Technochrom Plasmin Inhibitor

Plasmin INH

English

Intended Use

The Technochrom Plasmin Inhibitor (INH) is an *in vitro* diagnostic reagent kit for the quantitative determination of plasmin inhibitor activity, as an aid to diagnosis of congenital or acquired Plasmin Inhibitor deficiencies in patients, by means of automated or manual chromogenic methods.

Summary and principle

Plasmin Inhibitor is also known as α_2-plasmin inhibitor and is produced by the liver. It is a major inhibitor of plasmin therefore has an essential role in regulating fibrinolysis and hemostasis. [1,2]

Plasmin inhibitor deficiency can be congenital or acquired and has been reported in individuals with liver failure, amyloidosis, solid tumor, acute promyelocytic leukemia, and disseminated intravascular coagulation. Decreased levels of plasmin inhibitor have also been described in patients who received thrombolytic therapy and in those with other conditions associated with a hyperfibrinolytic state.[3]

Technochrom Plasmin INH is a chromogenic assay. Diluted plasma containing the Plasmin Inhibitor complexes with excess Plasmin added. The residue Plasmin cleaves the chromogenic substrate to release a colored product, para-nitroaniline, the intensity of which is inversely proportional to the Plasmin Inhibitor level. Absorbance is measured at 405 nm.

The buffer contains methylammonium chloride to eliminate any potential interference from α_2-macroglobulin present in the sample.[4]

Reagents

REF	CONTENT
5342631	80 T.

SUB Substrate; 2 x 2 mL, lyophilized reagent containing Pyr-Phe-Lys-pNA · HCl, TRIS, sodium chloride and sodium azide preservative.

RE Reagent; 2 x 2 mL, lyophilized reagent containing plasmin, bovine serum albumin, acetic acid buffer

BUF Buffer; 1 x 25 mL, liquid reagent containing TRIS, sodium chloride, methylammonium chloride and Proclin as preservative.

Precautions and warnings

For *in vitro* diagnostic use by health care professionals only.

Universal precautions for the use of chemicals and potentially biohazardous substances must be applied.

Handle waste as potentially biohazardous material and dispose according to locally accepted and approved laboratory instructions and procedures.

Discard all material in a safe and acceptable manner in compliance with relevant local disposal regulations.

Safety data sheet available for professional users on request.

The rules pertaining to disposal are the same as applied to disposing hospital waste.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

Allow all reagents to reach room temperature (18-25 °C) before use.

Substrate: each vial of Substrate is reconstituted with 2.0 mL purified water. After a reconstitution time of 15 minutes, Substrate is mixed for 10 seconds.

Reagent: each vial of Reagent is reconstituted with 2.0 mL purified water. After a reconstitution time of 15 minutes, Reagent is mixed for 10 seconds.

Buffer: buffer vial is ready to use.

For standardization tests, a reconstitution time of 30 minutes is recommended for all lyophilized reagents.

Do not use the reagent if you observe any change in appearance of components included in the kit or if you observe any damage in the packaging materials. Visible turbidity and flocculation are signs of microbial contamination.

Carefully swirl the vial just before use to ensure homogeneity.

Avoid foam formation.

Reagent storage and stability

Store at 2-8 °C.

Unopened reagents are stable until the stated expiration date indicated on the label.

Store reagents upright in their packaging.

Stability of all opened reagents in original vials:

at 2-8 °C (Closed cap)	4 days
at 18-25 °C (Open vial)	8 hours
At < -20 °C	6 months

Can be freeze/thawed once. Thaw the reagents rapidly in a 37 °C water bath.

Considering the numerous possible combinations of storage conditions (partly at 18-25 °C, partly at 2-8 °C), each laboratory should establish its own stability durations according to its practices if the reagent is stored partly at 2-8 °C. These durations should not exceed the figures mentioned above, which have been determined under controlled conditions.

Specimen collection and preparation

For 3.2 % citrated human plasma only.

Nine parts of freshly drawn venous blood are collected into one part 3.2 % trisodium citrate. Refer to CLSI Document H21 (current edition)[5] for further instructions on specimen collection, handling, and storage.

Patient plasma should be tested within 4 hours of blood collection or frozen immediately after centrifugation. Samples can be stored frozen at -20 °C for up to 24 months[5]. The

plasma may be thawed up to 2 freeze/thaw cycles (thaw rapidly at 37 °C) and must be tested within 4 hours.

Sample Dilution:

All plasma samples are diluted 1:20 in the kit buffer

Procedure

Materials provided

See "Reagents" section.

