



## INTENDED USE

The AggreGuide A-100 ADP Assay is used with the AggreGuide A-100 instrument in non-CLIA waived physician's office or clinical laboratory for the detection of platelet dysfunction in patients age 22 or older receiving P2Y12 antiplatelet drugs, prasugrel and ticagrelor, using 3.2% sodium citrated whole blood. The AggreGuide A-100 ADP Assay is a semi-quantitative assay. The level of platelet aggregation is determined by the platelet activity index (PAI) where values < 4.7 PAI suggest that platelet dysfunction is due to the presence of P2Y12 antiplatelet drugs, prasugrel and ticagrelor. The test results should be interpreted in conjunction with all other clinical and laboratory data available to the clinician.

## PRODUCT DESCRIPTION

The AggreGuide A-100 ADP Assay is an individual use, disposable assay cartridge for use with the AggreGuide A-100 instrument. The cartridge contains preloaded freeze-dried agonist. The level of platelet aggregation induced by the adenosine diphosphate (ADP) agonist in a sample of whole blood is detected within the cartridge. The amount of platelet aggregation is measured by detecting and quantifying the laser light scattering caused by platelet aggregates. P2Y12 inhibitor drugs e.g. clopidogrel, prasugrel, and ticagrelor are known to inhibit the level of platelet aggregation, causing platelet dysfunction.

## PRINCIPLE OF THE ASSAY

The AggreGuide A-100 ADP Assay is designed to measure platelet aggregation when a patient's whole blood is mixed with adenosine diphosphate (ADP), which activates platelets by binding to the ADP receptors on the platelet surface, resulting in platelet aggregation. P2Y12 inhibitors inhibit ADP-induced platelet aggregation by blocking the P2Y12 ADP receptor on the platelet surface.

## MATERIALS PROVIDED

AggreGuide ADP assay cartridges come individually sealed in Mylar® pouches. Each cartridge contains a lyophilized mixture of 10µM adenosine diphosphate and excipients to facilitate freeze drying.

## REAGENT STORAGE AND HANDLING

When receiving or opening a box of reagent cartridges, check the temperature indicator located on the outside of the box. If the indicator spot has turned black,

this indicates exposure to elevated temperatures and should not be used. Call customer support for a replacement.

- Store cartridges at room temperature, per the instructions on the box and pouches.
- Reagent cartridges should remain sealed in their Mylar pouch until ready for use to prevent damage by humidity.

## MATERIALS REQUIRED BUT NOT PROVIDED

- Blood collection tubes containing 3.2% sodium citrate.
- AggreGuide A-100 Instrument.
- Pipettor.

## PRECAUTIONS

- For *in-vitro* diagnostic use.
- The AggreGuide and its components should only be used as directed in the AggreGuide A-100 User's Manual.
- Do not use the AggreGuide ADP assay cartridge beyond the expiration date indicated on the case and the individual cartridge pouch.
- Cartridges should remain sealed in the Mylar pouch until ready for use.
- All patient blood samples should be handled as if capable of transmitting disease.
- Samples and used cartridges should be treated as bio-hazardous material and handled according to the institution's policies.

## SAMPLE COLLECTION AND HANDLING

- All whole blood samples must be assayed from vacuum collection tubes containing sodium citrate (3.2%).
- Blood should be tested within ½ - 4 hours of the blood draw.

## Instructions for Sample Collection Directly Into Vacuum

### Collection Tubes:

1. Whole blood may be collected from venous sites using a 19 or 21 gauge needle in 3.2% citrate vacuum collection tubes. Blood samples should be obtained from an extremity free of peripheral venous infusions.
2. Gently invert the sample tube at least 5 times to ensure complete mixing of the contents.

## Special Instructions if blood is obtained from an indwelling catheter:

1. Whole blood samples that are obtained from an indwelling catheter should be collected after sufficient discard (approximately 5 mL) has been drawn to clear the line. Ensure indwelling catheter is free of clots.

2. When using a syringe, transfer blood to the appropriate blood collection tube immediately after collection.
3. Gently invert the sample tube 5 times to ensure complete mixing of the contents.

