

## 1. What does Unique Patient Code on the Laboratory Request Form (LRF) mean?

The Unique Patient Code (UPC) is an identifier for tracking the serum sample test, which ensures the patient's identity/privacy, and is used for the result communication between physician and Viroclinics. Please clearly indicate the UPC on the serum sample tube. Please use one Laboratory Request Form per serum sample!

## 2. In case blood collection and pick-up are scheduled on the same day, how long can the serum sample remain at room temperature before the courier pickup?

The serum sample can be left at room temperature for up to 2 hours, after this time it should be stored temporarily in a refrigerator at max 4 ° C before it is picked up by the courier the same day. After 24 hours the serum sample must be stored between -20°C to -80°C degrees

## 3. How long can the serum sample be kept frozen before sending it to the Viroclinics laboratory in the Netherlands?

For quality and testing purposes it is vital that serum samples are stored between -20°C to -80°C degrees. In frozen condition the serum is preserved as needed for an unlimited period of time.

## 4. What is the minimum volume of serum needed for testing?

Please isolate 0.5 ml serum per patient (an absolute minimum of 0.25 ml should be provided).

## 5. How many serum tubes per patient do I need to send for testing?

Please send only one tube per patient together with one Laboratory Request Form. (1 sample = 1 patient = 1 LRF). In case you are shipping multiple serum samples please inform Viroclinics by sending an email to [AAV9-Screening@Viroclinics.com](mailto:AAV9-Screening@Viroclinics.com)

## 6. Which tube should be used for preparing the blood collection?

A serum separator tube needs to be used for blood collection. However, do not use anticoagulant-treated tubes: e.g., no EDTA-treated or citrate-treated. Example of blood collection tube or similar to be used:

<b>Product name</b>	BD Vacutainer ® SST™ II Advance 2,5ml
Device Listing Number	n/a
Premarket Submission Number	n/a
Product code	366882
Device Name	BD Vacutainer ® SST™ II Advance
Manufacturer	Becton, Dickinson and Company UK
Foreign Manufacturer Address	n/a
Product name	BD Vacutainer ® SST™ II Advance 2,5ml
Device Listing Number	n/a
Premarket Submission Number	n/a
Product code	366882
Device Name	BD Vacutainer ® SST™ II Advance
Manufacturer	Becton, Dickinson and Company UK
Foreign Manufacturer Address	n/a
Dimensions	75 x 13 mm



**7. Which tube should be used for preparing the serum sample?**

<b>Product name</b>	Sarstedt tube
2 ml, PP, flat, with assembled cap, sterile	
Device Listing Number	n/a
Premarket Submission Number	n/a
Product code	72.694.006
Device Name	Culture media, Non propagation transport
Manufacturer	Sarstedt tubes
Foreign Manufacturer Address	Sarstedt AG & CO, Sarstedtstraße 1, Nürnbrecht, Germany
Dimensions	10.8*44 mm

Or similar polypropylene tube



**8. Can the serum sample be stored in a heparin tube?**

No, please use a Sarstedt or Eppendorf tube (or similar polypropylene tube). It is not possible to test a serum sample stored in a heparin tube.

**9. Do I need to arrange the shipment box myself?**

No, it is the courier's responsibility to arrange a shipping box and dry ice. You only need to place the serum sample in a biohazard bag (provided by the courier), seal it, and place it in the shipping box.

**10. Does a temperature logger need to be added to the shipping box?**

No, a temperature logger is not needed, as the serum sample will be shipped on dry ice.

**11. At what temperature should the AAV9 Antibody Screening kit be stored (used only in Europe, Middle East, and Africa countries)?**

Please store the serum sample kit at room temperature.

**12. If the courier is asking for a point of contact at the testing lab, how should I respond?**

Please reach out to Viroclinics via email for assistance at [AAV9-Screening@Viroclinics.com](mailto:AAV9-Screening@Viroclinics.com).

**13. If I forgot to include the Laboratory Request Form in the shipping box, what should I do?**

Please send the Laboratory Request Form by email to: [AAV9-Screening@Viroclinics.com](mailto:AAV9-Screening@Viroclinics.com).

**14. If I forgot to mention the blood collection date on the Laboratory Request Form, what should I do?**

Please provide this information along with the Unique Patient Code by email to: [AAV9-Screening@Viroclinics.com](mailto:AAV9-Screening@Viroclinics.com).

**15. How are the test results provided back to the treating physician?**

The result will be reported within 4 working days after the serum sample arrives at Viroclinics. The AAV9 test result will be communicated directly by Viroclinics via email to the email address(es) provided on the Laboratory Request Form.

