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INNOVANCE® PFA P2Y

Revision bar indicates update to previous version.

Intended Use

The INNOVANCE® PFA P2Y is a test cartridge for the PFA-100® System and INNOVANCE® PFA-200 System intended for the detection of platelet P2Y12-receptor blockade in patients undergoing therapy with a P2Y12-receptor antagonist. For use in the clinical laboratory with citrated human whole blood.

Summary and Explanation

The PFA Systems consist of an instrument and a test cartridge in which the process of platelet adhesion and aggregation following a vascular injury is simulated *in vitro*[1-4].

INNOVANCE® PFA P2Y is used to detect platelet dysfunction induced by the blockade of the platelet P2Y12-receptor.

Principle of the Method

The PFA Systems together with INNOVANCE® PFA P2Y enable the detection of platelet ADP-receptor blockade in small samples of anticoagulated whole blood. INNOVANCE® PFA P2Y is a single use test cartridge for the PFA Systems consisting of a number of integrated parts including a capillary, a sample reservoir and a biochemically active membrane with a central circular aperture. Citrated whole blood is aspirated from the sample reservoir through the capillary and the aperture, thereby exposing platelets to high shear flow conditions. The membrane is coated with ADP, a physiologic agonist that activates platelets via ADP-receptor pathways (principally, P2Y1 and P2Y12). In addition, to enhance diagnostic performance, the membrane is coated with ionic calcium and prostaglandin E1 (PGE1). At the beginning of a PFA test, Dade® PFA Trigger Solution is dispensed on the membrane to dissolve the three reagents ADP, calcium and PGE1. During the test, platelets adhere to the membrane under high shear conditions. Then, due to the interaction with the membrane and the dissolved reagents, platelets become activated, release their granule contents, and start to aggregate. This process of platelet aggregation leads to platelet thrombus formation at the aperture, thereby gradually diminishing and finally arresting the blood flow.

The PFA Systems determine the time from the start of the test until the occlusion of the aperture, and report that time interval as the Closure Time (CT). The CT is an indicator of platelet function in the analyzed whole blood sample. Platelet plug formation in the PFA Systems is affected by low platelet counts and/or activity, a reduced plasma level of von Willebrand factor, and additionally, by a decreased hematocrit because of the flow process.

Reagents

Materials provided

INNOVANCE® PFA P2Y REF B4170-22

20 x INNOVANCE® PFA P2Y CARTRIDGE, INNOVANCE® PFA P2Y test cartridge

Composition

INNOVANCE® PFA P2Y: 20 µg Adenosine-5'-diphosphate (ADP), 5 ng Prostaglandin E1 (PGE1) and 125 µg ionic Calcium (as 431 µg calcium dichloride dihydrate ($CaCl_2$ x 2 H_2O)).

Warnings and Precautions

For *in-vitro* diagnostic use.

All blood samples and blood components should be treated as potentially infectious. All samples should be handled in accordance with good laboratory practices using appropriate precautions.

Protective equipment should be worn when inserting or removing with whole blood loaded cartridges from the carousel.

Do not disassemble the test cartridge.

There is a risk of exposure to blood droplets when removing the test cartridge from the carousel.

Preparation of the Test Cartridge

a. Allow the pouch containing the test cartridges to warm-up to 15 to 25 °C prior to opening. This takes approximately 15 minutes. After removal of the cartridge, immediately reseal the pouch.
b. Remove and discard the top foil from the test cartridge. This top foil only protects against dust and other particles. Performance and stability of the test cartridge is not affected in case of incomplete sealing by the top foil.
Note: If the top foil has clearly been damaged or is missing, do not use the test cartridge. Discard it in an appropriate waste container.
c. Place the test cartridge in the cassette of the PFA System in position **A** and push until the test cartridge securely snaps in place. (For details refer to the respective PFA System's Instruction Manual).