## SAMPLE COLLECTION PRECAUTIONS

- Improper blood collection techniques may cause erroneous results. If unexpected or questionable results are reported, repeat the test with a new sample and a new cartridge.
- Fresh whole blood samples in the appropriate collection device are required for use with the AggreGuide A-100.
- Do not freeze or refrigerate sample. Samples should be stored at room temperature.
- Collection of the blood sample should be performed with care to avoid hemolysis or contamination by tissue factors. Samples with any evidence of clotting should not be used.
- Thorough but gentle mixing of the collected blood sample with the anticoagulant is required. Five repetitions of gentle inversion of each tube is appropriate.
- Do not shake or agitate samples. Hand carrying of samples is preferred. Pneumatic tube systems and rockers should be avoided.
- Always ensure collection tubes are filled to the indicated fill volumes. At altitudes greater than 2500 feet (760 meters) above sea level, blood collection tubes may not fill to the specified volume, which results in an incorrect ratio of blood to anticoagulant. Users at these elevations should refer to their facility's blood collection protocols for instructions to properly fill blood collection tubes.
- Samples should be collected and handled according to the institution's policies and procedures pertaining to bio hazardous material.
- The cap of the collection tube should be replaced promptly after blood has been sampled to avoid pH changes in the blood sample.

## TEST PROCEDURE

1. Refer to the AggreGuide A-100 User's Manual for complete operating instructions.
2. Prior to starting the Assay, select ADP Assay from the drop down menu.
3. Open the Mylar® pouch and remove the cartridge.
4. Insert the cartridge into the AggreGuide A-100 sample chamber.
5. The AggreGuide will prompt user to prepare to pipette blood and press the READY button. Gently and slowly invert the sample tube 3 - 5 times before opening the tube and aspirating blood with pipettor.



US Patents 6,043,871, 7,393,690 B2, 7,262,059 B2



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6. The AggreGuide will prompt user to introduce the blood sample into the cartridge with the pipettor, and then press the RUN button.
7. The AggreGuide will begin the assay run. The platelet activity index (PAI) will be displayed once the test has completed.
8. Remove the cartridge and check for any visible bubbles larger than 1mm. If bubbles greater than 1mm are present, abort the test and repeat with a new cartridge.
9. If the cartridge shows no evidence of bubbles larger than 1mm, press SAVE.

## REPORTED RESULTS

Results are reported as Platelet Activity Index (PAI). The PAI represents the degree of ADP induced platelet aggregation in whole blood.

The PAI is related to the number of ADP-induced platelet aggregates in the blood sample. The PAI represents the level of platelet aggregation. Higher PAI values represent higher levels of platelet aggregation and lower PAI values represent lower levels of platelet aggregation (such low levels are referred to as platelet dysfunction). With the AggreGuide A-100 ADP Assay, results with PAI values less than 4.7 indicate platelet dysfunction due to P2Y12 inhibitor drugs.

The Limit of Blank (LOB) is 0.8 PAI, however any result below 2.1 PAI is reported simply as "LOW". Similarly, any results above 12.0 PAI is reported as "HIGH".

## ERROR MESSAGES

If the instrument displays an error message or there is a technical error while running a test, the assay run may be aborted by selecting "abort" during or after running a test. Please refer to the AggreGuide A-100 User's Manual for a detailed explanation of errors and troubleshooting.

## CALIBRATION

The AggreGuide is calibrated at the factory. There are no user calibrations.

## QUALITY CONTROL

The "QC2" quality control cartridge and included software features allow the user to test for any gross changes to the system that might diminish quality of the AggreGuide A-100 measurements.

Using a special quality control device called the "QC2 Cartridge" the A-100 tests the system that detects platelet aggregates. The QC2 quality control test is not a replacement for clinical laboratory validation, but does serve as a method of detecting gross failures of the A-100 system. The A-100 system requires that the QC2 test is performed every thirty days, or every 200 assays, whichever occurs

first. Additional A-100 assays cannot be performed unless a QC2 test has been successfully performed.

The manufacturer recommends that laboratory quality control testing be performed by the user to verify the assay reagent is performing to expectation. This is recommended each time a new lot or shipment of assay cartridges is received and as part of a regular quality control program including those that the user may be required to perform to comply with any local and state regulations, or other accrediting bodies' requirements.