Materials required (but not provided)

REF	5220110, Coagulation Reference	5 x 1 mL
REF	5020040, Coagulation CON N	5 x 1 mL
REF	5021055, Coagulation CON A	5 x 1 mL

- General laboratory equipment
- Coagulation analyzer such as Ceveron 100 series with the following capabilities: Wavelength: 405 nm, measuring temperature 37 °C.

Please note that the application on other analyzers can be validated by the manufacturer under their responsibility as long as the intended purpose and performance are not modified.

Test procedure

Sample Dilution

Dilute Samples 1:20 as described in section "Specimen collection and preparation".

Preparation of Calibration Curve

For Calibrator material use Coagulation reference referenced in section "Materials required (but not provided)".

The reconstituted calibrator is diluted 1:15, 1:30, 1:60 and 1:160 in buffer.

Pipetting scheme:

Step	Kinetic Assay
Reagent	50 µL
Diluted sample / calibrator / controls 1:20	50 µL
Mix well and incubate at 37 °C	3 minutes
Substrate	50 µL
Mix and measure increase in absorbance (mE/min)	10-50 seconds at 405 nm

With analyzers of the Ceveron 100 series, load the reconstituted and opened reagents into the instrument according to the recommendations of the instrument manual in positions as stated below:

Reagent	Position
Substrate	R13 – R17
Reagent	R13 – R17
Buffer	R1 – R4
Calibrator	C1 - C6

Calibration

A new calibration curve must be established when changing a reagent lot, after major maintenance or service of the analyzer, if indicated by quality control results and, when required, by laboratory control procedures and/or government regulations.

For traceability, see instructions for use of the Calibrator referenced in section "Materials required (but not provided)".

Quality Control

Two controls should be measured with each calibration, with freshly reconstituted reagents and within each run.

Coagulation CON N and Coagulation CON A are suitable controls.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits.

If the measured control value lies outside the limits previously established, the coagulation analyzer, the reagents, and the calibration should be examined.

Do not release patient results until the cause of deviation has been identified and corrected.

Results

Results are reported in % Plasmin Inhibitor.

Plot the Plasmin Inhibitor activity in percent against the increase in absorption (mE/min) at 405 nm for each calibrator. Read the percent Plasmin Inhibitor of the unknown sample from the calibration curve.

Limitations

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Interference Studies

Results are unaffected by hemoglobin up to 240 mg/dL, unconjugated bilirubin up to 59 mg/dL, conjugated bilirubin up to 70 mg/dL and lipids up to 1200 mg/dL.

Expected values

47 - 140 % Plasmin Inhibitor

Each laboratory should establish its own reference range.

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Plasmin INH

Performance characteristics

Precision

Sample	Mean [%]	Repeatability		Within Laboratory	
		SD	CV	SD	CV
CON N	114	5.1	4.5	7.6	6.7
CON A	45.7	3.8	8.3	7.3	16.0

Method Comparison

Patient samples were assayed using the Technochrom Plasmin INH and a chromogenic reference method:

Correlation coefficient: 0.968

Passing Bablok[6]: y = -4.2 + 0.968x

Assay Limits:

Detection Limit: 9 % Plasmin INH

Measurement range

9 % – 140 % Plasmin INH

Bibliography

1 Carpenter SL & Mathew P. α_2-Antiplasmin and its deficiency: fibinolysis out of balance. *Haemophilia* **14**, 1250-1254, (2008).

2 Aoki N. Discovery of α_2-plasmin inhibitor and its congenital deficiency. *J.Throm.Haemost* **3**,623-631 (2005).

3 Singh S, Saleem S & Reed GL. Alpha2-antiplasmin:The Devil You Don't Know In Cerbrovascular & Cardiovascular Disease. *Front. Cardiovasc. Med.* **7**:608899 (2020)

4 Meijer P *et al.* Criteria for specific measurement of plasmin inhibitor activity using an enzymatic procedure. *eJIFCC* **13**, 2, 61-66 (2001).

5 CLSI document H21-Ed-6, Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays: Approved Guideline-Sixth Edition., (2024).

6 Passing, H. & Bablok. A new biometrical procedure for testing the equality of measurements from two different analytical methods. Application of linear regression procedures for method comparison studies in clinical chemistry, Part I. *J Clin Chem Clin Biochem* **21**, 709-720, (1983).

Symbols

The following symbols and signs are used in addition to those listed in the ISO 15223-1 Standard:

GTIN Global Trade Item Number

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A point (period/stop) is always used in this instructions for use as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

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