

Multiplate[®] analyzer
*Cut-off-values ADPtest
and ASPItest*



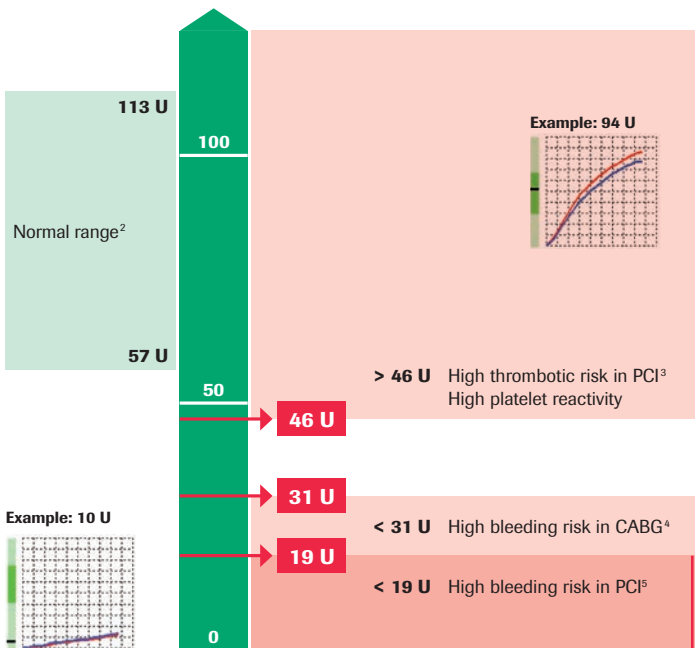
Cut-off values ADPtest

The cut-off values were established in hirudin blood samples.

Healthy individuals

AUC (U)¹

Patient on ADP receptor antagonist therapy



1. Multiplate AUC: 1U = 10 AU*min

2. ADPtest Package Insert (06673686001V2), 2012, Roche Diagnostics GmbH.

3. Sibbing, D., et al., Platelet reactivity after clopidogrel treatment assessed with point-of-care analysis and early drug-eluting stent thrombosis. *J Am Coll Cardiol*, 2009. 53(10): p. 849-856.

57 U - 113 U

Normal range (healthy blood donors)²

Expected values (5th to 95th percentile) have been established in a study with 53 healthy donors who have not ingested acetylsalicylic acid or clopidogrel within 10 days prior to testing.

> 46 U

High thrombotic risk in PCI³ - High platelet reactivity

In a study with 1,608 CAD patients undergoing percutaneous coronary intervention (PCI) with drug-eluting stent implantation low responders exhibited a 9.4 fold increased risk of definite ST within 30 days compared to normal responders, (2.2% vs. 0.2%; odds ratio [OR]: 9.4; 95% confidence interval [CI]: 3.1 to 28.4; p < 0.0001).

< 31 U

High bleeding risk in CABG⁴

Patients undergoing cardiac surgery (CABG) with impaired platelet function after discontinuation of dual anti-platelet therapy are at 3.7 fold increased risk of massive bleeding and 2.5 fold risk of platelet transfusion requirements.

< 19 U

High bleeding risk in PCI⁵

In a study with 2,533 CAD patients scheduled for drug-eluting stent PCI, patients were preloaded with 600 mg clopidogrel and subsequently tested with Multiplate ADPtest for clopidogrel response. The incidence of major bleeding was 2.6 fold higher in enhanced clopidogrel responders (n = 975) as compared with the remaining patients (n = 1,558) [21 (2.2%) vs. 13 (0.8%); OR 2.6, 95% CI 1.3 - 5.2; P = 0.005]. The lower cut-off value for bleeding in PCI vs. CABG can be explained by the less invasive approach of PCI and hence lower dependency on sufficient platelet function.

4. Ranucci, M., et al., Multiple electrode whole-blood aggregometry and bleeding in cardiac surgery patients receiving thienopyridines. *Ann Thorac Surg*, 2011. 91(1): p. 123-129.

5. Sibbing, D., et al., Antiplatelet effects of clopidogrel and bleeding in patients undergoing coronary stent placement. *J Thromb Haemost*, 2010. 8(2): p. 250-256.