There are no commercially available standard control materials for platelet aggregation testing. Blood drawn from healthy adult donors may be used for normal controls. It is suggested that each laboratory establish a control donor group. Such donors must not have taken any medication that is known to affect platelet function for at least 5 days and should have prior platelet aggregation tests that have fallen within the normal reference range established by the laboratory. The manufacturer recommends using donors whose PAI value is > 6.7. If the results do not fall within the expected range, a second donor should be tested. If the second control donor's results are also considered outside the reference range, the assay should be considered out of control and no further clinical testing should be performed. Please call technical support for assistance.

## ASSAY LIMITATIONS

The lyophilized reagent in the cartridge is hygroscopic and may degrade after prolonged exposure to room air. Therefore, the cartridge should be used shortly after removal from the Mylar pouch, a process that should only take a few minutes. Testing indicates that cartridges removed from the pouch operate properly when loaded with the blood sample up to 12 minutes after opening the pouch.

When results are not within the expected limits, the possibility of improper specimen collection or handling should be investigated. Repeat the test using a new cartridge and specimen.

Patients with inherited platelet disorders such as Von Willebrand Factor Deficiency, Glanzmann Thrombasthenia and Bernard-Soulier Syndrome have not been studied with the AggreGuide.

Patients with a known history of platelet counts < 150,000/ $\mu$ L have not been studied.

Many medications or compounds (prescription and non-prescription) are thought to affect platelet aggregation. Some of these materials have been tested for interference with the Assay, as reported in the section on Interferents, below. Therefore a thorough medication history of the patient should be taken and reviewed.

ADP-induced platelet aggregation operates on a different and independent biochemical pathway than the arachidonic acid (AA) pathway. Platelet dysfunction can exist with either pathway, both pathways, or neither pathway. This A-100 ADP assay should not be used for testing for aspirin-induced platelet dysfunction. Instead the AggreGuide A-100 AA Assay should be used to test for platelet dysfunction due to aspirin ingestion.

Ticagrelor is a potent inhibitor of platelet function, but reversible and relatively short-acting. "Full-Effect" is achieved within 3-6 hours after the ingestion of the loading dose, but in contrast to other anti-platelet therapeutics, only 60% of this effect remains at 24 hours post-ingestion<sup>2,3</sup> ("Not-Full-Effect").

Clinicians using the test to evaluate on-therapy residual platelet activity are advised to make observations within 3-6 hours of the most recent dose of ticagrelor.

AggreGuide test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.



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## INTERFERING SUBSTANCES

- The AggreGuide A-100 has been tested in subjects with hematocrit values ranging from 29.3% to 51.9%.
- The AggreGuide A-100 has not been tested in subjects with platelet counts less than 150,000/uL.
- Assay performance is not affected by hemolysis up to 600 mg/dL plasma free hemoglobin.
- No interference was observed with blood samples spiked with bilirubin up to 10 mg/dL.
- Assay performance was not affected by triglyceride levels between 66 and 361 mg/dL.
- Assay performance is not affected by the presence or absence of aspirin. Aspirin is known to inhibit platelet function by a different and independent mechanism (COX-1) than the P2Y12 pathway. Platelet dysfunction due to aspirin should not be evaluated with the ADP assay but by another assay such as the AggreGuide A-100 AA Assay
- Other potential interfering substances were screened to ascertain whether the Assay is effected by the presence or absence of the substance.
- The difference between the control mean and the interferent mean was tested using a Student's t-test. If the farthest limit of the 95% confidence interval of the estimate of the difference did not exceed 1.5 PAI (the  $d_{max}$  per protocol), then the substance was judged to not interfere with the assay.
- These substances appear in the following list.

Those substances tested for interference with effect limited to less than 1.5 PAI:

