

# Guideline for primary care providers

## SELF-TESTING OF INR DURING COVID-19 PANDEMIC 2020

Version:	1
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Target audience:	All clinical staff involved in the provision of primary care anticoagulation service commissioned by NHS Sheffield CCG

## Purpose

This guideline has been written purposely to be used during COVID-19 pandemic. The aim is to assist patients taking warfarin, who cannot be switched to an alternative anticoagulant ie a DOAC, to undertake self-testing of INR, in line with national guidance <sup>(2)</sup>.

The aim is to minimise INR monitoring workload across the system by reducing the need to attend hospital, GP or community pharmacy. This will also reduce patient / health care professional contact where social distancing measures cannot be maintained and therefore minimise the risk of spread of COVID-19 virus, protecting **BOTH** staff and patients.

## Scope of this document

This document aims to provide guidance for the self-testing of INR in primary care settings for appropriate patients with an interest to self-test their INR. These patients must already have their INR checked via a CoaguChek® machine either at STH anticoagulation clinic or by the patient's own GP practice / community pharmacist.

**This document is limited to self-testing of INR and does NOT include self-managing in primary care.**

[NICE guidance](#) supports self-monitoring of INR for patients with prosthetic mechanical valves and for those with AF. I.e. patients on long term treatment with warfarin<sup>(1)</sup>.

Warfarin is the most commonly prescribed vitamin K antagonist (VKA) anticoagulant; others include acenocoumarol and phenindione. They share the same monitoring principles. This document mainly refers to warfarin but does support patients self-testing their INR if on other VKA anticoagulants.

**This document is not applicable to patients receiving DOACs**

## Introduction

Warfarin patients who are eligible for self-testing (see [inclusion](#) and [exclusion](#) criteria) and have expressed an interest can be initiated on the self-testing programme with the aim of performing their INRs at home or other suitable location, once they have completed the training. **Note this training is currently limited due to the COVID-19 pandemic and therefore is self-led via Roche start up patient support pack, including step by step guide and training DVD. Further assistance from Roche is available over the phone (details [below](#)).**

This document is currently limited to existing patients whose INR is already monitored via a CoaguChek® meter. Point of care (CoaguChek®) INR may not be suitable for patients with certain medical conditions for example: anti-phospholipid syndrome, lupus, coagulopathy and other cardiac conditions. These patients would require certain blood test check prior to CoaguChek® meter being purchased to check their bloods results are within range for the test strips. See table below for normal blood test parameters for CoaguChek® test strips:

Table 1

Test limitations for CoaguChek® XS and INRange PT Test strips	
Bilirubin	up to 513 micromol/L (30mg/dL)
Haemolysis	up to 0.62 mmol/L (1000 mg/dL)
Triglycerides	up to 5.7 mmol/L (500 mg/dL)
Haematocrit	range between 25% and 55%
As per pack insert on CoaguChek® XS and INRange PT test strips <sup>(6, 7)</sup> .	

### Inclusion criteria

- Over 18 years of age.
- Long-term anticoagulation therapy with indication including: mechanical heart valve, AF, where DOAC is not suitable <sup>(2)</sup>.
- Patient has the manual dexterity, cognitive function, vision and ability to use the technology to test their INR.
- Patient must be able to understand English or have access to an interpreter (this could be family member) to safely follow the self-led training resources and receive dosage advice over the telephone.
- Patient must agree to only check INR as directed by their GP/community pharmacy and provide accurate INR results.

### Exclusion criteria

- Under 18 years of age.
- Blood results outside the parameters for the test strips (see [table 1](#)).
- Self-management of INR, this refers to the patient checking their INR and then self-adjusting the dosage of their anticoagulant medication by following an agreed protocol <sup>(1)</sup>.

### Self-testing of INR

- Roche Diagnostics report that supplies of CoaguChek® meters are currently low due to increased demand. It is working to increase availability in the UK. When devices are available, these should be prioritised for shielded patients at highest risk of COVID-19 infection.
- Patient must be informed of the cost involved in purchasing the CoaguChek® meter, currently at £299 vat exempt (due to long term treatment with warfarin, i.e. chronic condition. For further information see [HMRC](#). Note Roche does not charge eligible patients VAT). Interest free payment plans are available contact Roche for details on 0808 100 7666 or visit: [shop.coagucheck.com](http://shop.coagucheck.com).
- GP will need to prescribe the required CoaguChek® test strips, lancets and sharps guard. See [appendix 1](#) for details. It is recommended to issue an **acute prescription only** for these items so that they are not issued with each repeat unnecessarily.

- Once patient and GP have agreed to self-testing, patient can purchase the CoaguChek® meter. **Patient should watch the DVD provided by Roche prior to opening the meter box. The meter cannot be returned to Roche once it has been opened or used.** After watching the DVD, if the patient still wants to continue with self-testing of their INR, then the meter box can be opened and the step by step patient guide be followed. A training check list is provided by Roche in the guide to assist patients through the training of the meter. Freephone access to CoaguChek® care line (**0808 100 7666**) including one to one telephone training and free technical support is available if required. See patient sale pack for details.

- **Other support available for patients:**

Videos, articles and testimonials are available at <https://shop.coaguheck.com/support/> .

