

OncotypeDX® AR-V7 Nucleus Detect® Blood Collection and Transport Kit [REF] FM-00049
OncotypeDX® AR-V7 Nucleus Detect® Blood Collection and Transport Kit [REF] FM-00076

INDICATIONS AND USAGE

The OncotypeDX® AR-V7 Nucleus Detect Blood Collection and Transport Kit is intended for the collection and transportation of whole peripheral blood to be processed by the Epic Sciences, Inc. Clinical Laboratory.

MATERIALS AND METHODS

Kit Contents

- | | |
|------------------------|------------------------------|
| One 10mL Blood Tube | One Insulated Canister & Cap |
| One Conical Tube & Cap | One Phlebotomist Label Set |
| One Absorbent Sleeve | One FedEx Clinical Pak |

Material Required but Not Provided

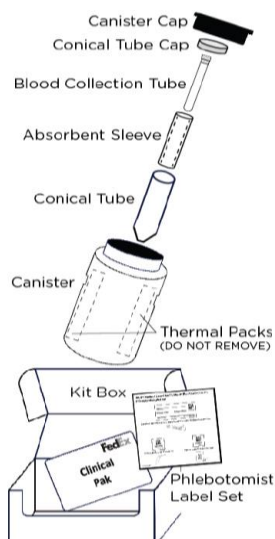
Material required for venipuncture whole blood collection (Sterile blood draw needle, tourniquet, alcohol wipes, and gauze.) A 21G or 22G needle is recommended by the blood tube manufacturer.

Storage and Handling

- When stored at room temperature (15°C to 30°C), the kit is stable through the expiration dating on the bottom of the kit box (same expiration date as the blood collection tube).
- Kit with blood sample should be stored at room temperature (15°C-30°C) pending shipment pickup.
- Samples must be received by the lab within 72 hours of blood draw. Overnight shipping using the included/pre-labeled FedEx Clinical Pak is recommended.
- The glass blood collection tube has the potential for breakage, precautionary measures should be taken during handling of the glass tube.
- The kit contains two thermal packs to maintain proper sample transportation temperatures. Do not remove the thermal packs from the canister.

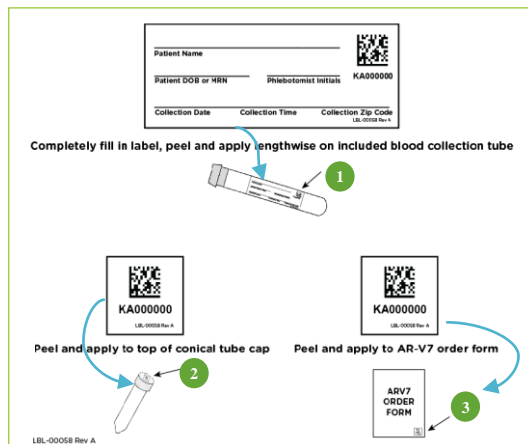
INSTRUCTIONS FOR USE

Kit Features



Preparing the Kit for Use

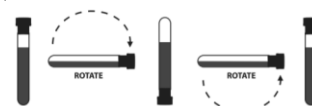
- Open the collection kit and inspect the included blood collection tube for damage and expiration. (Do not remove thermal packs or discard any items).
- Complete the AR-V7 Nucleus Detect Order form, fill out the blood tube label and apply all (3) phlebotomists labels as specified. Accuracy and completeness of the order form and tube label information including 2 patient identifiers is important and will prevent delays in sample processing.



IMPORTANT:
Ensure all information is populated and labels are applied as instructed

Collecting the Sample

- Using only the included blood collection tube, collect at least 8ml peripheral blood. It is recommended to collect specimen by venipuncture according to CLSI GP41-A6. The collection tube contains chemical additives, avoid possible backflow from the tube:
 - Keep patient's arm in the downward position during collection.
 - Hold tube with stopper in the upright position so that the tube contents do not touch the stopper or end of the needle during collection.
- After sample collection, it is important to immediately mix via gentle inversion 8 to 10 times. One inversion is a complete turn of the wrist, 180 degrees, and back per the figure below:



- Place filled blood collection tube into the absorbent sleeve and conical tube. Replace conical tube cap and ensure it is securely closed to prevent leakage. Place the sealed conical tube into the center of the canister between the thermal packs and replace the canister screw cap. Ensure canister screw cap is completely closed to prevent accidental leakage.

