Tsmart® INR

Instructions For Use **English**

avalun®

AVALUN SAS
7, Parvis Louis Néel
38000 Grenoble – France

CE 0086

Tsmart INR_IFU EN V6_1117

Index

	Description
1	Introducing the Tsmart® INR
2	Intended use
3	Test principle
4	Contents of the microcuvette
5	Cautions and warnings
5.1	Cautions
5.2	Warnings
6	Storage and handling
7	Operating conditions
8	Getting ready
9	Collecting a blood sample
10	INR measurement
11	Results
12	Cleaning and disinfection instructions
13	Quality Controls
14	Performance characteristics
15	Test limitations and interferences
16	List of symbols and icons

Description

This box contains Tsmart® INR microcuvettes individually packed in a pouch that must be used only with the LabPad® INR device manufactured by the Avalun company.
The number of microcuvettes is written next to the symbol Σ.

1 Introducing the Tsmart® INR

The Tsmart® INR microcuvettes are in-vitro diagnostic medical devices used for measuring the clotting activity of the blood. They can be used with whole capillary blood or non-anticoagulated venous blood.

Please read these instructions for use as well as the LabPad® INR user guide carefully to acquaint yourself with the Avalun products.

2 Intended use

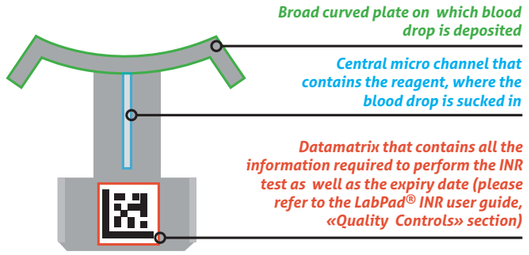
The Tsmart® INR microcuvettes used in combination with the LabPad® INR testing device make it possible to measure the Prothrombin Time (PT), INR value (International Normalized Ratio) and Quick Time (QT). This measurement is necessary for patients under oral anticoagulant treatment with Vitamin K Antagonists (VKA) who needs to regularly check their INR value. A unique correlation exists between INR and Prothrombin Time which depends on the biological parameters of the microcuvettes' lot. Before every measurement, these parameters are read from the microcuvette datamatrix.

Before starting to self-test, you must consult your physician in order to obtain an expected INR value as well as an INR therapeutic range that consists in a high value and a low value. Your physician will also provide your INR test frequency. In all circumstances, you are advised to follow the prescriptions from your physician and advice from healthcare professionals.

Contraindications concerning the LabPad® INR use are provided by your physician.

3 Test principle

A new Tsmart® INR microcuvette must be inserted inside the LabPad® INR. A series of Quality Controls start, including integrity check of the microcuvette (see section 13 Quality Controls). When the device is ready, a blood sample from a fingertip is dropped on the microcuvette curved plate. The blood is mixed with the reagent that is inside the microcuvette and biological reactions then begin. The LabPad® INR initiates an optical analysis of these reactions in order to display the result on the device screen



4 Contents of the microcuvette

Each microcuvette contains a reagent that gives its whitish color to the central micro channel. It contains a human recombinant thromboplastin to which adjuvants and a heparin inhibitor have been added.

5 Cautions and warnings

5.1 Cautions

Before any use, check the expiry date on both the box and the individual pouch. In case of doubt, contact your reseller.
Likewise, the lot number printed on the individual pouch must be identical to the one printed on the box. If this is not the case, contact your reseller.
You will find a silica gel desiccant in each individual pouch: it is an indicator of the humidity level inside the pouch. Humidity level that is too high may damage the reagent properties.
Do not open this sachet; do not eat its content. Check its color:

if it is orange,
the microcuvette can be used

if it is green,
the microcuvette cannot be used; use a new microcuvette

Do not forget to insert a microcuvette in the device **BEFORE** you prick your finger. Do not drop the blood sample directly in the LabPad® INR.

5.2 Warnings

The INR test result is linked to the action of the VKA oral anticoagulants but this action may be modified in the vent of interaction with other drugs taken simultaneously. Consult your physician if you take any other drug or if the dosage of the latter is modified.

Similarly, some changes in diet and certain disorders can have an impact on this anticoagulant action; in case of doubt, contact your physician.

6 Storage and handling

Store the Tsmart® INR microcuvettes in their individual pouch until they are used. You can store them between 15° and 25°C until the expiry date printed on the pouch.
Before using a microcuvette, check the desiccant color (see section 5.1 Cautions).