Storage and Stability

INNOVANCE® PFA P2Y in the unopened pouch is stable at 2 to 25 °C until the expiry date printed on the label. The test cartridge is stable 3 months after opening and reclosing the pouch when stored at 2 to 25 °C. After removal of the top foil, the test cartridge is stable for 12 hours at 15 to 25 °C.

Materials required but not provided

1. PFA-100® System, with software version 3.0 or higher, or INNOVANCE® PFA-200 System.
2. Dade® PFA Trigger Solution, PFA TRIGGER, REF B4170-50
3. Evacuated blood collection tubes or syringes containing 3.8 % (0.129 M) or 3.2 % (0.105 M) buffered sodium citrate (1 part anticoagulant to 9 parts blood).
4. Pipetting devices capable of measuring up to 800 µL.

For details refer to the respective PFA System's Instruction Manual.

Specimen

Specimen Collection and Preparation

All investigations of platelet function are strongly dependent on the correct method of blood collection. Venipuncture should be performed using a 21G or larger needle (20G or 19G).

Blood should be drawn directly into an evacuated plastic or siliconized glass tube or syringe containing 3.8 % (0.129 M) or 3.2 % (0.105 M) **buffered** sodium citrate (1 part anticoagulant to 9 parts blood). **The use of unbuffered sodium citrate anticoagulant is not recommended.**

Important! After sample collection, ensure proper mixing of anticoagulant by gently inverting the tube by hand 3 to 4 times. Discard the sample if there is a venous collapse or stoppage of blood flow during collection. Samples must be stored undisturbed at 15 to 25 °C and are stable for 4 hours. **The collection method (both citrate concentration and venipuncture method) should be kept consistent.**

Procedure

Sample Loading

The following steps must be performed in sequence without interruption:

a. Mix the blood sample by inverting the collection tube gently by hand 3 to 4 times. Holding the cassette with test cartridge on a flat surface, pipette 800 µL of blood into the smaller opening (sample reservoir opening) of the test cartridge by dispensing slowly along one of the inside surfaces. This will reduce the possibility of air entrapment in the sample reservoir.
Note: PFA Systems are incapable of detecting bubbles in the test cartridge.

b. Place the cassette with the test cartridge in position A into the incubation well of the PFA Systems so that the cassette is flush to the carousel surface. **Do not apply pressure to the sample reservoir opening.**

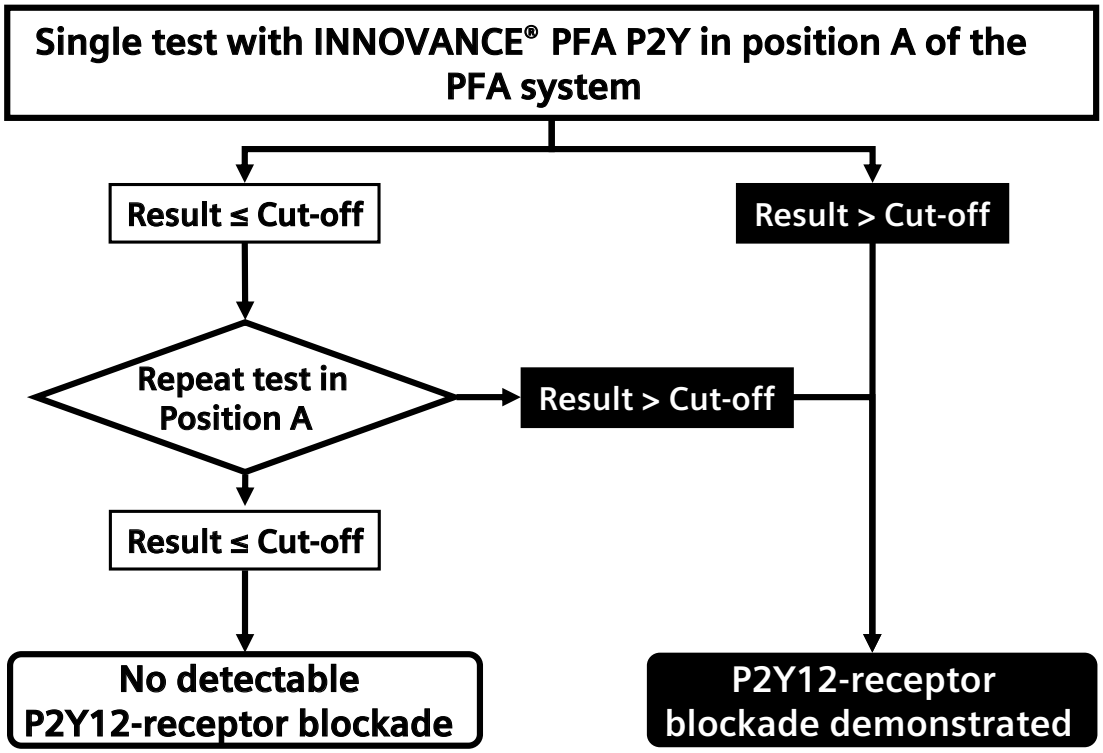
c. Start the test.

