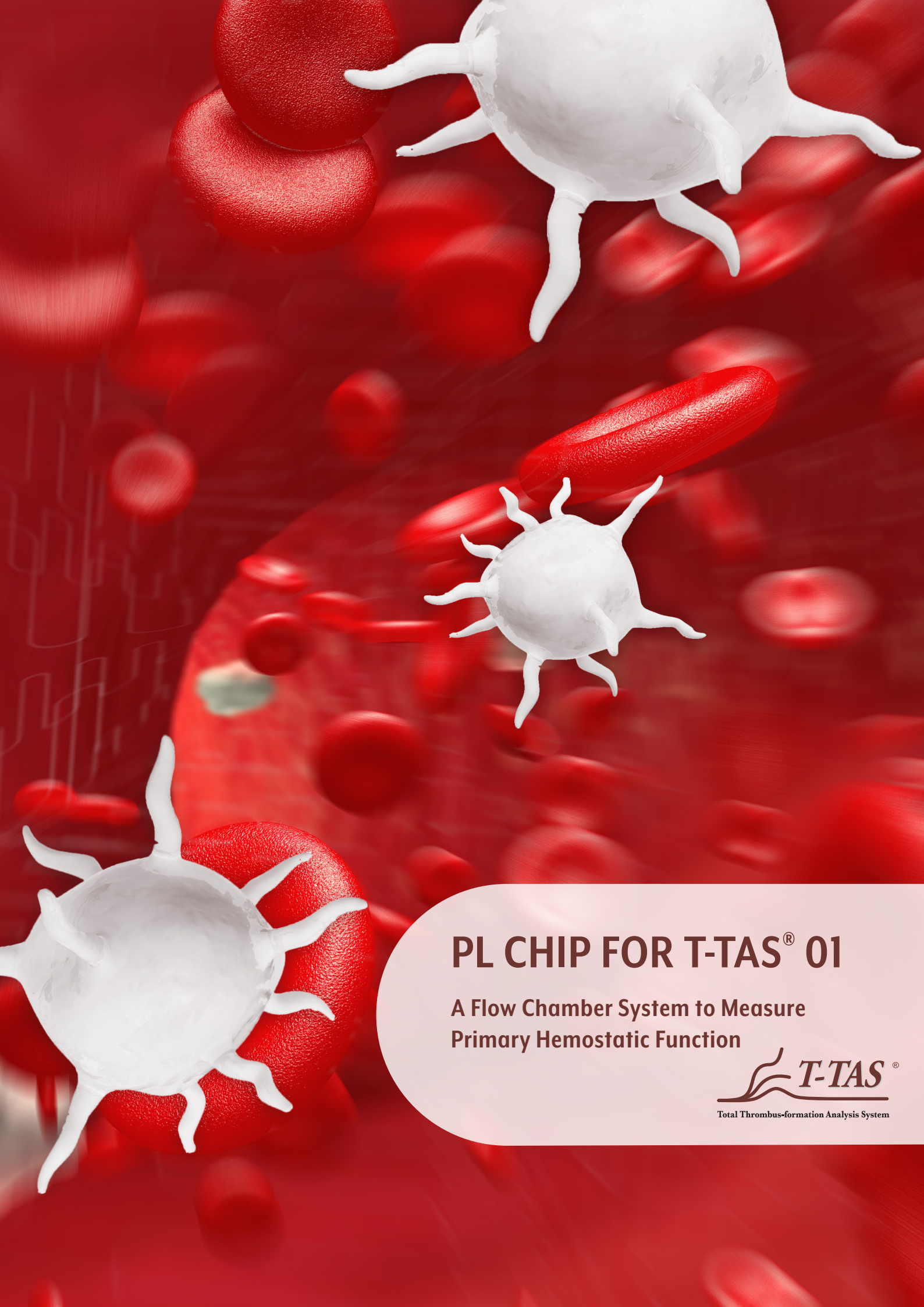


PL CHIP FOR T-TAS® 01

A Flow Chamber System to Measure Primary Hemostatic Function

T-TAS®

Total Thrombus-formation Analysis System

WHERE CLINICALLY SIGNIFICANT BLEEDING IS POSSIBLE...