7 Operating conditions

Place the LabPad® INR on a stable, flat and vibration-free surface. The ambient temperature must be between 15° and 32°C and the humidity level less than 85%.
The Tsmart® INR microcuvette must also be at room temperature (see section 6 Storage and handling). As the reagent present inside the microcuvette is sensitive to humidity, you are advised to refrain from using the Tsmart® INR under high humidity conditions. Once the pouch is open, the microcuvette should be used within 10min.

8 Getting ready

Please refer to the LabPad® INR user guide.
Check that the operating conditions are fulfilled (see section 7 Operating conditions) and that you have prepared all you need for the test:

- a single-use lancet or a lancing device with a new needle. Check that they are adapted to INR measurement; a 21G lancet is recommended. Please refer to the manufacturer's instructions for use or seek the advice of a healthcare professional.
- dressing gauze or a paper tissue
- a bandage

9 Collecting a blood sample

Wash your hands with warm soapy water and dry them thoroughly with a towel or a lint-free cloth. Insert a Tsmart® INR microcuvette and drop the blood sample when the user interface asks you to. You have 2 min. to do so.

Use the lancet or the lancing device to prick the side of a fingertip of your dominant hand: your right hand if you are right-handed or left if you are left-handed. Use the lancet or the lancing device with your opposite hand to obtain a blood drop. A minimum volume of 3µL of blood is required to fill the central micro channel. Do not squeeze your finger, as this may lead to incorrect results.

The required blood drop should be deposited within 15 seconds after pricking, as the natural coagulation process will have already begun. When you drop the blood, be careful not to touch or hold the microcuvette, and not to spread the blood on the microcuvette's plate (see the LabPad® INR user guide). Make sure you fill the microcuvette in one go. Keep your finger positioned above the microcuvette's plate until the device screen changes with a beep tone.

If you did not manage to drop the blood sample properly, discard the microcuvette and start again by pricking another finger. Do not add blood once the measurement has begun. If necessary, wipe the excess blood from your finger and apply the bandage.

10 INR measurement

The default value of the measurement is the INR value. Please refer to the LabPad® INR user guide "Measurements" section.

This result can be related to a therapeutic range if this latter has been previously determined (see the LabPad® INR user guide, "Therapeutic range for INR measurements" section).

To eject the Tsmart® INR, place the LabPad® INR upside down and push the side blue button. Discard it preferably in a bin dedicated to biological waste (see the LabPad® INR user guide, "How to discard the microcuvette" section).

11 Results

If the result is outside the therapeutic range, consult your physician.
In the event of an abnormal result, repeat the test. If the result is still abnormal, consult your physician.

INR value ranges from 0.8 to 8, Prothrombin Time (PT) between 7.2 and 72 seconds, Quick Time (QT) between 10 and 110%. If the result is out of range, an error message is displayed; in this event, refer to the LabPad® INR user guide "Error messages" section.

12 Cleaning and disinfection instructions

Once the microcuvette is taken from its pouch, it can be used immediately, provided storage and operating conditions are fulfilled (see sections 6 & 7).
For cleaning the device, please refer to the LabPad® INR user guide "Cleaning" section.

⚠ Caution

No spray must be used on the device.

13 Quality Controls

The LabPad® INR testing device is a technologically advanced system that automatically runs several autotests before starting the measurement. When a problem that could prevent the test from being performed occurs, an error message is displayed on the device screen. The standard error message is "Error XX", XX being the error reference number (see the LabPad® INR user guide "Error messages" section).

14 Performance characteristics

INR CV results are precise within <6% using capillary blood and <5% using venous blood in the therapeutic range. These performance data are based on several clinical studies conducted on capillary blood and venous blood in comparison with a laboratory reference as well as the WHO tilt-tube method. They are available for healthcare professionals only, upon request.

15 Test limitations and interferences

• Bilirubin	up to 513 µmol/L (30mg/dL)
• Hematocrit range	between 25 and 55%
• Hemolysis	up to 1 000mg/dL (Hemoglobin)
• Triglycerides	up to 11.3 mmol/L (1 000mg/dL)

Use of an alternative method of measurement is recommended in the event of a transition period with a heparinized treatment.

The clotting factor sensitivity for Factors II, V, VII and X has been evaluated. Data are available for healthcare professionals only, upon request.

If the presence of anti-phospholipid antibodies (APAs) is known or suspected, refrain from using. Such presence may cause incorrect results.
Do not use with New Oral Anti Coagulants (NOACs).

16 List of symbols and icons

Σn	Contains <n> microcuvettes	CE 0086	EC marked device
	Do not reuse	REF	Catalog number
	Please consult instructions for use	GTIN	Global Trade Item Number
IVD	For in-vitro diagnostic use	LOT	Lot number
	Manufacturer		Expiry date Format: YYYY-MM-DD
	Store at		Discard in a bin dedicated to biological waste