Test Procedure

INNOVANCE® PFA P2Y testing is strictly limited to position A of a PFA System. Position B must not be used!

- Run a single test with INNOVANCE® PFA P2Y in position A of the PFA Systems.
- If the INNOVANCE® PFA P2Y closure time obtained in this initial test exceeds the analytical cut-off, a platelet P2Y12-receptor blockade has been demonstrated (please also refer to chapter “Limitations of Procedure”).
- In case the INNOVANCE® PFA P2Y closure time obtained with the initial test is below or equal to the analytical cut-off, please repeat the test with the same blood sample again in position A of the PFA System following the instructions in the sub-chapter "Sample loading".
- If the INNOVANCE® PFA P2Y closure time of the repeat test exceeds the analytical cut-off, a P2Y12-receptor blockade has been demonstrated (please also note the chapter "Limitations of Procedure").
- If the INNOVANCE® PFA P2Y closure time of the repeat test is again below or equal to the analytical cut-off, a P2Y12-receptor blockade is not detectable.

The test procedure is summarized in the following flow-chart:



Disposal of used test cartridge

Remove the cassette carefully from the carousel. Hold the cassette in one hand, while removing the test cartridge with the other hand by gently pulling the bottom of the test cartridge sideways until it unsnaps. Dispose the test cartridge in a suitable biohazard waste container.

Quality Control

System

At the start of each workshift, perform "Self Test" from the "Maintenance Menu". For details refer to the respective PFA System's Instruction Manual.

Cartridge

General performance

For the purpose of QC testing it is recommended to establish a control donor group. The Dade® PFA Collagen/EPI Test Cartridge (Col/EPI) may be used to qualify control donors. The qualified QC donors should have a Col/EPI closure time near the middle of the reference range established by the laboratory and acceptable replicate results.

The following procedure is an example of how to establish a control donor group:

1. Potential donors should not have any diseases or take medications known to influence platelet function.
2. Test the sample buffered with 3.8 % sodium citrate of each potential donor only with Col/EPI cartridges twice.
3. Qualify the donor if the printed duplicate mean is within 102 to 146 seconds and the CV is less than or equal to 15 %. (Note: This range was determined from the mean CT ±22 seconds of blood samples collected in 3.8 % buffered sodium citrate from 127 ostensibly healthy adults in a Germany based multicenter study, see also "Expected Values" in the Instructions for Use "Dade® PFA Collagen/EPI Test Cartridge and Dade® PFA Collagen/ADP Test Cartridge".)
   Note: The acceptable range may need to be modified depending on the mean CT established by individual laboratories for healthy adults.

It is recommended that the laboratory run the quality control procedure in a manner consistent with its established quality control program and in conformance with local, state, and/or federal regulations or accreditation requirements.

