



ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
800-522-2787



Qarad EC-REP BV
PAS 257
2440 Geel
Belgium

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AAV5 DetectCDx™

AAV5 DetectCDx Specimen Shipping Kit

ARUP LABORATORIES

The AAV5 DetectCDx™ Specimen Shipping Kit is an optional specimen shipping kit for in vitro diagnostic use only that may be used by clinical laboratories for transporting human plasma specimens collected in 3.2% sodium citrate from patients with hemophilia A who are seeking AAV5 DetectCDx testing at (1) ARUP Laboratories at 500 Chipeta Way, Salt Lake City, UT 84108, or (2) Medicover at Institut für Medizinische Diagnostik Berlin-Potsdam GbR, a Medicover affiliate, Nicolaistraße 22 12247 Berlin-Steglitzaddress, Germany. This kit is for professional use only.

For additional information about AAV5 DetectCDx and valoctocogene roxaparovec, please visit www.aav5detectcdx.com.

Ordering Instructions

The optional AAV5 DetectCDx Specimen Shipping Kit is available on request (ARUP Part Number 56651). For more information about the shipping kit, or to order the shipping kit, visit www.aav5detectcdx.com or contact your local coordinating center.

Plasma Collection Instructions

1. Collect the patient's whole blood in a 3.2% sodium citrate tube.
 - o The blood collection tube must be filled per the manufacturer's guidelines to prevent an elevated concentration of sodium citrate in the collected sample. Samples that exceed 7.3% sodium citrate cannot be evaluated and may require patient redraw.
2. Centrifuge the specimen and separate the plasma within 72 hours of collection.
 - o A delay in this step could potentially cause the sample to yield a result of Not Detected.
 - o The Clinical and Laboratory Standards Institute (CLSI) recommends that sodium citrate **tubes be spun at 1,500 RCF for 15 minutes to achieve platelet-poor plasma** (platelet count <10,000 per mL).
3. Transfer 1 mL (min: 0.5 mL) of plasma into the pour-off (transport) tube.
 - o Failure to provide sufficient volume may require patient redraw.
4. Complete the Test Requisition Form. This form can be found at www.aav5detectcdx.com or by contacting your local coordinating center.
5. Label the transport tube with the patient's initials, UBC Patient ID Number, and the UBC Test Order Number.
 - o The UBC Patient ID Number and Test Order Number can be found on the Test Requisition Form or can be obtained by contacting your local coordinating center.

6. Freeze sample immediately at -10°C or below.
 - o If immediate freezing is not possible, refrigerate plasma at 2°C to 8°C immediately after processing. A delay in this step could potentially cause the sample to return a result of Not Detected.
 - o Plasma specimens may be refrigerated for up to 72 hours before freezing or stored frozen at -10°C or below for up to 6 months.

Shipping Instructions

All AAV5 DetectCDx™ specimens must be shipped frozen on dry ice.

1. Make courier arrangements by visiting www.aav5detectcdx.com or by contacting your local coordinating center. Please check your email for the notification of pickup date and time.
2. Place the completed Test Requisition Form in the specimen transport bag with the transport tube containing the frozen plasma. Use a single transport bag per patient specimen.
3. Place the specimen transport bag in an insulated box containing dry ice (box and dry ice will be provided by the courier at the time of pickup).

Warnings and Precautions

When drawing blood or working with patient specimens, universal precautions for bloodborne pathogens should be observed.

Limitations

- For in vitro diagnostic use only
- For professional use only
- For prescription use only

Kit Components

The AAV5 DetectCDx shipping kit includes the following components:

- 12 each: Tube, Round False Bottom, Standard Transport, 4 mL screw cap, nonsterile. This component is a CE-marked specimen transport tube manufactured by Sarstedt, Inc.
- 12 each: Biohazard Bag (6x6) inches
- 12 each: Pre-printed Labels (2.25x1.25) inches
- Collection and shipping instructions (this document)