There are e-learning courses that can be accessed on [www.strokeprevent.live](http://www.strokeprevent.live)

**Patient support groups, see individual charities:**

Anticoagulation Europe [www.anticoagulationeurope.org](http://www.anticoagulationeurope.org)

Arrhythmia Alliance [www.heartrhythmcharity.org.uk](http://www.heartrhythmcharity.org.uk)

AF association [www.atrialfibrillation.org.uk](http://www.atrialfibrillation.org.uk)

## Patient competency and comparison review

- GP or community pharmacist to discuss service provider responsibilities and that of the patient. Patient to be given a copy of their responsibilities see [appendix 2](#).
- Due to the current pandemic patient competency cannot be checked. If the patient requires assistance, support can be provided by Roche via the telephone, as above or as seems appropriate by the GP/community pharmacist. Once the patient is confident in using the meter, they can inform their GP/community pharmacy who will then give the patient a date to telephone in their INR result.
- A comparison review with the meter is recommended every 6 months. The GP/community pharmacy can do this by performing a test on the clinic CoaguChek® meter and comparing with the patients' self-test result to check the patients' technique and that their meter is performing effectively. This review can be established post pandemic once safe to do so.

## Dosing

- Dosing of warfarin should be provided by the patient's GP practice/community pharmacy by phone and letter as soon as possible after receiving the patients INR result.
- It is recommended that appropriate Computerised Decision Support Software (CDSS) e.g. INRstar N3 as approved by NHS Sheffield CCG be used for dosing.

- INRstar will not make dose recommendations if the INR is less than 1.3 or greater than 5.0. In these circumstances dosing must be carried out manually using the guidance below.
- For warfarin dose adjustment guidance please refer to section 2: Warfarin dose adjustments in the [Anticoagulation monitoring service SOP](#) <sup>(4)</sup>.

### Care of equipment <sup>(3)</sup>

- Cleaning instructions can be found in the self-training guide and should be followed closely.
- Any questions about maintenance or operation of the patient's own CoaguChek® meter the patient should be advised to contact the Roche Helpline (0808 100 766).
- The operating temperature of the meter is 15-32°C. Therefore:
  - Advise patients to store and use their meter in a warm room. If the CoaguChek® meter has been stored in a cold place it should be allowed to reach room temperature before a test is performed; this may take 30 minutes to 1 hour.
  - The CoaguChek® meter should be kept out of direct sunlight and extremes of temperature avoided. If travelling to hot countries and the temperature is greater than 30°C the CoaguChek® meter should be kept in a cool bag unless in an air-conditioned room.
- The CoaguChek® testing strips can be stored between 2-30°C
- Avoid getting the meter wet.

## References

- 1) **NICE DG14:** Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek® XS system).  
Published date: 24 September 2014 Last updated: 19 December 2017

<https://www.nice.org.uk/guidance/dg14>

- 2) **NHS England and Improvement:** Specialty guides for patient management during the coronavirus pandemic. Clinical guide for the management of anticoagulant services during the coronavirus pandemic.  
31 March 2020 Version 1

<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0077-Specialty-guide-Anticoagulant-services-and-coronavirus-v1-31-March.pdf>

- 3) STH Anticoagulation Clinic CoaguChek® Self-Testing Initiation, training and quality control reviews.  
February 2018 Issue 2

- 4) NHS Sheffield CCG Anticoagulation Monitoring Service SOP.  
Version 4 April 2017

<https://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/prescribing%20guidelines/Sheffield%20CCG%20ANTICOAGULATION%20MONITORING%20SERVICE.pdf>

- 5) CoaguChek® XS System User Manual, Roche Diagnostics.  
Version 8.0 2017

<https://diagnostics.roche.com/us/en/resource-center-pages/coaguheck-xs-system-user-manual-04837991001-07.html> [Accessed 21/05/2020].

- 6) CoaguChek® XS PT Test Strip Package Insert, Roche Diagnostics.  
Version 6.0 2017

<https://diagnostics.roche.com/us/en/resource-center-pages/coaguheck-xs-package-insert-2016-05967694001.html> [Accessed 21/05/2020].

- 7) CoaguChek® XS PT Test PST Test Strip Package Insert, Roche Diagnostics.  
Version 4.0 2019

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## Appendix 1

### Items to be prescribed by GP for self-testing of INR.

Due to the limited supplies currently available, Roche Diagnostics may supply either the CoaguChek® INRange or the CoaguChek® XS meter

Product	Quantity	Cost (as of April 2020)
<b>CoaguChek® INRange meter- strips can also be used in XS meter</b>		
CoaguChek XS PT Test PST testing strips (Roche Diagnostics Ltd)	24 strips	£70.63
<b>CoaguChek® XS meter- strips can only be used in XS meter</b>		
CoaguChek XS PT testing strips (Roche Diagnostics Ltd)	24 strips	£70.63
CoaguChek Softclix lancets 0.8mm/21gauge (Roche Diagnostics Ltd)	50 lancets	£1.96
Sharpsguard disposal unit 1litre Yellow (Daniels Healthcare Ltd)	1 unit	£0.87

It is recommended to issue an **acute prescription only** for these items, so that they are not issued with each repeat unnecessarily.

## Appendix 2

### Patient responsibilities

**Patients name:**

**Date of birth:**

**NHS number:**

Action	Date completed/agreed
Patient has watched the DVD provided by Roche.	
Patient has followed the step by step guide provided by Roche.	
Patient is able to set up the CoaguChek® meter as per User Manual.	
Patient is aware of optimal storage conditions for the CoaguChek® meter.	
Patient is able to insert/remove code chip and understands the significance of it. Patient knows to match code chip to the code on the test strip.	
Patient is aware of how to store and handle CoaguChek® test strips, in particular replacing the lid immediately after removing a test strip and then using this test strip within 10 minutes.	
Patient is able to use lancet device provided without problems and apply blood drop to the test strip within 15 seconds.	
Patient is able to obtain an INR reading.	
Patient to report INR accurately to service provider even if INR falls outside of range.	
Patient to only check INR as agreed/recommended by service provider.	
Patient to follow anticoagulation dosage instructions as set out by service provider.	
Comparison review discussed with patient.	