

truCOLLECT™-RUO
Specimen Transport Kit (10)
PN 520184

Whole blood specimen dry stabilization, transport, and storage

For Research Use Only
Not for use in diagnostic procedures



UNIVERSAL PRECAUTIONS

Universal Precautions should be followed on all specimen samples, regardless of whether a sample is known to contain an infectious agent. Laboratories handling specimen samples are advised to comply with applicable parts of the following governmental and clinical standards, or their equivalent in the country of use:

- Centers for Disease Control (CDC), Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections, published 1987, updated 1996
- Clinical and Laboratory Standards Institute (CLSI), GP17-A3 Clinical Laboratory Safety; Approved Guideline - Third Edition, published 2012, ISBN 1-56238-797-9
- Clinical and Laboratory Standards Institute (CLSI), M29-A4 Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline, Fourth Edition, published 2014, ISBN 1-56238-961-0
- Occupational Safety and Health Administration (OSHA), 29 CFR 1910.1030 Bloodborne Pathogens
- International Standards Organization (ISO) 15190:2003, Medical Laboratories – Requirements for Safety

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REVISION HISTORY

Revision	Date	Description of change
A	3/17	As released

INTENDED USE

The truCOLLECT™-RUO Specimen Transport Kit is intended for remote collection of whole blood, its controlled desiccation, and storage. The truCOLLECT-RUO Specimen Transport Kit is intended for use in life science applications, such as molecular biology. For DNA extraction, this kit is designed to be used with the truCOLLECT-RUO DNA Extraction & Purification Kit (PN 520236). This Research Use Only (RUO) product is not intended for the diagnosis, prevention, or treatment of a disease. The truCOLLECT-RUO is not designed nor is it intended for direct touch specimen collection (e.g., blood finger stick).

INTRODUCTION

Analysis of whole blood specimens is a fundamental, high-value technique for biomedical and life science research. For biomarker analysis, while freshly collected specimens are desired, the logistics of collection, stabilization, and long-term storage of fresh blood are problematic and expensive. An alternative to fresh blood is a dried blood specimen collection card technique (e.g., Dried Blood Spot). Dried blood cards, while having stability benefits and lower cost, were not designed for advanced analytical molecular biology techniques. DNA extraction from dried blood specimens remains difficult to adapt for use in downstream NGS-based analysis, due to inherently low DNA yields.

The truCOLLECT-RUO Specimen Transport Kit is specifically designed for remote collection of whole blood, its controlled desiccation, and storage. With the truCOLLECT-RUO system, whole blood specimens are collected in either EDTA venipuncture vacutainers or EDTA blood capillary tubes and easily transferred onto a porous fiber swab. The swab is attached to a 2D barcoded cap for sample identification and tracking. After applying anticoagulated blood onto the porous swab, the cap/swab assembly is immediately inserted into a vial containing an immobilized desiccant and sealed. This vial enables consistent operator-independent, dry-stabilization of the specimen. In addition, this vial also minimizes sample-to-sample reproducibility, operator error, and environmental contamination. The sealed container can be shipped, in accordance with current shipping regulations, using standard shipping methods at ambient temperature.

In an appropriate laboratory environment, DNA is recovered from such dry-stabilized blood samples using Covaris Adaptive Focused Acoustics (AFA™). Uniquely, AFA-energetics™ ensures rapid rehydration and detachment of blood cells from the truCOLLECT-RUO swab. The DNA extraction buffer which is optimized for AFA-energetics, enables the efficient downstream isolation and subsequent column-based purification of high quality, molecular biology grade DNA.