<u>Interferent</u>	<u>Test Concentration</u>	<u>Units</u>
Acetaminophen	15.7	mg/dL
Aminocaproic acid	0.90	mg/dL
Caffeine	11.0	mg/dL
Captopril	0.276	mg/dL
Catechin	2.54	mg/dL
Chlorpromazine	0.303	mg/dL
Cilostazol	2.22	mg/dL
Cimetidine	2.99	mg/dL
Dextran 40	2,425	mg/dL
Diltiazem	0.0090	mg/dL
Dipyridamole	1.01	mg/dL
Fish Oil	32.0	mg/dL
Gabapentin	2.7	mg/dL
Glipizide	0.30	mg/dL
Glucosamine HCl	0.203	mg/dL
Heparin	340.5	U/dL
Ibuprofen	21.8	mg/dL
Insulin	0.00053	mg/dL
Liraglutide	0.0168	mg/dL
L-Thyroxine	5.00	mg/dL
Metformin	1.20	mg/dL
Norfluoxetine	0.0695	mg/dL
Norverapamil	0.056	mg/dL
Omeprazole	0.755	mg/dL
Oxypurinol	1.36	mg/dL
Pravastatin	0.0207	mg/dL
Prednisone	0.121	mg/dL
Propranolol	0.102	mg/dL
Salicylic Acid	2.87	mg/dL
Sitagliptin	0.12	mg/dL
Streptokinase	40200	U/dL
Theophylline	5.70	mg/dL
Valsartan	1.17	mg/dL
Warfarin sodium	7.50	mg/dL

In the case of three potentially interfering substances, the farthest limit of the 95% CI did exceed the 1.5 PAI value of  $d_{max}$ .

t-Test Estimates, PAI				
<u>Interferent</u>	<u>Test Concentration</u>	<u>Units</u>	<u>Difference Of The Means (PAI)</u>	<u>Difference to 95% CI Limit (PAI)</u>
Amlodipine	0.0075	mg / dL	-0.7	- 1.6
Daunorubicin	5.625	mg / dL	-1.2	-1.9
Nitroglycerin	10	mg / dL	-2.6	-2.9

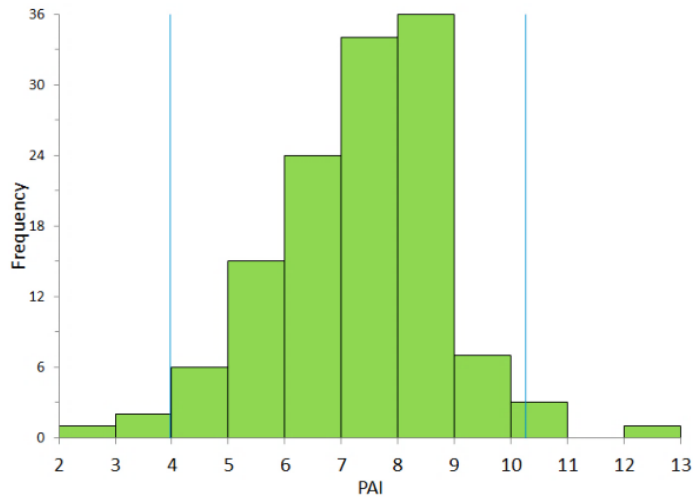
## SERVICE

The AggreGuide is not intended to be serviced by the user. Instruments in need of service must be returned to AggreDyne, Inc. If there are problems related to the AggreGuide, call AggreDyne Customer Support. Customer/Technical Support 866-800-1955

## PERFORMANCE CHARACTERISTICS

### Reference Range

The reference interval was calculated from AggreGuide A-100 ADP assay Platelet Activity Index (PAI) measurements of blood samples collected at baseline, prior to administration of a P2Y12 inhibitor. The nonparametric 5<sup>th</sup>-95<sup>th</sup> percentile limits and their associated 90% confidence intervals were calculated and are reported below. A histogram of baseline PAI results and the reference interval (blue lines) is also provided.



Reference Interval ( N=129 )		
Limit	PAI	( 90% CI )
Lower	4.0	( 3.1 to 4.7 )
Upper	10.3	( 9.6 to 11.6 )

### Expected Values In the Intended Use Population:

Table of Baseline PAI Values (absence of P2Y12 inhibitor treatment)

Baseline Off-Therapy	N = 280	PAI
PAI Value	Mean	7.16
	Median	7.4
	10% Quantile	4.7
	1 <sup>st</sup> Quartile	5.9
	3 <sup>rd</sup> Quartile	8.4
	90% Quantile	9.5

For the purposes of this study, operational definitions were established to describe the nominally expected effect of the P2Y12 drugs on platelet function.

“Full-Effect” describes those drugs that are both potent and observed at times of full pharmacological effect.

“Not-Full-Effect” describes those drugs that were not expected to reach full inhibition of platelet function at the package-insert specified doses used in the study (clopidogrel), or a drug that had reached a waning pharmacological time point in which full inhibition had subsided (ticagrelor at 24-hours post-loading).

