DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Coag S INR TEST KIT

PT-INR TEST FOR COAG S POC DEVICE

Cat. No.: 86025	**25 x Reagent cuvette**
	1 x 6 ml Buffer vial
	2 x 0,2 ml Coag CONT I-II
Cat. No.: 86010	**10 x Reagent cuvette**
	1 x 6 ml Buffer vial

PRODUCT NAME

Coag S INR TEST KIT, PT-INR test for Coag S POC device.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Coag S INR TEST KIT is a recombinant human thromboplastin reagent -produced by genetic technology in Escherichia Coli- with solvent and controls used exclusively for determination of International Normalized Ratio (INR) dimension of Prothrombin Time (PT) on Coag S Point of Care (POC) device.

SUMMARY AND EXPLANATIONS

Coag S INR TEST Reagent is a recombinant human thromboplastin, which contains recombinant human tissue factor, lipids and calcium ions. The PT-INR test is a sensitive screening test for the extrinsic coagulation pathway. Coag S INR TEST as a reagent for PT-INR is highly sensitive to vitamin K antagonists, decreased level of factors in extrinsic pathway (factor II, V, VII, and X), hereditary or acquired coagulation disorders and liver failure. Therefore, the PT-INR by Coag S INR TEST KIT is optimally used for presurgical screening and monitoring for oral anticoagulant therapy (OAT), as well.

PRINCIPLE

Coag S INR TEST Reagent dissolved in buffer, as a calcium thromboplastin, induces the formation of fibrin clot after addition of patient's blood or plasma sample. The time of this clotting process is measurable only with optical, turbidimetry Coag S device. The mixing ball helps the reconstitution and sample mixing before the measurement.

ACTIVE INGREDIENTS

Coag S INR TEST Reagent (R1) in cuvette is a freeze-dried, recombinant human thromboplastin from Eserichia Coli with lipids and fibrinogen. The cuvette closed with aluminium foil containing mixing ball.

Coag S INR TEST Buffer in vial (R2) is a solvent, which contains calcium ions and preservative.

Coag S INR TEST Coag CONT I-II controls in vials are derived from human, anticoagulated, freeze-dried, pooled human plasma from healthy donors with preservative. Coag CONT I-II controls represent two different measuring range.

PRECAUTIONS

- Person installing the Coag S INR TEST KIT must be a trained laboratory professional!
- By calculating with inappropriate data (RFID) erroneous results may occur!
- Coag S INR TEST KIT, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagent coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- According to the present knowledge the reagent does not contain any particles which can spread from animal to human!
- Each donor unit used in the preparation of this control tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the reagent beyond the expiration date printed on the label!
- Do not use components from a different lot!
- After pushing ball into the Reagent cuvette, check that the ball has fallen down to the bottom of the cuvette.
- Take care at removing the foil, valid measurement requires all amount of the reagent.
- Strictly avoid contamination of buffer (R2) during its application. Always use new disposable pipette tips and close the vial after use!

PREPARATION

For preparation of Coag S INR TEST Reagent follow the instructions of Coag S device and its manual.

Coag S INR TEST Coag CONT I-II controls are dissolved with 200µl distilled water. Allow them to stand at room temperature (20-25°C) for at least 30 minutes. The gently horizontal mixing is recommended during the reconstitution. Swirl the vial gently and horizontal again before use, but do not shake!

SPECIMENS

Coag S INR TEST KIT could use with three different type of samples:

- Fresh capillary blood. To obtain it, follow the operation instructions provided by the manufacturer of the finger sticking device. Capillary blood samples require immediate application.
- Freshly decalcified venous whole blood.
- Freshly decalcified plasma.

To obtain decalcified samples, mix nine parts of freshly drawn venous blood with one part trisodium

citrate (3,2%; 109mmol/L). The use of higher concentration of trisodium citrate (3,8%; 129mmol/L) is not recommended. Mix the blood carefully before testing, or centrifuge plasma also before testing. The measurement must be performed within 24 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

TEST PROCEDURE

Coag S INR TEST is a one-stage PT-INR test, which can be used only with Coag S POC device according to the protocol detailed below. Please follow the instructions of Coag S device and its manual:

1.	**Warm up the Coag S INR TEST KIT to 20-25°C**	**~15min**
2.	**Switch on the Coag S**	
3.	**Choose the type of sample in the relevant menu point of Coag S**	
4.	**Start the Coag S and enter patient ID**	
5.	**Put the box next to the left side of Coag S for RFID uploading**	
6.	**Prepare one cuvette, push the ball into the Reagent cuvette**	**~1min**
7.	**Remove the aluminium foil of the cuvette containing reagent (R1) with care**	
8.	**Place this new cuvette into measuring block of Coag S**	
9.	**Add Buffer (R2) into Reagent cuvette**	**200µl**
10.	**Reagent incubation automatically starts**	**1min**
11.	**Add sample into Reagent cuvette**	**20µl**
12.	**Close the lid, wait for result**	**~2min**

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program. Controlling of Coag S INR TEST can be carried out only with lot specific Coag CONT I-II according to the above protocol after choosing the relevant control menu point of Coag S.

STORAGE AND STABILITY

Coag S INR TEST KIT in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	**20-25**	**2-8**
Reagent cuvette (R1)	**2 hours**	**-**
Buffer vial (R2)	**4 months**	**till Expiry date**
Coag CONT I-II	**4 hours**	**-**

EXPECTED RESULTS

Coag S INR TEST KIT test results can be reported exclusively only in INR unit. INR means the clotting time of the sample divided by the mean normal prothrombin time (MNPT) raised to the power of International Sensitivity Index (ISI) [$INR=(PT/MNPT)^{ISI}$]. Lot dependent values for INR calculation and control ranges can be found on RFID label in the box. The INR is the only officially recognized dimension of the result at vitamin K antagonists treated patients.

The normal range expressed in INR is 0,8-1,2. Every laboratory should determine its own reference range.

LIMITATIONS

Coag S INR TEST KIT and/or its components exclusively used with Coag S device.

PERFORMANCE CHARACTERISTICS

The reproducibility test of Coag S INR TEST KIT on Coag S device gives the following results:

	Intra-Assay		**Inter-Assay**	
Sample	**1**	**2**	**3**	**4**
n	**15**	**15**	**38**	**38**
Mean (INR)	**1,02**	**3,19**	**1,05**	**3,22**
CV (%)	**1,805**	**1,082**	**5,825**	**3,331**

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable finger stick device (lancet) and accessories (antiseptic spray, swabs).
- Coag S accessories (pipette tips; pipettes; capillary)
- Distilled water for Coag CONT reconstitution.
- Coag S POC device

BIBLIOGRAPHY

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2. CLSI: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline-Second Edition. CLSI document: H47-A2; 28:20; 2008.
3. CLSI: Point-of-Care Monitoring of Anticoagulatioin Therapy; Approved Guideline. CLSI document: H49-A; 24:23; 2004.
4. De Caterina R et al: Vitamin K antagonists in heart disease: Current status and perspectives (Section III). Thromb Haemost; 110: 1087-1107; 2013.

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SYMBOLS			
	Manufacturer		Use-by date
LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged		Fragile, handle with care
	Keep dry		Temperature limit
	Biological risks		Consult instruction for use
	Caution	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <*n*> tests		This side up
CE	CE mark		