
- The PCR product cannot be stored prior to loading it onto the microarray. Use immediately**.**

**INFINITI PLUS® Analyzer**

- **Read the INFINTI Analyzer Operator's Manual before operating the instrument.** Pay particular attention to "Notes".
- Follow the Caution and Safety Warning in the Operator's Manual.
- Refer to the Installation Requirements Section when installing the instrument.
- Refer to the Errors Section when errors are encountered while operating the instrument.
- Refer to the Help Section when problems are encountered.

**STORAGE / STABILITY**

| | |
|---|---|
| BioFilmChip Microarray: | 24 months Refrigerated (2 to 8$^{o}$C) |
| Amplification Mix: | 3 years Frozen (-30 to -15$^{o}$C) |
| Intellipac Reagent: | 18 months Refrigerated (2 to 8$^{o}$C) ***Note:*** Remove the Intellipac from the INFINITI PLUS Analyzer and store refrigerated as soon as possible. Do not use after Intellipac has been opened for four weeks or more. |

***Note:*** Specific product expiration date is printed on the product label.

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**MATERIALS PROVIDED (SUFFICIENT FOR 48 TESTS)**

- The INFINITI CYP450 2C19PLUS kit (03-8190-02) is comprised of:
    - Product Number 03-1190-02: INFINITI CYP450 2C19PLUS BioFilmChip® Microarray Magazine. 4 magazines per package
    - Product Number 03-2190-02 INFINITI CYP450 2C19PLUS Intellipac® Reagent Module 24 tests per module; 2 modules per package
      Each Intellipac module contains:
      1.1 ml ASPE Master Mix:
      dNTPs
      Labeled-dCTP
      Allele Specific Primers
      Extension Reaction Buffer

      2.6 ml Hybridization Buffer
      SSC
      Hybridization Positive Control
      Sodium Azide Preservative 0.08%

    - Product Number 03-3190-02: CYP450 2C19PLUS Amplification Mix 4 x 250µl of PCR reaction master mix vials containing:
      dNTPs
      PCR Primer Mix
      $MgCl_2$
      PCR Reaction Buffer

- INFINITI® Wash Buffer 125mL (Catalog # 112-0330-00)

**REAGENTS REQUIRED BUT NOT PROVIDED BY AUTOGENOMICS**

- DNA Extraction Kits - The INFINITI CYP450 2C19PLUS Assay can detect the CYP450 2C19 allelic mutations using genomic DNA isolated from blood with sufficient purity, i.e., with the ratio of absorbance at 260nm to absorbance at 280nm of ≥ 1.60. Any DNA extraction method that meets this specification may be used. The INFINITI CYP450 2C19PLUS Assay has been tested with several commercially available kits. The user can contact AutoGenomics for further information.
- Molecular-grade water (DNAse and RNAse free)

  Platinum Taq DNA Polymerase (Invitrogen, Catalog # 10966-018)
  OR
  INFINITI Taq DNA Polymerase 2 (30µl Catalog # 12-0480-00)

**EQUIPMENT**

**The following equipment is required but not provided with the assay reagents**

- INFINITI® PLUS Analyzer (Catalog # 10-0020-99)
- INFINITI® PipetteTips (Catalog # 11-0080-00)
- INFINITI® Tip Barrel Plugs (Catalog # 11-0070-00)

- INFINITI® Waste Tray Liners (Catalog # 11-0020-00)
- INFINITI® Waste Tray Stir Bars (Catalog # 11-0060-00)
- INFINITI® 48 Well Plates (Catalog # 11-0100-00)
- Reusable INFINITI® 48 Well Lid (Catalog # 11-0010-00)
- 8-well flat strip caps (Axygen, Catalog # PCR-2CP-RT-C)
- Thermocycler (Eppendorf Mastercycler Pro with aluminum block recommended)
- Pipettors
- Mini Centrifuge
- Microfuge Tube Racks
- Vortex mixer
- 1.5 mL Microcentrifuge Tubes

## SPECIMEN COLLECTION AND STABILITY

- This test is to be used only with whole blood collected in EDTA. Specimens should be kept refrigerated (2°C to 8°C) and extracted within nine (9) days from the day the specimen was collected. Do not freeze/thaw blood samples.