Surgery

Interventional Procedures

Trauma

Comprehensive Hemophilia Treatment Center

...it's important to know if the patient's primary hemostasis is normal.

PRIMARY HEMOSTASIS CAN HAVE A MAJOR IMPACT ON:

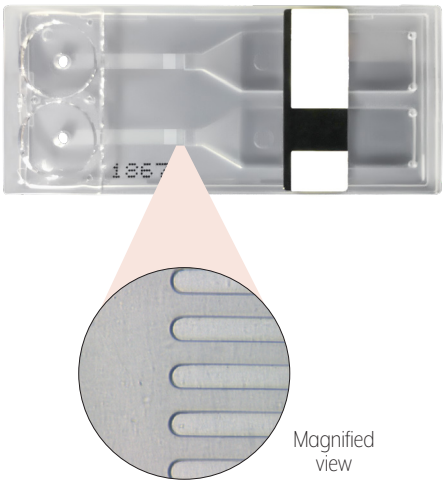
- Hospital resources and blood product management.[1,2]
- Pre-surgical wait times and surgical delays.[3,4]
- Treatment decisions and outcomes.[1,5]

MEASURING PRIMARY HEMOSTASIS CAN HELP EVALUATE IF:

- The patient might benefit from platelet transfusion.
- Pre-surgical primary hemostasis has been restored.
- Active bleeding is associated with impaired platelet activity.
- Platelet activity is significantly impaired in association with interventional procedures.
- Antiplatelet therapy is showing the desired effect

INTRODUCING THE PL CHIP FOR T-TAS 01

The first ex-vivo flow chamber model of in-vivo primary hemostasis available for clinical use.



THE TECHNOLOGY

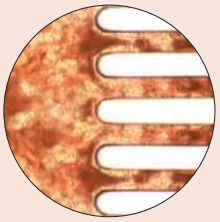
Uses physiological arterial shear stress to assess platelet thrombus formation (primary hemostasis) in whole blood.

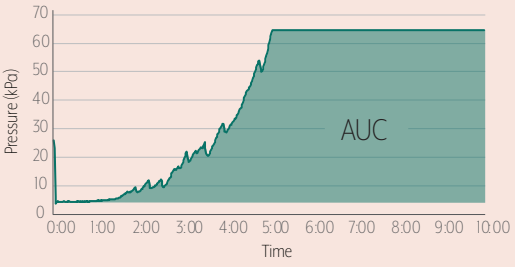
Contains flow chamber with 26 collagen-coated microcapillaries.

Generates results within 40 minutes of sample collection.

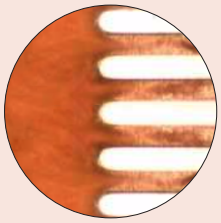
Accommodates two samples per chip.

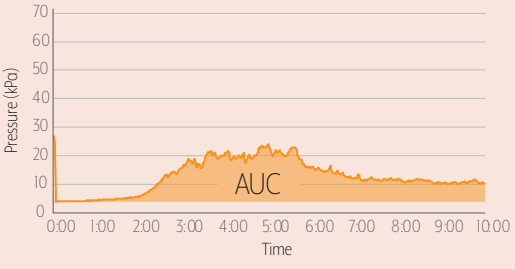
The test measures primary hemostatic function as the area under the pressure-time curve (AUC). An AUC< 260 suggests abnormal primary hemostatic function.





NORMAL, no primary hemostatic defect identified. Platelet aggregation increases pressure. Flow impeded.



