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Do wszystkich Wykonawców

Dot. postępowania w trybie przetargu nieograniczonego na dostawę odczynników do badań laboratoryjnych

1. **Pytanie** - dotyczy części nr 3. Czy Zamawiający wyrazi zgodę na zaoferowanie testu według załączonej metodyki?

TECHNOCHROM® C1-INH

(GB)

PRODUCT DESCRIPTION

INTENDEND USE

Diagnosis of hereditary angioneurotic edema (HANE).
The C1-esterase inhibitor (C1-INH) is a regulatory protein that functions as an inhibitor of several serine proteases in the complement system, the kallikrein-kinin system, the coagulation cascade and in fibrinolyse.

TEST PRINCIPLE

C1-Esterase + C1-INH ⟶ [C1-Esterase C1-INH] + C1-Esterase (rest)
(excess)

C_2H_5CO-Lys(ε -Cbo)-Gly-Arg-pNA + H_2O —(C1-Esterase)→ C_2H_5CO-Lys(ε -Cbo)-Gly-Arg-OH + pNA

COMPOSITION

Reagent kit for 30 photometric C1-Esterase inhibitor determinations.

mL	reagent	other data
1 x 3	Substrate C1-1	18 µmol, AcOH; C_2H_5CO-Lys (ε -Cbo)-Gly-Arg-pNA, p.m. = 729.8
1 x 3	C1-Esterase	human
1 vial	Coagulation Reference for C1-INH	ca. 130% = 1.2 U C1-INH/mL (See label for reconstitution volumes
1 x 1	Coagulation Control A for C1-INH	lyophilized abnormal plasma
1 x 1	Coagulation Control N for C1-INH	lyophilized normal plasma
1 x 25	Sample Buffer A	Tris (6.1 g/L)-NaCl (15 g/l)-Buffer pH 7.4
1 x 20	Reaction Buffer B	Tris (6.1 g/L)-NaCl (15 g/l)-Buffer pH 8.5

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water
- For the endpoint method: 50 % acetic acid.

WARNING AND PRECAUTIONS

- IVD for in vitro diagnostic use
- All blood and plasma samples and products have to be regarded as potentially infectious and handled with appropriate care and in compliance with the biosafety regulations in force and must be disposed of in the same way as hospital waste.
- Each single donor plasma and each lot of Coagulation Control are tested and found negative for HBs_2Ag, HIV 1/2 Ab and HCV Ab. However, universal precautions (treating all human source materials as if potentially infectious) should be exercised.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2...8 °C.

Stability after reconstitution:
The reconstituted reagents are stable for 6 hours at reaction temperature.
Reconstituted reagents may be stored at –20°C.
The vials can be only frozen once. Upon storage, caps should be screwed tightly.
Frozen reagents should be used within one month.
DO NOT FREEZE THE SUBSTRATE -BUFFER MIXTURE

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

Plasma preparation:
Mix 9 parts of venous blood and 1 part sodium citrate solution (0.11 mol/L) and centrifuge for 15 minutes at a RCF of at least 2500 (corresponding to DIN 58905). The plasma sample may not be stored at room temperature for more than three hours; otherwise the sample has to be frozen immediately after centrifugation.

Sample preparation:
Before testing the plasma samples are diluted with Sample Buffer A at a ratio of 1:11 (0.05 mL sample + 0.50 mL Buffer A). Samples with C1-INH activity > 115% should be diluted 1:22.

PREPARATION OF REAGENT

All reagents including distilled water should have reached room temperature before use. The lyophilized reagents are dissolved in the volume of distilled water indicated and are ready for use after 10 minutes. For standardization test a reconstitution time of 30 min is recommended.

PERFORMANCE OF THE TEST

C1-Esterase and the diluted sample are kept at room temperature, the Substrate-Buffer mixture at +37°C. Measurements are done at 37°C.

Mixing the Substrate C1-1 with reaction Buffer B:

Kinetic determination		End-point determination
1 part 5 parts	Substrate C1-1 Reaction Buffer B	1 part 4 parts

Pipetting scheme: Pipette into plastic tubes or cuvettes.

Kinetic Determination		End-point determination
100 µL 100 µL 5 minutes	diluted sample C1-Esterase incubation 37°C	100 µL 100 µL 5 minutes
500 µL	Substrate-Buffer mixture incubation 37°C	500 µL 3 minutes
The extinction increase is measured at 405 nm at 37°C. During 4 min the reaction is linear.	acetic acid 50%	200 µL The extinction is measured at 405 nm against blank.

LIMITATION OF THE TEST

In inflammatory processes the activity of the acute phase-protein C1-INH may be far above the normal value. It is recommended to test samples with values above 115% C1-INH once more in a dilution of 1:22.

ANALYSES RESULTS

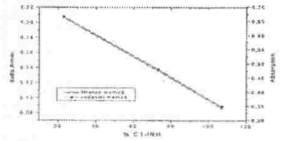
CALCULATION OF THE RESULTS

To establish a reference curve 3 serial dilutions of Coagulation Reference are prepared and tested together with an optional blank (sample buffer A) reading.

Predilute the Coagulation Reference 1:11 with sample buffer A (0.05 mL plasma + 0.50 mL buffer A). From this predilution prepare a series of dilutions (1:1, 1:2, 1:4) also with sample buffer A (the 1:1 dilution corresponds to the 1:11 predilution). This series should be tested in the same way as a patients sample in the assay. The absorption increase (ΔA/min) in the kinetic method or the absorption (A) in the end-point method are plotted on linear graph paper as readings for 120, 60 and 30% C1-INH value and are plotted to give a linear calibration curve. The blank reading may be used in the reference curve as the 0 % C1-INH value.

The control plasmas Coagulation Control A and N are predilluted 1:11 (0.05 mL plasma + 0.50 mL Buffer A) with sample buffer A and may be read off directly from the reference curve. The values should fall within the confidence limits printed on the label of the control plasma.

Example; manual method (kinetic and endpoint):



All samples diluted 1:11 can be directly read off from the calibration curve.
For samples diluted other than 1:11 the % activity read off from the calibration curve has to be converted as follows:

$$\frac{\%\ \text{C1-INH (calibration curve)}}{11} \times \text{actual dilution ratio} = \%\ \text{C1-INH of sample}$$

Thus in samples diluted 1:22 the C1-INH activity is twice the value read off from the calibration curve.

REFERENCE RANGE

0.70-1.30 U C1-INH/mL (70 – 130 % of normal)

STANDARDIZATION

The Reference Standard C1 INH recalibrated against the WHO plasma standard 88/262. Concentrations are lot-dependent, consult the label on the vials.

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

PRECISION

Reproducibility was determined with different samples (in series and day to day). The following results were obtained:

	Intra assay:		Inter assay:	
sample	sample 1	sample 2	sample 1	sample 2
n	12	12	6	6
MV %H	98.5	53.4	96.8	54.6
SD (%)	3.09	2.81	2.45	2.79
CV (%)	4.02	4.89	2.58	4.2

COMPARISON OF METHODS OR CORRELATION

Following correlation (%) was obtained in comparing TECHNOCHROM C1INH with:
C1INH EIA (Quidel) $y = 0.8267x + 11.493$ $R^2 = 0.81$

LITERATURE

Please contact Technoclone or your local distributor for literature or technical applications for the test.

Odpowiedź: Zamawiający wymaga zaoferowania w części nr 3 odczynników zgodnie z opisem w Załączniku nr 4.3 do specyfikacji istotnych warunków zamówienia.

DYREKTOR
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