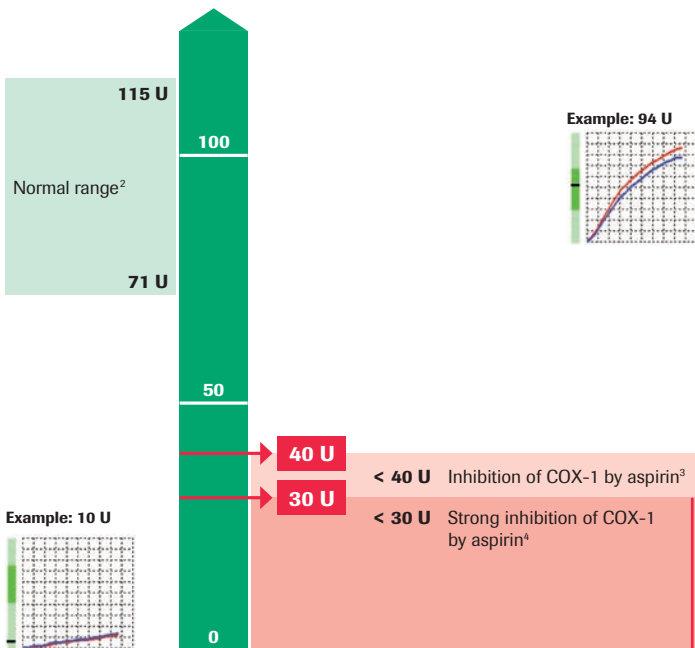
Cut-off values ASPItest

The cut-off values were established in hirudin blood samples.

Healthy individuals

AUC (U)¹

Patient on aspirin therapy



1. Multiplate AUC: 1U = 10 AU*min

2. ASPItest Package Insert (06673821001V2), 2012, Roche Diagnostics GmbH.

3. Al-Azzam, S.I., et al., The prevalence and factors associated with aspirin resistance in patients premedicated with aspirin. *Acta Cardiol*, 2012. 67(4): p. 445-448.

71 U - 115 U

Normal range (healthy blood donors)²

Expected values have been established in a study with 50 healthy donors who have not ingested acetylsalicylic acid or clopidogrel within 10 days prior to testing.

< 40 U

Inhibition of COX-1 by aspirin³

Study performed with 418 patients under aspirin therapy. Aspirin resistance is associated with female gender and diabetes.

< 30 U

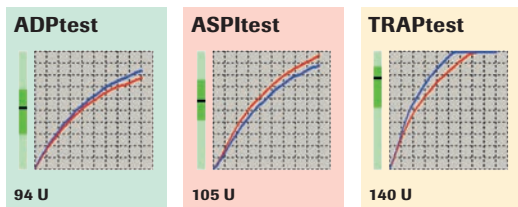
Strong inhibition of COX-1 by aspirin⁴

Cut-off for response/non-response to aspirin was evaluated in a study including 76 patients under aspirin treatment.

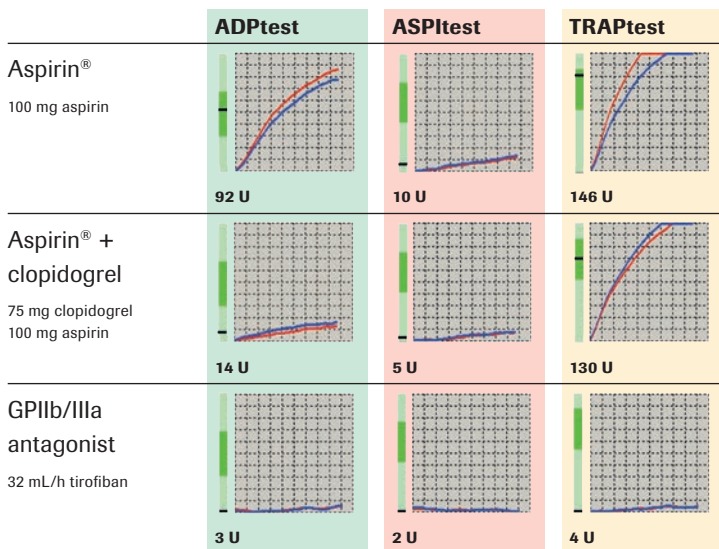
4. von Pape, K.-W., et al., [Control of aspirin effect in chronic cardiovascular patients using two whole blood platelet function assays. PFA-100 and Multiplate]. *Hamostaseologie, 2007. 27(3):* p. 155-60; quiz 161-2.

Typical examples of test results

Healthy individual with no platelet inhibition



Medication **Normal responder**



Multiplate AUC: 1U = 10 AU*min

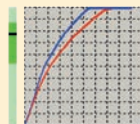
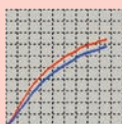
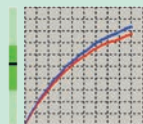
Low responder

Comments

ADPtest

ASPItest

TRAPtest

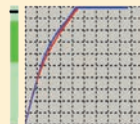
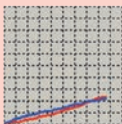
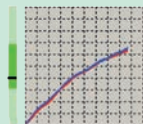


94 U

81 U

140 U

Aspirin[®]
low-response



69 U

20 U

166 U

Clopidogrel
low-response

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Version 2.0

