

Exceptions to the Quality Assurance Agreement / Look Back requirements

Following exception is applicable for all Norwegian centers:

In the Octapharma Look Back Procedure it is currently stated under

1.3 Additional Information:

Look Back / Post Donation Notifications are NOT required for Octapharma:

- reactive anti HBc test results (if HBsAg test **and HBV NAT** are negative)

In Norwegian:

1.3 Tilleggsinformasjon:

Look Back eller Post Donation meldinger skal ikke sendes til Octapharma ved:

- reaktiv anti HBc test resultat (hvis HbsAg test **og HBV NAT** er negative)

As HBV NAT is performed at Octapharma laboratory, information about HBV NAT negative test result is not available at the time of a reactive anti HBc test result.

Therefore the requirement will be changed to:

Look Back / Post Donation Notifications are NOT required for Octapharma:

- reactive anti HBc test results (**if HBsAg test is negative**)

In Norwegian:

Look back eller Post donation meldinger skal ikke sendes til Octapharma ved:

- reaktiv anti HBc test resultat (**hvis HBsAg test er negative**)

In case HBV NAT is reactive, a Look Back will be initiated routinely.

This exception is becoming effective by January 1st, 2019.

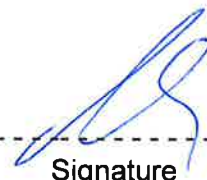
For OCTAPHARMA AG:

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28. 11. 2018

Date



Signature