“Clinical Truth” describes the expectation that no subjects that are off-treatment with P2Y12 inhibitors will exhibit platelet dysfunction, and that all subjects that are on-treatment at Full-Effect will exhibit platelet dysfunction.

### Method Comparison

The AggreGuide A-100 ADP Assay was validated by means of a clinical trial studying ADP-induced platelet aggregation in the presence of the P2Y12 inhibitor drugs prasugrel, ticagrelor and clopidogrel. The AggreGuide A-100 Assay performance evaluation was based on detection of platelet dysfunction response to drug from the prasugrel and ticagrelor arms of the study because these potent P2Y12 inhibitors can elicit more consistent, substantial and identifiable pharmacological response which enables cut-off-point based assay device sensitivity determinations.

Clopidogrel is a less potent P2Y12 inhibitor that is known to exhibit substantial variability in pharmacological response, especially with the loading dose of 300 mg recommended by the manufacturer [see drug prescribing Information]. Thus,

a cut-point based assessment of the device sensitivity to clopidogrel at the manufacturer recommended loading dose was not suitable for determining assay device performance.

With ticagrelor, the sensitivities (95% CI) of this device that were evaluated at Full-Effect clinical status, within 3 - 6 hrs of loading-dose and after 7-days of maintenance-dose, were found have respective sensitivities of 0.906 (0.825, 0.952) and 0.839 (0.770, 0.890), whereas at 24-hrs post-loading, with a Not-Full-Effect clinical status, the sensitivity was found to be 0.571 (0.491, 0.652). Clinicians must be aware of the clinical status of the antiplatelet therapeutic with respect to dose timing and pharmacodynamics of the P2Y12 inhibitor in use, especially in connection to ticagrelor.

Each drug's individual effect may be dependent on dosage and timing of measurement after the most recent dose. See clinical trial performance data that follows in this Package Insert. Also see the prescribing information for each respective anti-platelet medication.

### QUALITATIVE AGREEMENT

Qualitative Agreement of the AggreGuide A-100 ADP Assay (PAI), the VerifyNow PRU Test, and Clinical Truth (CT);

Table of Negative Percent Agreement (NPA), Positive Percent Agreement (PPA) and Total Percent Agreement (Total PA). Clinical truth data set is the Full-Effect data set using ticagrelor and prasugrel. Cut off for VN PRU Test used was 184 PRU.

	Agreement:	Agreement:		
		NPA	PPA	Total PA
AggreGuide A-100 ADP Assay PAI versus VerifyNow PRU Test	<b>Proportion</b>	<b>91%</b>	<b>88%</b>	<b>89%</b>
	Exact 95% CI -	86%	84%	86%
	Exact 95% CI +	95%	91%	91%
AggreGuide A-100 ADP Assay PAI versus Clinical Truth	<b>Proportion</b>	<b>92%</b>	<b>89%</b>	<b>90%</b>
	Exact 95% CI -	87%	85%	87%
	Exact 95% CI +	95%	92%	92%
VerifyNow PRU Test versus Clinical Truth	<b>Proportion</b>	<b>97%</b>	<b>99%</b>	<b>98%</b>
	Exact 95% CI -	93%	97%	96%
	Exact 95% CI +	99%	100%	99%