As part of routine quality control, collect a whole blood specimen from one individual of the control donor group once each week of testing or whenever the institution wishes to verify the performance of the respective system. Test this donor's blood specimen twice with INNOVANCE® PFA P2Y in position A of the PFA System. INNOVANCE® PFA P2Y is fully functional if both CT obtained are below or equal to the analytical cut-off. If one or both CT are above the analytical cut-off, repeat this procedure with the sample of a second individual from the laboratory´s control donor group. If one or both CT from the second individual are also above the analytical cut-off, contact Siemens Healthcare Diagnostics for assistance.

If both results of the second individual are below or equal to the analytical cut-off, the platelet function status and medication history of the first individual should be suspected. The first individual should be excluded from the INNOVANCE® PFA P2Y control donor group.

Results

The results of INNOVANCE® PFA P2Y are reported by the PFA Systems as Closure Time (CT) in seconds (s). Following the test procedure for INNOVANCE® PFA P2Y the CT obtained indicates whether platelets with the P2Y12-receptor blockade are present in the specimen measured. **In general, INNOVANCE® PFA P2Y closure times ≤ 106 seconds are considered "normal", while those exceeding 106 seconds are viewed as "abnormal".**

An INNOVANCE® PFA P2Y CT above the analytical cut-off in patients who are not under therapy with anti-platelet drugs may indicate the need for further diagnostic testing. Results should always be evaluated in conjunction with clinical history, clinical presentation and other laboratory findings (e.g. complete blood count (CBC) or platelet aggregometry). In cases where INNOVANCE® PFA P2Y results do not agree with the clinical assessment, additional tests should be performed.

Limitations of the Procedure

1. Microthrombi in the sample or particulates introduced into the sample from the environment could adversely affect the test results and/or cause a cancellation of the test due to the detection of a flow obstruction.
2. Only a CT above the analytical cut-off could reflect reduced platelet function caused by an abnormally low hematocrit level (< 29 %) and/or an abnormally low platelet count (< 101,000/µL). Specimens with hematocrit levels > 50 % or platelet counts > 475,000/µL have not been evaluated.
3. Patients with inherited disorders of primary hemostasis such as von Willebrand Factor Deficiency (VWD) or inherited severe platelet disorders such as Glanzmann Thrombasthenia and Bernard-Soulier Syndrome have not been studied with INNOVANCE® PFA P2Y. INNOVANCE® PFA P2Y is not intended for use in patients with these types of inherited disorders.
4. The performance characteristics of INNOVANCE® PFA P2Y have not been established for agents affecting primary hemostasis or platelet function other than P2Y12-receptor antagonists and acetylsalicylic acid (ASA).
5. INNOVANCE® PFA P2Y generates analytical results based on platelet P2Y12-receptor blockade. The correlation to clinical outcomes has not been established.
6. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Interfering Substances

1. Hemolysis may interfere with test results. The lysis of red cells indicated by the presence of free hemoglobin could affect the PFA CT for two reasons: 1) reduction in hematocrit and 2) release of ADP. Therefore, use of hemolytic blood for PFA testing is not recommended.
2. Certain fatty acids and lipids found in various human diets are widely known to inhibit platelet function[5,6]. Neutral lipids, such as cholesterol, generally have no effect on platelet function[7].
3. Although not evaluated, it is well known that GPIIb/IIIa-receptor antagonists as well as desmopressin acetate (1-deamino-8-D-arginine vasopressin; DDAVP) interfere with the PFA test principle independently of the test cartridge type used[8-10].
4. Commonly used drugs or certain substances in food may influence the closure time of the INNOVANCE® PFA P2Y cartridges. The table below summerizes substances which affect the closure time (prolongation) of INNOVANCE® PFA P2Y cartridges at the given and higher concentrations (according to an internal study). The results of the spiked sample and the native sample (same donation and position in the system) were evaluated for each substance using a paired t-test. A p-value < 0.05 was defined as significant interference.