KIT CONTENTS

Item	Amount per sample	Amount included per kit (10 samples)
truCOLLECT-RUO cap/swab with barcode	1	10
truCOLLECT-RUO desiccant/storage container	1	10
0.1 ml PCR tubes	1	10
Tamper evident indicator	1	10
Product Insert	n/a	1

ACCESSORIES

Item	Part number
truCOLLECT™-RUO DNA Extraction & Purification Kit (10) – Column Purification	520236

Equipment Required:

1. Precision pipette or transfer pipette to remove blood from primary collection tube and place into the 0.1 ml PCR tube for sample transfer.
2. Powder-free disposable gloves

SAMPLE COLLECTION, DRY STABILIZATION, AND STORAGE

This procedure is intended for blood specimens collected into EDTA Blood Collection Tubes (BCT) or blood collection devices such as the MiniCollect EDTA system (i.e., Greiner Bio-One). The truCOLLECT-RUO is not to be used for direct touch specimen collection (e.g., finger stick). The specimen must be transferred from the primary blood collection device onto truCOLLECT-RUO swab as described in the procedure below.

WARNING: As biological specimens are potentially a biohazard, Good Laboratory Practices must be followed. Appropriate equipped laboratory, trained personnel, and supplies (such as gloves, glasses, and clothing) are required to handle lab materials safely.

1. Identify the type of specimen and the date of specimen transfer on the label of the desiccant/storage container.
2. Transfer up to 100 μ l of the sample from the primary blood collection tube to a 0.1 ml PCR tube, using a precision pipette or transfer pipette.
3. Open the desiccant/storage container by gently pressing upwards on the tab on the cap attached to the container.
4. Carefully remove the truCOLLECT-RUO cap/swab assembly as shown in Fig. 1

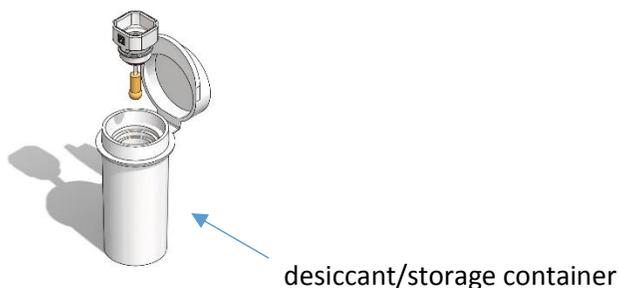


Figure 1: Opened truCOLLECT

5. If desired, scan and note the 2D barcode number on the side of the cap/swab assembly as shown in Fig. 2

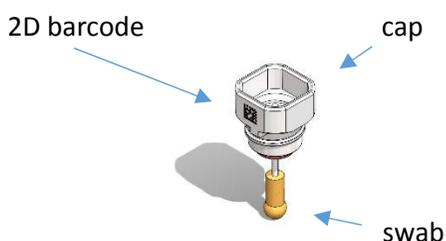


Figure 2: cap/swab assembly

CAUTION: Do not touch the truCOLLECT swab area

6. Fully immerse the swab portion of the truCOLLECT-RUO cap/swab into the 0.1 ml PCR tube containing aliquoted blood to collect the sample. Wait 5 seconds to make sure that the sample has wicked into the swab. Alternatively, use a pipette to apply a nominal volume of sample (up to 35 µl) directly to the swab.

NOTE: The truCOLLECT-RUO cap/swab can be loaded by dipping the swab end into whole blood collected into blood collection devices such as MiniCollect (Greiner Bio-One). Follow steps 3. to 7.

7. After sample application, verify no blood is dripping from the swab and, being careful to avoid touching the walls of the container, immediately insert the cap/swab into the desiccant/storage container.
8. Carefully snap close the desiccant/storage container cap.

CAUTION: The desiccant/storage container needs to be firmly closed to ensure sample dry stabilization.

9. If needed, apply the tamper evident indicator tape to the desiccant/storage container by centering and wrapping the label over the cap and affixing to opposite sides of the container, careful not to cover the sample information on the label.
10. Samples may be stored at room temperature until processing.
11. If shipping is required, dry the sample overnight in the desiccant/storage container.
 - a. For domestic shipments in the United States, please follow the USPS Packaging Instructions for nonregulated infectious materials (USPS Packaging Instructions 6G): http://pe.usps.com/text/pub52/pub52apxc_023.htm#ep1000450
 - b. For international shipments, please follow http://pe.usps.com/text/pub52/pub52c3_024.htm, section 346.325 Nonregulated Materials, which identifies the packaging requirements that must be met for international mail.
 - c. Always comply with current shipping regulations.