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**SPECIFICITY:**

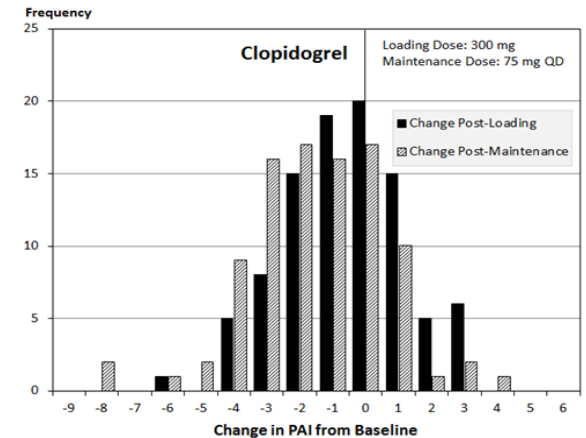
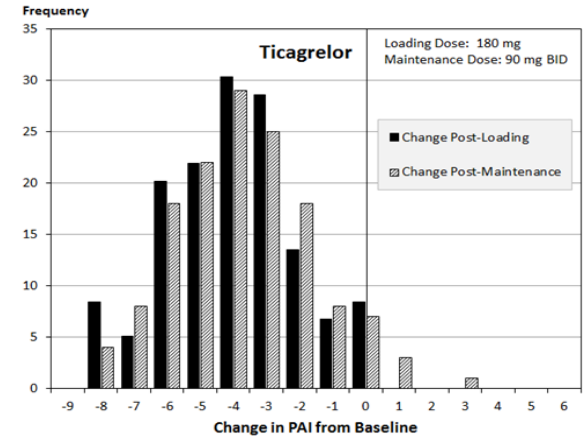
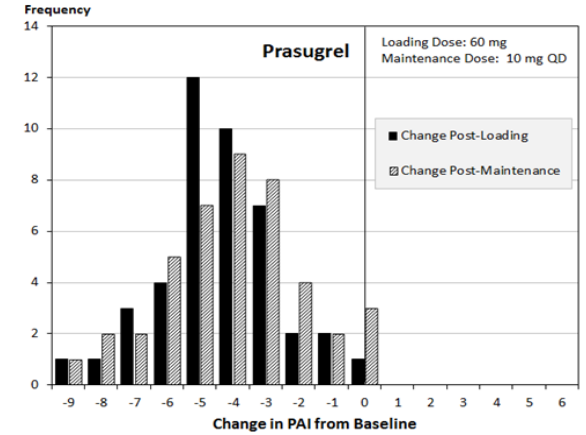
Subjects were tested for platelet function at baseline clinical status ( post-81mg aspirin, but pre-P2Y12 drug) to assess specificity against Clinical Truth. All subjects are in the identical clinical truth status baseline and are reported in the aggregate (All) as well as study arm.

A-100 PAI Specificity		
Arm at Baseline	N	Specificity (95% CI Limits)
All	280	0.907 (0.867 – 0.936)
prasugrel & ticagrelor subjects	186	0.919 (0.871 – 0.951)
prasugrel subjects	43	0.907 (0.774 – 0.973)
ticagrelor subjects	143	0.924 (0.867 – 0.961)
clopidogrel subjects	94	0.883 (0.802 – 0.933)

**SENSITIVITY:**

Subjects were tested for platelet function after administration of P2Y12 anti-platelet drug to assess sensitivity against Clinical Truth.

Sensitivity—Full Effect					
High Potency Anti-Platelet Therapeutics Stratified by Dose Status with Exact Confidence Intervals					
Anti-Platelet Drug	N	Clinical Status	Timing (time from dose)	A-100 PAI (95% CI Limits)	VerifyNow PRU (95% CI Limits)
Prasugrel	43	Full-Effect	Post-Loading (24 hours)	1.000 (0.918 – 1.000)	0.977 (0.877 – 0.996)
	43		Post-Maintenance (7 days)	0.907 (0.784 – 0.963)	0.977 (0.877 – 0.996)
Ticagrelor	85		Post-Loading (3 – 6 hours)	0.906 (0.825 – 0.952)	1.000 (0.957 – 1.000)
	143		Post-Maintenance (7 days)	0.839 (0.770 – 0.890)	0.986 (0.951 – 0.998)
	143	Not-Full-Effect	Post-Loading (24 hours)	0.571 (0.491 – 0.652)	0.860 (0.794 – 0.908)



**Difference in PAI Value from Baseline to On-Treatment Observations.**

Frequency vs. Change in PAI from Baseline at Post-Loading and Post-Maintenance time points for each of the three P2Y12 inhibitor medicines tested. Baseline PAI observation, established "0" per subject. Changes in PAI after Administration of P2Y12-inhibitor Medications:

Medication	Clinical State	Mean PAI Change
Prasugrel	Baseline	0.0 PAI
	Post-Loading	-4.9 PAI
	Post-Maintenance	-4.4 PAI
Ticagrelor	Baseline	0.0 PAI
	Post-Loading	-4.5 PAI
	Post-Maintenance	-4.2 PAI
Clopidogrel	Baseline	0.0 PAI
	Post-Loading	-1.0 PAI
	Post-Maintenance	-2.0 PAI