## ASSAY PROCEDURE

### DNA Extraction

- Follow the instructions provided with the DNA extraction kit used.
- Extracted DNA samples should be kept refrigerated (2°C to 8°C) and assayed within two (2) days from the day the specimen was extracted. Extracted DNA samples can be stored frozen (-15°C to -30°C) for up to 5 years. Do not freeze/ thaw samples more than three times.

#### SPECIMEN REQUIREMENTS

- Purified DNA that is at a concentration of ≥25 ng/µL and has a ratio of A260/280 ≥1.6.

### PCR Reaction

***Note:***

- Keep Taq DNA polymerase on ice.
- Completely thaw reagents on ice.
- Vortex the amplification mix tube for 2 to 5 seconds then centrifuge briefly to bring the contents to the bottom of the tube.
- To avoid contamination, a separate area is recommended for assembly of the PCR reaction. Decontaminate pipettes and all work surfaces with freshly prepared 10% bleach.
- Filter tips and gloves must be used when handling specimens and controls.
- The PCR product cannot be stored prior to testing. Use immediately.

1. Prepare the PCR master mix.

***Note:*** Volumes given below are per reaction. Calculate the amount of each reagent needed based on the number of reactions. It is advisable to allow at least a 10% excess.

| | |
|---|---|
| Amplification mix | 17.9 µL |
| Platinum Taq polymerase | 0.1 µL |
| Total volume of PCR Master mix | 18.0 µL |

OR

IF USING INFINITI Taq DNA Polymerase 2:

| | |
|---|---|
| Amplification mix | 17.9 µL |
| Taq polymerase 2 | 0.1 µL |
| Total volume of PCR Master mix | 18.0 µL |

2. Gently vortex the PCR master mix then dispense 18 µL of master mix into wells of the 48-well plate.

3. Add 2 µL of sample DNA (≥25 ng/µL) to each well.

| | |
|---|---|
| PCR master mix | 18.0 µL |
| Sample DNA | 2.0 µL |
| Total volume of amplification reaction | 20.0 µL |

4. Place the 48-well plate, sealed with 8-well flat strip caps, in a thermocycler and immediately start the amplification reaction using the following program.

| Step No. | Temperature °C | Time | No. of Cycles |
|---|---|---|---|
| 1 | 94 | 2 min. | N/A |
| 2a<br>b<br>c | 94<br>62-56 (-0.5°C/cycle)<br>72 | 30 sec.<br>30 sec.<br>30 sec. | 12x |
| 3 | 94<br>55<br>72 | 30 sec.<br>30 sec.<br>30 sec. | 30x |
| 4 | 72<br>4 | 2 min.<br>Hold | N/A |

***Note:*** Step 1 is set at 100% ramp rate. After each cycle in step 2b the temperature is decreased by 0.5°C. When using an Eppendorf Mastercycler EP with the ramp rate set at 75%, the total cycling time is 1 hour and 45 minutes (± 5 min). If using other thermocycler models we recommend adjusting the ramp rate in order to obtain an equivalent total cycling time.

5. Loading the INFINITI® PLUS Analyzer .

Load the 48WP in the appropriate orientation (with well A1 in the back left corner) and cover with a clean INFINITI® Reusable 48 Well Lid. Load the assay-specific magazines, Intellipac, and INFINITI® Static Free Pipette tips into the INFINITI® PLUS Analyzer. Check the level of the Wash buffer in the bottle on the left side of the Analyzer.

**6. Operation of the** INFINITI® PLUS Analyzer

For operation of the INFINITI® PLUS and instructions for cleaning the reusable 48 well lid, refer to the INFINITI® PLUS Analyzer Operator's Manual (EM-34041).

## QUALITY CONTROL

It is recommended that positive controls (heterozygous and/or homozygous samples) be included in each test run. In addition, a negative control (i.e., wild type sample) and a no template control (i.e., molecular grade water) should also be included in each test run. Coriell DNA samples (www.coriell.org) are suitable positive controls for many of the detected genotypes. Please contact AutoGenomics for recommendations on use of Coriell DNA.