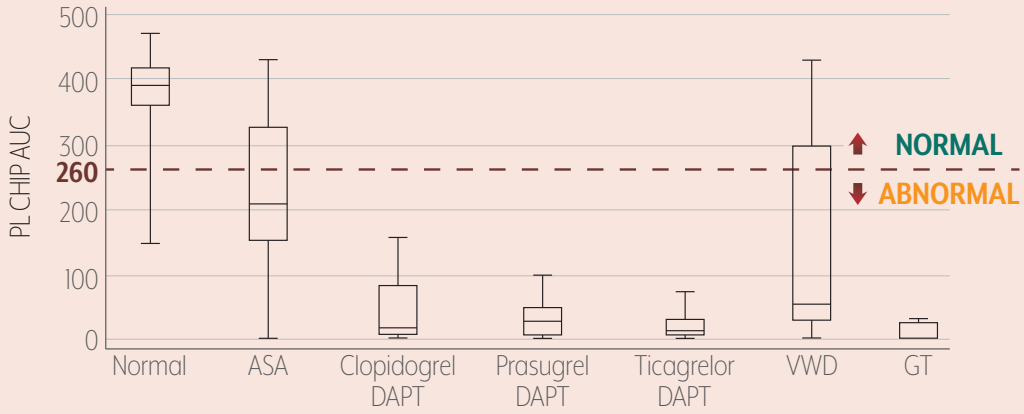


ABNORMAL, abnormal primary hemostatic function. Lack of platelet aggregation. Flow uninterrupted.

CLINICAL PERFORMANCE

The T-TAS 01 PL assay cutoff is sensitive and specific to abnormal primary hemostasis.[6-9]

AUC RESULTS BY PATIENT TYPE



ASA, aspirin monotherapy, DAPT, dual antiplatelet therapy, VWD, von Willebrand disease, GT, Glanzmann's thrombasthenia

THE T-TAS 01 PL ASSAY SELECTIVELY MEASURES PRIMARY HEMOSTATIC FUNCTION

Not influenced by secondary hemostatic function[10]

Significant correlation with intensity of antiplatelet therapy, VWF antigen, VWF activity, and factor VIII activity levels[10,11]

Dose-response relationship with medications known to affect primary hemostatic function[10]

PARAMETER	VALUE	95% CI
Normal*	95.8%	91.1 - 98.0%
ASA**	68.4%	55.5 - 79.0%
Clopidogrel DAPT**	100.0%	81.5 - 100.0%
Prasugrel DAPT**	100.0%	78.2 - 100.0%
Ticagrelor DAPT**	100.0%	76.8 - 100.0%
VWD**	72.0%	50.6 - 87.9%
GT**	100.0%	43.9 - 100.0%