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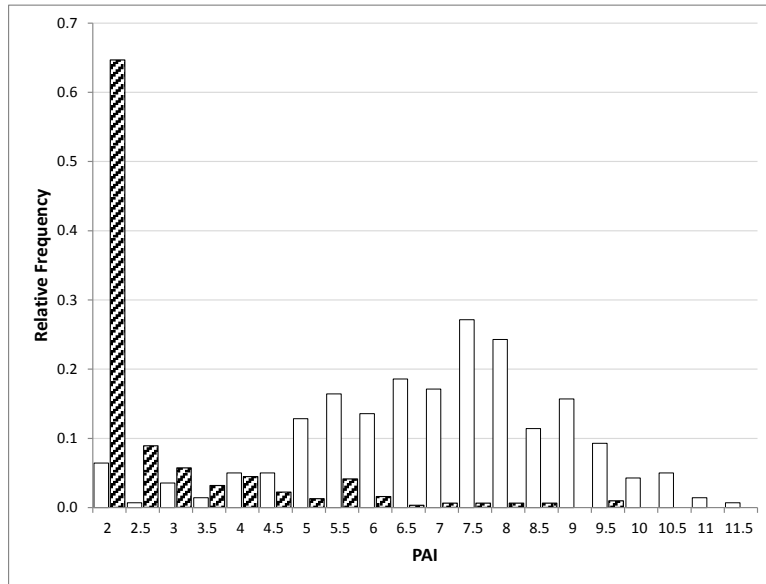


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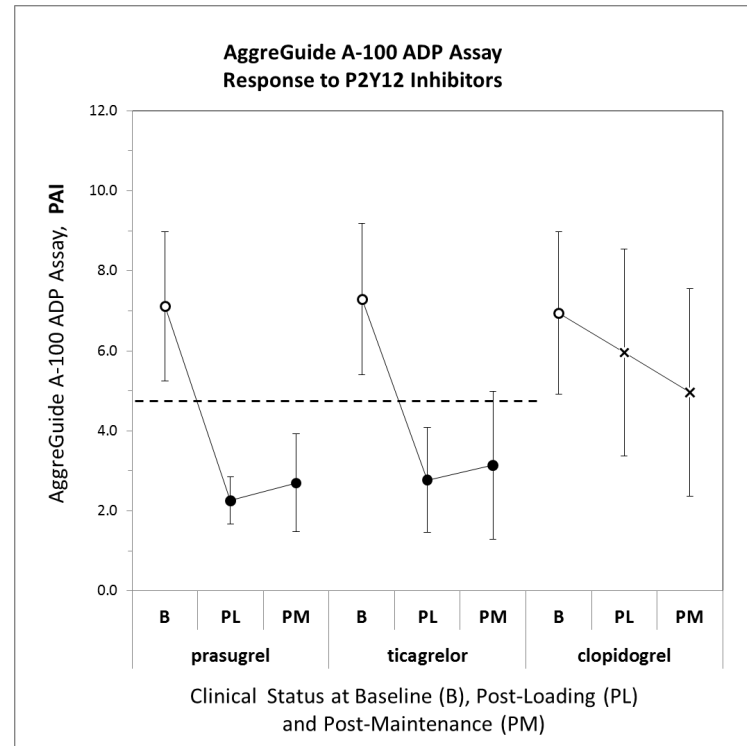


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Histogram Of PAI Values At Baseline (solid white bars) and After Administration Of Potent P2Y12 Inhibitors At Full-Effect (filled bars).



Average of AggreGuide A-100 ADP Assay values in various clinical states of P2Y12-inhibitor treatment. Clinical truth points used in the device validation are shown as circles, representing Baseline (open circles, B) or Full-Effect clinical states (filled circles). Clopidogrel points at Not-Full-Effect ('X') are shown but were not included in the validation analysis.



Expected Values in the Intended Use Population: Off-Therapy (Baseline, **B**) and On-Therapy with P2Y12 Inhibitors (**PL**, post-loading; **PM**, post-maintenance).

Clinical truth data set utilized P2Y12 inhibitors in clinical states of high potency and at full-effect to establish sensitivity, marked in **BOLD** font.

81 mg aspirin prior to baseline and each morning daily.