- Maintain calibration of thermocycler according to manufacturer's specifications.
- Maintain calibration of INFINITI® PLUS Analyzer according to AutoGenomics' specifications.
- Maintain calibration of pipettes according to manufacturer's specifications.

## LIMITATIONS

The results obtained from the INFINITI CYP450 2C19PLUS Assay should be used and interpreted only in the context of the overall clinical diagnosis. AutoGenomics is not responsible for any clinical decisions that are taken.

## INTERPRETATION OF RESULTS

The INFINITI CYP450 2C19PLUS Assay is designed to detect and genotype CYP450 2C19 mutations. The assay results are provided as a genotype "call", indicating which genotype was detected in the sample (i.e., *1/*1, *1/*2, *2/*2, etc.).

For example,

- If the sample is *1/*3, the report will show CYP2C19 [*3-Het] and "W" for the rest of the alleles listed.
- If the sample is *2/*2, the report will show CYP2C19 [*2-Mut] and "W" for the rest of the alleles listed.
- If the sample is *2/*17, the report will show CYP2C19 [*2-Het], CYP2C19 [*17-Het] and "W" for the rest of the alleles listed.
- If the sample is wild-type for the alleles detected, the report will show "W" for all alleles listed.

No information is provided for CYP450 2C19 alleles not listed in the report. These alleles may or may not be present in the sample.

When the assay is not completed, and no genotype call is made, the assay will need to be repeated. The report displays a message which indicates the reason why no genotype call was made. When an error occurs (e.g., "low DNA"), an Error Log is generated which identifies the problem. Please refer to the Trouble Shooting section of the INFINITI Analyzer Operator's Manual.

## PERFORMANCE CHARACTERISTICS

### Analytical Specificity

Studies related to specificity were conducted during assay development. PCR primer specificity was determined by amplicon size on a gel and sequencing the amplicon. DPE primer specificity was determined by the correct calls made by the assay using known genomic samples. Capture probe specificity was determined by hybridizing different oligos and demonstrating that correct oligo hybridizes to the known spot.

### Limits of Detection (analytical sensitivity)

The analytical sensitivity (Limit of Detection) of the INFINITI CYP450 2C19PLUS Assay was assessed by analysis of six (6) blood samples at concentrations of 250, 200, 100, 25, 10, and 5 ng DNA/µL. Two (2) samples were *1/*1,

one (1) sample was *1/*2, one (1) sample was *2/*2 and two (2) samples were *1/*17. Sample genotypes were determined by bi-directional sequencing. The concentration was determined by spectrophotometry. The DNA was extracted using the Qiagen QIAamp DNA Blood Mini Kit Catalog# 51106. Twenty (20) replicates of each sample were assayed for a total of 720 tests.

The Limit of Detection study demonstrated that the INFINITI CYP450 2C19PLUS Assay can detect the target mutations at the recommended DNA concentration of 25ngDNA/µL. The assay requires 2µl of the DNA sample for 50ng DNA input per test.

**Analytical Specificity – Method Comparison**

The INFINITI CYP450 2C19PLUS Assay was compared to bi-directional sequencing as the comparator method. Three sites were used for the comparison studies. Each site tested its own patient samples with the INFINITI CYP450 2C19PLUS Assay. Patient samples were de-identified to protect patient's identity.

The results of the comparison studies comparing the INFINITI CYP450 2C19PLUS Assay to bi-directional sequencing is provided in Table 2.

**Table 2 Agreement between INFINITI™ CYP450 2C19PLUS Assay with Bi-directional Sequencing**

| Sample | # of samples | % agreement of INFINITI CYP450 2C19PLUS Assay with bi-directional sequencing | |
|---|---|---|---|
| | | 1st time run | Final (after one repeat) |
| *1/*1 | 95 | 97.9 | 100 |
| *1/*2 | 64 | 95.3 | 100 |
| *2/*2 | 10 | 100 | 100 |
| *1/*3 | 2 | 100 | 100 |
| *1/*4 | 1 | 100 | 100 |
| *1/*8 | 2 | 100 | 100 |
| *1/*17 | 69 | 98.6 | 100 |
| *17/*17 | 18 | 100 | 100 |
| *2/*6 | 1 | 100 | 100 |
| *2/*17 | 15 | 100 | 100 |
| *8/*17 | 1 | 100 | 100 |
| All | 278 | 97.8 | 100 |