Shipping the Sample

- Fold and place the completed order form, a copy of the patient's insurance information, and any other relevant documents into the kit box along with the canister.
- Place the collection kit box directly into the pre-addressed FedEx Clinical Pak provided. Seal the Pak and store at room temperature pending shipment.
- Sample processing is time sensitive, ensure FedEx pickup is scheduled for the same day the sample is collected.
- All samples should be sent via the provided FedEx Priority Overnight service FedEx Clinical Pak to:

Epic Sciences, Inc.
ATTN: Clinical Laboratory
9381 Judicial Drive, Suite 200
San Diego, CA 92121

WARNINGS AND PRECAUTIONS

1. Do not use blood collection tube if cloudiness or precipitate is visible in the preservative reagent of the unused blood tube as this is a possible sign of product deterioration.
2. The preservative in the blood collection tube is subject to expiration which may impact test performance, do not use expired blood collection tubes.
3. Do not use any blood collection tube other than the tube provided with each collection kit.
4. Do not refrigerate or freeze kit or any of its contents.
5. Blood samples should be placed into the collection and transport kit after blood draw and scheduled for same day shipping pickup. Do not refrigerate or freeze patient blood samples prior to shipment.
6. The kit contains components which are uniquely serialized, matched, and tracked. Please do not mix any components between kits.
7. Do not open or unpackage the kit until time of blood draw.

FAQ

Question	Answer
Is the patient required to fast before blood collection?	No, the patient is not required to fast before collection.
Are special specimen collection tubes required for the assay?	Yes, there is one camo top tube included in the specimen collection kit to be used for this test only. Please use only the provided tubes for specimen collection.
Can I submit a specimen on a Friday?	Blood draws may be performed Monday through Friday and should be shipped on the same day for FedEx next day (Mon-Sat) delivery.
How long are samples stable during transport in the blood collection kit?	Samples received within 72 hours of collection will be processed normally. Samples received outside the 72-hour window will be discarded and a failure report issued. A re-order can be processed using a fresh blood draw.
How do I order additional collection kits?	Typically, kits will be automatically replenished. You can request additional kits by contacting your local sales representative or the Customer Service team. Kit orders are usually processed within a day and are received within 48-72 hours.
Does the blood collection tube contain any preservatives?	Yes, the provided blood collection tube contains a chemical preservative to support the 72-hour sample stability.

TROUBLESHOOTING

Issue	Solution
<p>The blood collection tube is broken or otherwise damaged and is no longer usable.</p> <ul style="list-style-type: none"> • Vacuum is broken • An issue occurred during blood collection • Tube is expired 	<p>Utilize a new kit to complete the blood draw. Please return the entire damaged kit in the provided, pre-paid clinical pak along with a brief note describing the tube damage. A replacement kit will then be issued according to the pre-defined replenishment schedule.</p> <p>Note: Do not mix kit components between kits. Utilize a new kit if necessary.</p>
<p>I do not have a test requisition form, or it is unclear on how to complete the requisition form.</p>	<p>Orders must be accompanied by a complete test requisition form to prevent delays in processing and to ensure sample integrity. Online requisition forms can be accessed through the Genomic Health order portal. For help with obtaining or completing a requisition form please contact Customer Service.</p>
<p>Unable to schedule shipment for same day as blood draw.</p>	<p>The sample is stable for up to 72 hours after blood draw. A shipment pickup should be scheduled as soon as possible and ensure delivery within 72 hours (Mon-Sat). Do not refrigerate or freeze the sample or kit while waiting for shipment.</p> <p>Note: The laboratory does not receive shipments on Sundays.</p>

CONTACT INFORMATION



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Customer Service:

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