

Sirolimus Therapeutic Drug Monitoring Assay Procedure

1. How should sirolimus be monitored?

At present, sirolimus must be measured by an assay based on high-performance liquid chromatography (HPLC). The necessary laboratory equipment will not be widely available and validated at the time of launch and, therefore, Wyeth have set up a central laboratory service to monitor sirolimus blood concentrations at Harefield Hospital in Middlesex.

2. How often should sirolimus be monitored?

Although you will be familiar with monitoring existing immunosuppressants, there are some important differences when monitoring sirolimus, due to its long half-life of 62 hours. The maximum monitoring frequency envisaged is weekly, for example during tapering of cyclosporin. After a simple dose change, sirolimus measurements made before one week will be of little value. Once a steady state concentration has been reached trough concentrations can be monitored infrequently.

3. What type of sample should be taken for assay

A whole blood trough sample should be used for the measurement of sirolimus concentrations – this should be collected as an EDTA anticoagulated sample, as for cyclosporin and tacrolimus monitoring.

4. Sample collection

Your hospital either has, or shortly will have a Hays DX collection box on site. All samples for the measurement of sirolimus should be put into one of the packing boxes supplied (up to 10 samples tubes per box) with your standard laboratory request form. We would recommend that clinician / laboratory staff responsibility for this is established within the centre.

This box should then be deposited in the Hays DX collection box before 5.00pm. All boxes will be collected by Hays DX (Monday to Friday) and delivered overnight and should arrive at the central laboratory by 9.00am the following morning.

Further supplies of boxes can be ordered directly from Hays DX – please allow up to five working days for delivery.

5. Assay process

Samples received at Harefield will be assayed overnight on the day of delivery. Results will then be faxed back to the centre of origin on the morning following the assay run. In the majority of cases, results for the measurement of sirolimus will be available within 48 hours of taking the blood sample.

Please note that there is no weekend collection from Hays DX collection boxes, and that the central laboratory will not perform assays routinely at the weekend. Hence, for samples sent on a Friday, results will not be available until the following Tuesday.

Sample taken & placed into packing box	Sample(s) collected from Hays DX box	Sample(s) delivered to central lab	Assay run overnight	Results faxed
Monday	Monday pm	Tuesday am	Tuesday pm	Wednesday am
Tuesday	Tuesday pm	Wednesday am	Wednesday pm	Thursday am
Wednesday	Wednesday pm	Thursday am	Thursday pm	Friday am
Thursday	Thursday pm	Friday am	Friday pm	Saturday am
Friday	Friday pm	Saturday am	Monday pm	Tuesday am
Saturday	Monday pm	Tuesday am	Tuesday pm	Wednesday am
Sunday	Monday pm	Tuesday am	Tuesday pm	Wednesday am

6. Confirmation of results

It is important that you include your standard laboratory request forms with any samples that you send to the central laboratory at Harefield Hospital. This form should include a fax number, to which all results for your centre will be sent.

7. Costs

The central laboratories cost for monitoring sirolimus will be a charge of £32.50 per sample. This cost will be billed to your unit by the central laboratory.

8. Contacts

Queries regarding the monitoring of sirolimus in samples from patients outside Wyeth clinical trials should be referred to;

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