



ECAA INR QC PLASMA SET

For the Quality Control of CoaguChek *POCT* Monitors

Introduction

Oral anticoagulant treatment requires frequent and reliable PT testing to maintain the blood coagulation level within target limits. These are referred to in WHO terms as international normalised ratios (INR). Too much treatment can result in a bleeding tendency whereas too little does not protect from thrombosis.

To meet the increasing need for community testing of INR, 'point of care' instruments have been developed for community physicians to undertake testing and dosing of their patients, or for patients themselves to undertake self testing and self-dosage of oral anticoagulant drugs.

CoaguChek 'Point of care' PT testing monitors have been shown to be variable in their performance and with evidence of inter-batch variation. Quality control of the monitors appears necessary to ensure accurate INR reporting.

Principle

The European Concerted Action on Anticoagulation (ECAA) INR QC plasma sets comprise 5 human plasma samples with a range of INR values that have been certified with INR by manual PT testing with the relevant WHO international reference preparation (IRP) by a group of reference laboratories within the EU.

These plasmas are to be tested by the operator of the 'point of care' instrument and the result for each plasma in the set should fall within the acceptable target range assigned to the plasmas defined in the EC-approved ECAA Technology Implementation Plan (15% deviation or less from the certified manual value with an individual plasma).

Materials Supplied

5 x 0.5ml Lyophilised Human Plasma
1 x 3.0ml Reagent Grade Water
1 x 3.0ml Calcium Chloride solution

Materials required but not Supplied

Pipette and tips capable of transferring 0.5ml plasma accurately to the test strip.

Procedure

1. Reconstitute each vial of control plasma with 0.5ml of the Reagent Grade Water provided.
2. Allow each vial to stand for 10 minutes at room temperature, and no longer than 30 minutes.
3. Swirl each vial to mix the contents.
4. Prepare the 'point of care' instrument to perform a test.
5. Add 0.5ml of Calcium Chloride solution to the vial containing Plasma 1 and mix well.
6. Apply the recalcified plasma to the test strip within 15 seconds of adding the calcium chloride and record the measured INR.
7. Repeat Steps 4 to 6 for Plasmas 2 to 5.

Acceptable Results

The measured INR values should be within the specified INR limits for each of the QC plasmas (see above).

Failure of the INR values to fall within the target range with one or more plasmas indicates the need to repeat the test procedure on the set of 5 QC plasmas.

Interpretation

Failure of the 'point of care' instrument to perform as expected with one or more test samples may be caused by a number of reasons, either instrument or test strip related. If on repeat testing the error persists (15% deviation or more from certified INR values) with one or more test plasmas from the set of 5, users should contact the care provider for advice prior to accepting patients' test results.

The above procedure should be repeated separately on any different automated procedure if more than one is in use in a laboratory or following a change of batch of test strips.

References

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Certification of ECAA plasmas (batch number B-777-1) on CoaguChek (CoaguChek S) and CoaguChek XS monitors *in terms of WHO human and rabbit IRP*

CERTIFIED VALUES	CERTIFIED MEAN	QC ACCEPTABLE RANGE
CoaguChek & CoaguChek S		
Plasma 1	2.2	1.9 - 2.5
Plasma 2	3.1	2.6 - 3.5
Plasma 3	1.8	1.5 - 2.1
Plasma 4	4.2	3.5 - 4.8
Plasma 5	2.7	2.3 - 3.1
CoaguChek XS		
Plasma 1	2.2	1.9 - 2.5
Plasma 2	2.7	2.3 - 3.1
Plasma 3	1.9	1.6 - 2.2
Plasma 4	3.5	2.9 - 4.0
Plasma 5	2.4	2.0 - 2.7