Drug Category	Substance	Concentration	Concentration (S.I. units)	Influence on closure time
Anti-platelet drug	Cilostazol	5 µg/mL	13.5 µmol/L	prolongation
	Tirofiban	0.1 µg/mL	0.2 µmol/L	prolongation
Thrombolytic	Streptokinase	100 IU/mL	100,000 IU/L	prolongation

Non-interfering Substances

The following substances and drugs do not affect the closure time of the INNOVANCE® PFA P2Y cartridges when present in plasma at the concentrations indicated. When evaluating samples spiked with the respective substance and the native samples (same donation and position in the system) using a paired t-test, the p-value was > 0.05.

Drug Category	Substance	Concentration	Concentration (S.I. units)
ACE inhibitor	Captopril	25 µg/mL	115.1 µmol/L
Alcohol	Ethanol	5 µg/mL	85.7 mmol/L
Antiarrhythmic	Lidocaine	25 µg/mL	106.7 µmol/L
Antibiotic	Penicillin G	20,000 IU/mL	20,000,000 IU/L
Antidepressant	Fluoxetine	25 µg/mL	80.8 µmol/L
Anticoagulant	Low molecular weight heparine	1.5 IU/mL	1500 IU/L
Antioxidant	Catechin	25 µg/mL	86.2 µmol/L
	α-Tocopherol	25 µg/mL	58.0 µmol/L
Beta-Blocker	Propranolol	25 µg/mL	96.4 µmol/L
Bronchodilator	Theophylline	25 µg/mL	138.8 µmol/L
Diuretic	Hydrochlorothiazide	25 µg/mL	84.0 µmol/L
Anti-inflammatory drug	5-Aminosalicylic acid	50 µmol/L	50 µmol/L

Drug Category	Substance	Concentration	Concentration (S.I. units)
Glucocorticoid	Betamethasone	25 µg/mL	63.7 µmol/L
Calcium channel blocker	Diltiazem	25 µg/mL	60.3 µmol/L
Coronary vasodilator	Nitroglycerin	0.1 µg/mL	0.4 µmol/L
Analgesic	Ibuprofen	25 µg/mL	121.2 µmol/L
	Acetaminophen	25 µg/mL	165.4 µmol/L
Phosphodiesterase inhibitor	Caffeine	20 µg/mL	103.0 µmol/L
Phosphodiesterase V inhibitor	Sildenafil	5 µg/mL	10.5 µmol/L
Thyroid hormone	L-Thyroxine	0.4 µg/mL	0.5 µmol/L
Statin	Pravastatin	25 µg/mL	58.9 µmol/L
Anti-platelet drug	Acetylsalicylic acid	50 µmol/L	50 µmol/L
	Dipyridamole	10 µg/mL	19.8 µmol/L

Expected Values

Clinical Study in Individuals pre/post ASA Usage

134 ostensibly healthy individuals with no previous history or laboratory results indicative of platelet dysfunction induced by intrinsic platelet defects, VWD or exposure to platelet inhibiting agents were included in this single center clinical study. Closure times of blood samples collected in 3.2 % and 3.8 % buffered sodium citrate pre- and 24 hours post-ingestion of 300 mg ASA were determined and compared to evaluate the impact of ASA.

Non-parametric statistical analysis revealed a just statistically significant but clinically negligible impact of the ingestion of 300 mg ASA on the closure time of INNOVANCE® PFA P2Y from blood samples collected in 3.2 % or 3.8 % buffered sodium citrate.

Clinical Study pre/post Clopidogrel Usage in Cardiovascular Disease Patients

Cardiovascular disease patients not taking but scheduled to receive Clopidogrel were tested in this multicenter clinical study. These individuals had no history or laboratory results indicative of platelet dysfunction induced by intrinsic platelet defects, VWD or exposure to platelet inhibiting agents other than ASA. Those patients who actually received a loading dose of 600 mg Clopidogrel were tested again with INNOVANCE® PFA P2Y 6 to 24 hours after the intake of Clopidogrel.