Six (6) No Calls 1st time run. Correct calls on repeat. No incorrect calls

**Assay Inter-Laboratory Reproducibility**

A three-site study was conducted to demonstrate the reproducibility of the INFINITI CYP450 2C19PLUS Assay. The study involved three lots of the INFINITI CYP450 2C19PLUS Assay. The sites ran identical samples comprised of twelve (12) genomic whole blood samples. The sites were blinded to sample identity. At each site, each sample was run in duplicate per day/operator for five non-consecutive days.

Overall correct calls for the inter-laboratory reproducibility study was 95.2%. Results of the inter-laboratory reproducibility study are summarized in table 3.

**Table 3 Inter-Laboratory Reproducibility of the INFINITI CYP450 2C19PLUS Assay by Genotype**

| Genotype[a] | Samples Tested | Site | Genotype Calls | First Time Run | | | |
|---|---|---|---|---|---|---|---|
| | | | | Correct Calls | Incorrect Calls | No Calls | % Correct Calls |
| ***1/*1** | 2 | 1 | 40 | 39 | 0 | 1 | 97.5% |
| | | 2 | 20 | 20 | 0 | 0 | 100% |
| | | 3 | 20 | 17 | 1 | 2 | 85.0% |
| | | total | 80 | 76 | 1 | 3 | 95.0% |
| ***1/*2** | 3 | 1- | 60 | 59 | 0 | 1 | 98.3% |
| | | 2 | 30 | 30 | 0 | 0 | 100% |
| | | 3 | 30 | 30 | 0 | 0 | 100% |
| | | total | 120 | 119 | 0 | 1 | 99.2% |
| ***2/*2** | 2 | 1 | 40 | 38 | 1 | 1 | 95.0% |
| | | 2 | 20 | 19 | 0 | 1 | 95.0% |
| | | 3 | 20 | 13 | 0 | 7 | 65.0% |
| | | total | 80 | 70 | 1 | 9 | 87.5% |
| ***1/*3** | 1 | 1 | 20 | 20 | 0 | 0 | 100% |
| | | 2 | 10 | 10 | 0 | 0 | 100% |
| | | 3 | 10 | 10 | 0 | 0 | 100% |
| | | total | 40 | 40 | 0 | 0 | 100% |
| ***1/*17** | 2 | 1 | 40 | 39 | 0 | 1 | 97.5% |
| | | 2 | 20 | 16 | 0 | 4 | 80.0% |
| | | 3 | 20 | 19 | 0 | 1 | 95.0% |
| | | total | 80 | 74 | 0 | 6 | 92.5% |
| ***17/*17** | 2 | 1 | 40 | 40 | 0 | 0 | 100% |
| | | 2 | 20 | 18 | 0 | 2 | 90.0% |
| | | 3 | 20 | 20 | 0 | 0 | 100% |
| | | total | 80 | 78 | 0 | 2 | 97.5% |
| **Total** | 12 | | 480 | 457 | 2 | 21 | 95.2% |

[a] determined by bi-directional sequencing [b] after one repeat

**Drug Interference**

Evaluation of potential interference from the following substances demonstrated that presence of these compounds do not interfere with the INFINITI CYP450 2C19PLUS Assay.

| Substance Added | Concentration | |
|---|---|---|
| Bilirubin | 0.8 mg/dl | 8 mg/dl |
| Heparin | 133 u/dl | 1333 u/dl |
| Di-potassium EDTA | 360 mg/dl | 1.8 g/dl |
| Hemoglobin | 10 g/dl | 20 g/dl |
| Triglycerides | 150 mg/dl | 500 mg/dl |
| Human albumin | 3g/dl | |
| Human IgG | 3g/dl | |

**Sample Carry-Over**

No sample carry-over was detected when 300ng of a positive sample was followed by 10ng of a second positive sample, and when 300ng of a positive sample was followed by a "No Template Control" or water. All genotype calls were 100% correct.

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