**16. How long a serum sample will be kept at Viroclinics after the test is performed?**

After the test is performed, the sample is being stored at Viroclinics for 1 month and is disposed after 1 month.

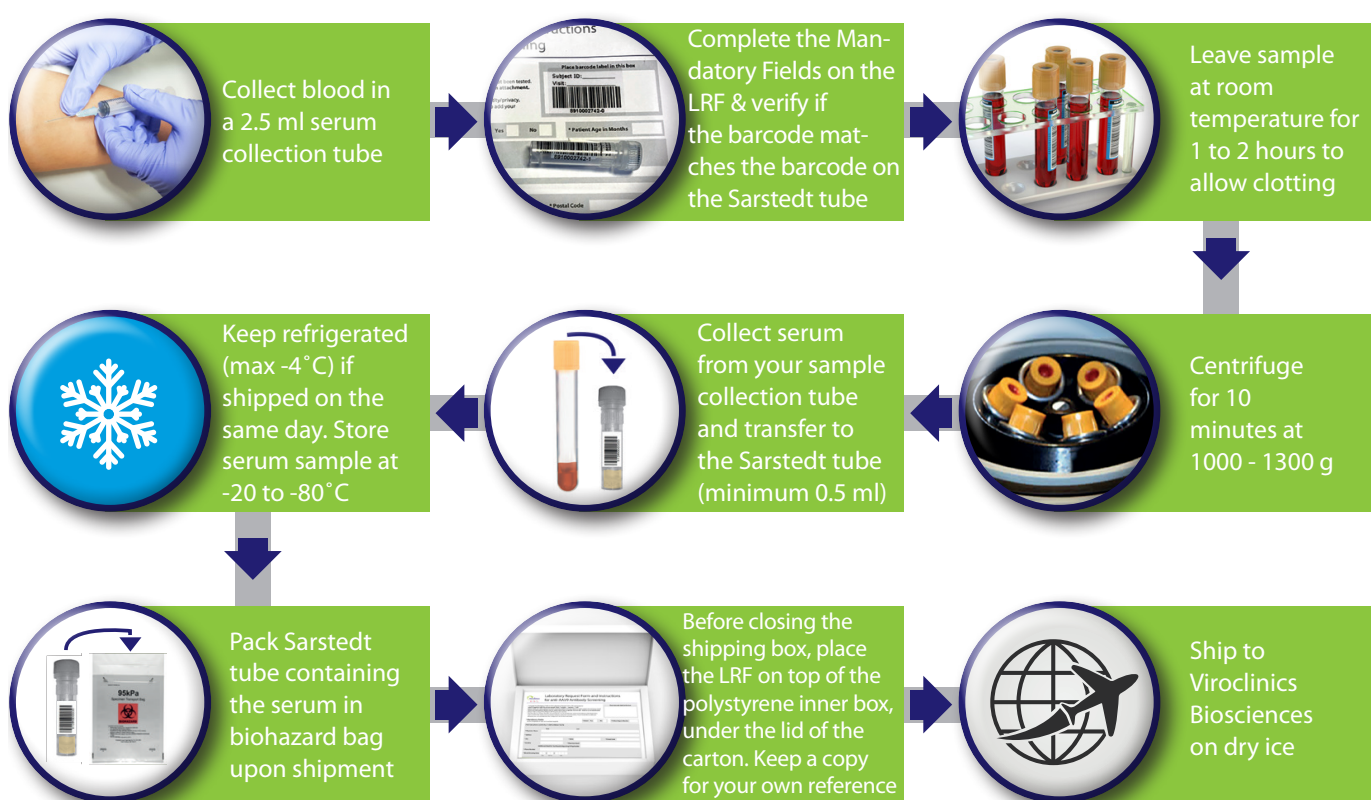
## 17. What standards does Viroclinics comply with?

Viroclinics-DDL is accredited for ISO 15189 by the Dutch Board of Accreditation (RVA). Viroclinics is specialized in the analysis of samples from both clinical trials and patient samples. With a strong track record and a specialty in respiratory viruses, focusing on vaccines, antibodies and antiviral compounds, they recently became highly proficient in the analysis of antibody and cell mediated responses. Viroclinics offer validated assays to detect antibodies against AAVs, vectors and target inserts.

## 18. How does Viroclinics deal with privacy data?

Viroclinics Biosciences, Viroclinics-DDL Diagnostic Laboratory provide its services on a global scale. If applicable, they comply with local privacy regulations. The company is based in the EU (The Netherlands). The framework of this privacy policy is therefore based on the European General Data Protection Regulation (GDPR or AVR).

## 19. What is the general overall process flow?



Please reach out to [AAV9-screening@viroclinics.com](mailto:AAV9-screening@viroclinics.com) once you need further assistance.