Additionally, cardiovascular disease patients receiving 75 mg Clopidogrel for at least 7 days were tested.

Analytical cut-off derivation

122 donors were included in the derivation of the analytical cut-off. Patients with an abnormal closure time of the Dade® PFA Collagen/ADP Test Cartridge (Col/ADP) were excluded. The analytical cut-off was derived by separately calculating the 95th percentile of the closure times of these patients obtained in 3.2 % buffered sodium citrate and 3.8 % buffered sodium citrate samples prior to the intake of a Clopidogrel loading dose. The 95th percentiles of the closure times in 3.2 % buffered sodium citrate and 3.8 % buffered sodium citrate samples were not statistically different. Therefore, the 95th percentile of closure times from 122 cardiovascular disease patients collected in 3.8 % buffered sodium citrate was defined as the analytical cut-off for INNOVANCE® PFA P2Y:

106 seconds

Analysis of the 95th percentiles of closure times from the 134 ostensibly healthy individuals pre and post 300 mg ASA in 3.2 % and 3.8 % buffered sodium citrate also showed no statistically significant differences from the analytical cut-off.

Therefore, this analytical cut-off is valid for:

- Samples in 3.2 % buffered sodium citrate as well as samples in 3.8 % buffered sodium citrate
- Individuals free of ASA as well as individuals on ASA therapy
- Ostensibly healthy individuals as well as cardiovascular disease patients

As differences in donor population, and other factors may affect results, it is recommended that each laboratory demonstrates transference of the provided analytical cut-off (refer to CLSI guideline C28-A3[11]). If transference of the analytical cut-off cannot be verified, the laboratory should establish its own analytical cut-off.

Performance Characteristics

Precision

Within-run Coefficient of Variation

In a study carried out on ostensibly healthy individuals the following data were obtained: For the determination of within-run precision, the coefficient of variation (CV) of two consecutive measurements with INNOVANCE® PFA P2Y in position A of the PFA-100® System was 10.0 % (mean CV of 525 replicate measurements).

Between-run Coefficient of Variation

Specimens collected from 20 ostensibly healthy volunteers in 3.2 % buffered sodium citrate were measured with INNOVANCE® PFA P2Y twice in position A of the PFA-100® System 30 minutes (run 1) and 240 minutes (run 2) after venipuncture. The mean of the two runs was used to calculate the mean between-run CV of 7.7 %.

Detection of P2Y12-Receptor Blockade in 3.2 % buffered sodium citrate

Patients measured 6 to 24 hours after a loading dose of 600 mg Clopidogrel and patients measured after at least 7 days ingestion of 75 mg daily Clopidogrel were analyzed separately. The analytical cut-off and the testing algorithm for INNOVANCE® PFA P2Y were used to detect the presence or absence of P2Y12-receptor blockade.

	N	**INNOVANCE® PFA P2Y CT ≤ 106 s (normal)**	**INNOVANCE® PFA P2Y CT > 106 s (abnormal)**
Patients 6 – 24 hours after a 600 mg Clopidogrel loading dose	**136**	**33** (24.3 %)	**103** (75.7 %)
Patients receiving 75 mg Clopidogrel daily (≥ 7 days)	**95**	**27** (28.4 %)	**68** (71.6 %)

Detection of P2Y12-Receptor Blockade in 3.8 % buffered sodium citrate

Patients measured 6 to 24 hours after a loading dose of 600 mg Clopidogrel and patients measured after at least 7 days ingestion of 75 mg daily Clopidogrel were analyzed separately. The analytical cut-off and the testing algorithm for INNOVANCE® PFA P2Y were used to detect the presence or absence of P2Y12-receptor blockade.