P2Y12 Inhibitor	Clinical Status	Loading Dose	Maintenance Dose	N	PAI Values				
					Mean	SD	1st Quartile	Median	3rd Quartile
PRASUGREL	<b>B</b>	-	-	43	<b>7.1</b>	<b>1.8</b>	<b>6.0</b>	<b>7.2</b>	<b>8.0</b>
	<b>PL</b>	60 mg	-	43	<b>2.2</b>	<b>0.6</b>	<b>2.0</b>	<b>2.0</b>	<b>2.3</b>
	<b>PM</b>	-	10 mg QD	43	<b>2.7</b>	<b>1.2</b>	<b>2.0</b>	<b>2.0</b>	<b>2.9</b>
TICAGRELOR	<b>B</b>	-	-	143	<b>7.3</b>	<b>1.9</b>	<b>6.0</b>	<b>7.5</b>	<b>8.5</b>
	<b>PL</b>	180 mg	-	85	<b>2.8</b>	<b>1.3</b>	<b>2.0</b>	<b>2.0</b>	<b>3.1</b>
	<b>PM</b>	-	90mg BID	143	<b>3.1</b>	<b>1.8</b>	<b>2.0</b>	<b>2.0</b>	<b>3.5</b>
CLOPIDOGREL	<b>B</b>	-	-	94	<b>6.9</b>	<b>2.0</b>	<b>5.5</b>	<b>7.0</b>	<b>8.6</b>
	<b>PL</b>	300 mg	-	94	6.0	2.6	3.6	6.3	8.0
	<b>PM</b>	-	75 mg QD	94	5.0	2.6	2.0	4.6	6.8

## PRECISION

### Quality Control with the QC2 Device

The “QC2” quality control device is used to make an evaluation of the electro-optical behavior of the AggreGuide A-100 to ensure that gross changes in the system have not occurred. This test is performed by inserting the QC2 device into the A-100 and starting the test that is performed automatically by the system software. No user interpretation is needed for the test. See the AggreGuide A-100 User’s Manual for details.

### Whole Blood Precision Testing

Testing was conducted at three levels of PAI. Each of the Within-Date imprecision standard deviation values are < 0.5 PAI, the acceptance criterion for the levels of PAI tested. (Between-Date and Within-Laboratory imprecision may include variability due to changing platelet biology within each donor, and therefore should not be evaluated against the acceptance criterion. Also, the use of %CV in cases where the measurand value approaches zero is not appropriate because the %CV expression becomes arbitrarily large.)

<u>PAI Level</u>	<u>Mean</u>	<u>Repeatability</u>	<u>Between Run</u>	<u>Within Date</u>
High ( PAI > 6.7 )	3 Date x 11 Run x 3 Observations			
	8.5	0.46	0.15	<b><u>0.48</u></b>
		5.4%	1.8%	5.6%
Mid-Level: 3.7 < PAI < 5.7	3 Date x 9 Run x 3 Observations			
	4.6	0.47	0	<b><u>0.47</u></b>
		10.2%	0.0%	10.2%
Low Level: ( PAI < 3.7 )	3 Date x 7 Run x 3 Observations			
	0.62	0.27	0.12	<b><u>0.30</u></b>



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Manufactured by:  
AggreDYNE, Inc.,  
10530 Rockley Road, Suite 150  
Houston, Texas, USA 77099  
866-800-1955



EC Authorized Representative:  
MT Promedt Consulting, GmbH,  
Altenhofstr. 80  
66386 St. Ingbert, Germany

## STABILITY

**Shelf-Life Stability:** Reagent cartridges are shipped with labeling indicating shelf-life expiration. Do not use reagent cartridges that have expired. In addition, reagent cartridge boxes (carton of 20 pouched cartridges) have a thermally-sensitive indicator which turns black in the event that the box has been exposed to high temperatures. If this indicator is black, do not use the cartridges within that box.

**Blood Sample Stability:** Bench testing indicates that the AggreGuide A-100 ADP Assay should be conducted on blood samples that are between 30 minutes and four hours of having been collected.

**In-Use (Open Pouch) Stability:** Reagent cartridges are shipped and stored in a sealed Mylar® pouch until the time to perform an assay. Immediately prior to running the assay, open the pouch and perform the steps necessary for the assay. These steps should not take more than a few minutes from the time the pouch is opened until the blood is successfully loaded into the cartridge. Testing indicates that these cartridges are stable for at least 12 minutes after the pouch is opened.



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