*Negative agreement, **Sensitivity

PERFORMANCE CHARACTERISTICS

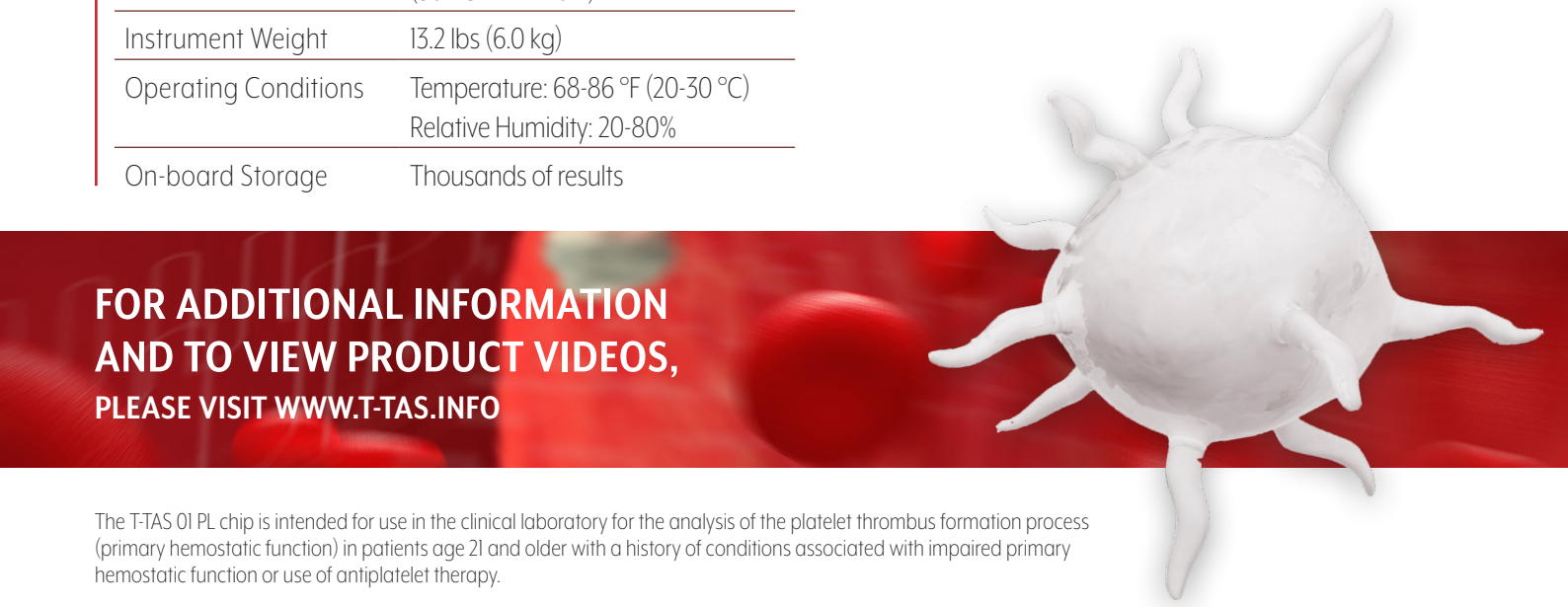
Reference Range	270.0 – 447.7 AUC
Cutoff	AUC < 260
Assay Imprecision	SD ≤ 39 AUC 2.8% CV (high AUC) 19.6% CV (low AUC)
Reportable Range	0.3 – 467.7 AUC

SPECIFICATIONS

Sample Type	BAPA-anticoagulated whole blood
Sample Volume	320 µL
Test Duration	≤ 10 minutes
Sample Stability	Up to 6 hours
Reagent Storage	PL Chip: 4-8 °C BAPA tube: 15-30 °C
Open Pouch Stability	Up to 8 hours
Quality Control	Internal QC External QC (donor blood samples)
Instrument Dimensions (L x W x H)	14.2" x 12.6" x 9.7" (36 x 32 x 24.7 cm)
Instrument Weight	13.2 lbs (6.0 kg)
Operating Conditions	Temperature: 68-86 °F (20-30 °C) Relative Humidity: 20-80%
On-board Storage	Thousands of results

ORDERING INFORMATION

ITEM	CATALOG NUMBER
T-TAS 01 Total Thrombus Formation Analysis System Instrument	18001
PL Chip for T-TAS 01 20 Chips	18002
PL Chip Reservoir Set for T-TAS 01 100 sets	18003
BAPA Tube for T-TAS 01 (3 mL) 50 tubes	18004



FOR ADDITIONAL INFORMATION AND TO VIEW PRODUCT VIDEOS,
PLEASE VISIT WWW.T-TAS.INFO

The T-TAS 01 PL chip is intended for use in the clinical laboratory for the analysis of the platelet thrombus formation process (primary hemostatic function) in patients age 21 and older with a history of conditions associated with impaired primary hemostatic function or use of antiplatelet therapy.

Physicians should use their clinical judgment and experience when deciding how to diagnose and treat patients and in the use of the PL Chip for T-TAS 01 in the treatment of the patient. Please refer to the PL Chip for T-TAS 01 Package Insert and T-TAS 01 User's Manual for full instructions on sample collection and handling, and all other test procedures.

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ZACROS

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