	N	INNOVANCE® PFA P2Y CT ≤ 106 s (normal)	INNOVANCE® PFA P2Y CT > 106 s (abnormal)
Patients 6 – 24 hours after a 600 mg Clopidogrel loading dose	**132**	**22** (16.7 %)	**110** (83.3 %)
Patients receiving 75 mg Clopidogrel daily (≥ 7 days)	**92**	**13** (14.1 %)	**79** (85.9 %)

Diagnostic Specificity

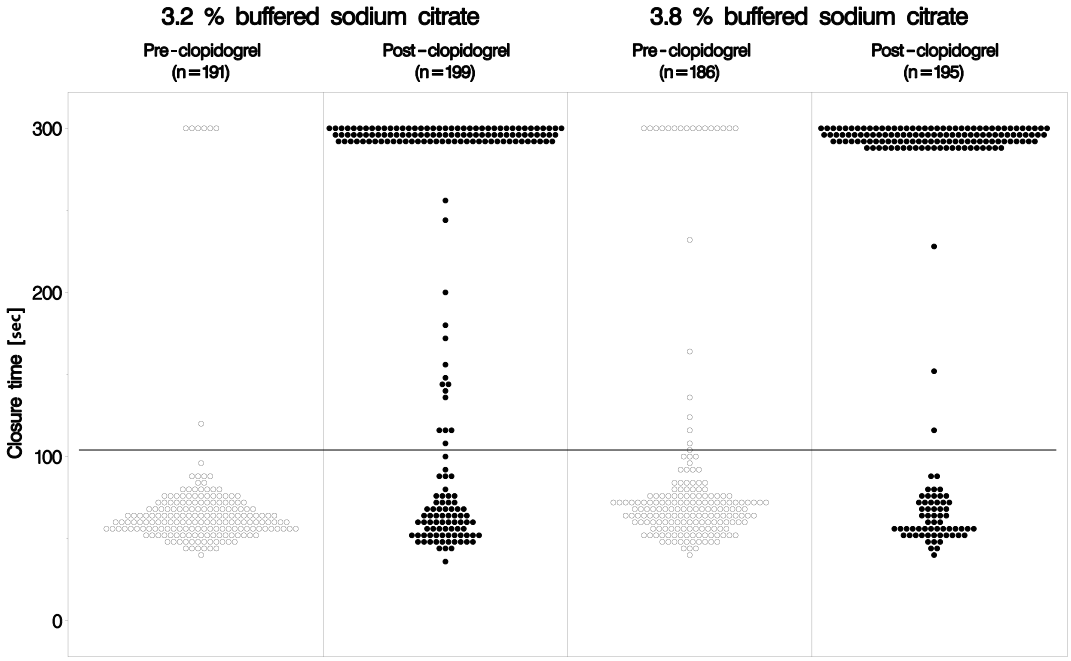
The specificity of INNOVANCE® PFA P2Y based on the analytical cut-off and the recommended testing algorithm was determined from the results of patients not taking Clopidogrel and ostensibly healthy individuals 24 hours after the intake of 300 mg ASA.

	3.2 % buffered sodium citrate	3.8 % buffered sodium citrate
Specificity (patients)	**95.2 %** (N = 206)	**87.9 %** (N = 190)
Specificity (healthy individuals)	**98.5 %** (N = 134)	**91.8 %** (N = 134)

Note: Patients with an abnormal closure time of the Dade® PFA Collagen/ADP Test Cartridge (Col/ADP) were excluded from the determination of the diagnostic specificity. Including these patients would result in a diagnostic specificity of 92.1 % for 3.2 % buffered sodium citrate and 85.4 % for 3.8 % buffered sodium citrate.

Distribution of results

The distributions of INNOVANCE® PFA P2Y closure time pre- and post-ingestion of Clopidogrel depending on the anticoagulation used are depicted in the following histograms (line represents the analytical cut-off):



Concordance Study

Results from 199 patients either 6 to 24 hours after receiving a loading dose of ≥ 300 mg Clopidogrel or on 75 mg Clopidogrel daily for at least 7 days were used for the statistical

analysis of concordance between INNOVANCE® PFA P2Y and whole blood aggregometry (WBA) with 10 µM ADP.

Using the statement on drug efficacy in the prescribing information of PLAVIX[12] as guidance, an inhibition of the aggregation signal recorded with WBA of > 40 % was used to define the detection of P2Y12-receptor blockade by the assay either 6 to 24 hours after a loading dose of 300 or 600 mg Clopidogrel or after at least 7 days of 75 mg Clopidogrel daily. The analytical cut-off of 106 seconds and the testing algorithm for INNOVANCE® PFA P2Y were used for the detection of P2Y-receptor blockade by INNOVANCE® PFA P2Y in the same samples.

The following two-by-two table was calculated from the results of both methods for the detection of P2Y-receptor blockade:

		INNOVANCE® PFA P2Y closure time > 106 seconds	
Inhibition of WBA 10 µM ADP > 40 %	**No**	**Yes**	Total
No	**46**	**16**	62
Yes	**27**	**110**	137
Total	73	126	199

Applying agreement statistics to the two-by-two table above a Cohen's Kappa coefficient of 0.52 was calculated indicating a moderate agreement between the two methods[13].

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Definition of Symbols

	Do not reuse	CCYY-MM-DD	Use By
LOT	Batch Code	REF	Catalogue Number
	Caution, consult accompanying documents		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
NON STERILE	Non-sterile	CE	CE mark
CONTENTS	Contents	→	Reconstitution volume
LEVEL	Level		

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SIEMENS

CE

Dade® PFA Trigger Solution

PFA TRIGGER

Numatytasis naudojimas

Padėti aptikti trombocitų disfunkciją citruotame visos sudėties žmogaus kraujyje.

Reagentai

Tiekiamos medžiagos

PFA TRIGGER, REF B4170-50

3 x 11 ml, PFA TRIGGER, Dade® PFA skatinamasis tirpalas

Sudėtis

Dade® PFA skatinamasis tirpalas: izotoninis druskos fiziologinis tirpalas (0,9 %)

Įspėjimai ir atsargumo priemonės

Skirta *in vitro* diagnostikai.

Reagento paruošimas

Dade® PFA Trigger Solution yra paruoštas naudojimui.

Laikymas ir stabilumas

Stabilumas nuo 16–26 °C temperatūroje:

galiojimo pabaigos datą žr. etiketėje.

Stabilumas prietaise:

60 dienų.

Jei Dade® PFA skatinamajame tirpale matyti drumstumas ar nuosėdos, jį reikia išmesti.

Būtinos, bet netiekiamos medžiagos

PFA sistema

Papildomos medžiagos ir eksploataciniai ištekliai, aprašyti PFA sistemos naudojimo vadove.

Procedūra

Dade® PFA skatinamąjį tirpalą galima naudoti nepriklausomai nuo tyrimo kasečių ir partijos numerio. Išsamesnės informacijos apie tyrimo procedūros principą, būtinas papildomas medžiagas, tyrimo rezultatų skaičiavimą, vidinę kokybės kontrolę ir specifines eksploatavimo ypatybes galite rasti tyrimo kasečių naudojimo instrukcijose ir atitinkamame PFA sistemos naudojimo vadove.

Simbolių apibrėžimai

	Nenaudoti pakartotinai		Sunaudoti iki
LOT	Partijos kodas	REF	Katalogo numeris
	Perspėjimas, žr. kartu pateiktus dokumentus		Gamintojas
EC REP	Įgaliotasis atstovas Europos Bendrijoje		Turinio pakanka atlikti <n> tyrimų
	Biologinis pavojus	IVD	*In Vitro* diagnostikos medicinos įrenginys
	Temperatūros apribojimas		Žr. naudojimo instrukcijas
	Nesterilu		CE ženklas
CONTENTS	Sudėtis		Tirpinimo tūris
LEVEL	Lygis		

Dade® yra Siemens Healthcare Diagnostics prekinis ženklas.

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