IndiTreat® Specimen Collection Kit

Instructions For Use- EN English

2CX-SCK-01

IFU is available in other languages at:
www.inditreat.com/eIFU

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Intended use

The intended use for the IndiTreat® Specimen Collection Kit is to facilitate the transportation of living tumor specimens obtained via needle biopsy or endoscopic biopsy to laboratories performing in vitro diagnostic IndiTreat® testing. The testing population from which the specimens are obtained are patients with colorectal cancer. The IndiTreat® Specimen Collection Kit is a single-use accessory device and is not intended to detect or measure colorectal cancer.

Intended user

Intended users of the IndiTreat® Specimen Collection Kit are healthcare professionals and laboratory professionals.

Intended use environment

The IndiTreat® Specimen Collection Kit is intended to be used within hospital departments such as surgery, radiology, pathology, or other hospital departments where tumor biopsies are taken.

Basic principles of the procedure

The IndiTreat® Specimen Collection Kit contains a specialized ready-to-use, single-use buffer capable of supporting the viability of specimen samples during transportation for up to 24 hours after sampling. The IndiTreat® Specimen Collection Kit also contains a temperature logging device to monitor the temperature that the specimen has been exposed to during shipment.

Limitations

- Do not store the specimen in fixative solutions (e.g. formalin/formaldehyde) prior to transferring the specimen to the Specimen Transport Buffer as this could interfere and compromise the specimen's cellular viability and quality.
- Do not at any time store the specimen on dry ice or at freezing temperature conditions as this could compromise the specimen's cellular viability and quality.

Components included

Components included	**Description**
Specimen Transport Buffer	Specialized preserving buffer capable of supporting the viability of specimen during transportation for up to 24 hours.
Specimen Shipping Bag	A leak-proof pouch containing absorbent material for shipping the specimen.
Temperature logger	Temperature logging device capable of logging the shipment temperature.

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Components required, but not included

Component	Description
Cooling shipping box • 2cureX recommends the IndiTreat® Shipping Container. See section for ORDERING INFORMATION	Shipping box with cooling for shipment of specimen in compliance with UN3373 requirements for road and air transport.
Equipment required to obtain a needle biopsy	Needle biopsy instrument for collecting approximately 30 mg of tumor biopsy.
Printed and signed IndiTreat® Requisition Form • Visit ordering.inditreat.com to retrieve your IndiTreat® Requisition Form	Printed and signed requisition form for the specimen.

Warnings and precautions

- Do not reuse the Specimen Transport Buffer. It is only intended for single use.
- Do not use the Specimen Transport Buffer after its expiry date.
- Do not use the Specimen Transport Buffer if it has been stored outside the indicated storage temperature for a prolonged time.
- Do not use the Specimen Transport Buffer if there is sign of leakage or a broken vial.
- Do not use the Specimen Transport Buffer if the buffer is not colorless.
- The Specimen Transport Buffer contains calcium chloride ($CaCl_2$) dihydrate which is an eye irritant. The product is not classified as dangerous for use.

CRMR or endocrine disrupting substances

The IndiTreat® Specimen Collection Kit does not contain toxic carcinogenic, mutagenic or reprotoxic chemicals, or other endocrine-disrupting substances.

Disposal

- Discard the Specimen Collection Kit box, and unused Specimen Shipping Bag and Specimen Transport Buffer as general waste or according to your local waste procedure.
- Used components that have been in contact with a specimen are discarded as biological waste/clinical waste.
- Unused temperature loggers are returned to 2cureX for multiple use. Contact 2cureX or your local distributor for advice (see SUPPORT section).
- Damaged temperature loggers deemed non-functional shall be discarded as electrical waste (WEEE) [1].

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Storage and stability

The Specimen Transport Buffer must be stored at 2-8°C under dark conditions and kept away from direct sunlight as stated on the label. Check the label on the Specimen Transport Buffer for the expiration date.

The vial containing Specimen Transport Buffer is a single-use product. Once the Specimen Transport Buffer has been opened and the specimen has been transferred to the vial, it is stable for up to 24 hours during storage/transportation at conditions indicated on the vial label.

Sterility

- The Specimen Transport Buffer is aseptically prepared and filtered.
- The Specimen Transport Buffer meets the EU standards for endotoxin levels (≤1.0 EU/ml).

Procedure

It is recommended that the user reads these instructions before use

Procedure step	Task
STEP 1: Keep Specimen Transport Buffer cold	• Remove the Specimen Transport Buffer from the refrigerator (2-8°C) and place the vial in a beaker with ice. ⚠ **CAUTION - RISK OF DAMAGE TO SPECIMEN** Do not place the Specimen Transport Buffer on dry ice or at a sub-zero temperature as this will negatively impact the specimen quality and viability.
STEP 2: Collect Specimen	• Collect the specimen according to your local procedure. • If tissue is sampled by needle biopsy, this should preferably be secured using a 16G needle or larger. The number of biopsies using this 16G needle size must be at least three which equals appr. 30 mg of tissue. If a smaller needle is used the number of biopsies should be increased accordingly. To optimize successful specimen viability, avoid collecting tissue with visible necrosis and apoptosis. ⚠ **WARNING – RISK OF INFECTION** The specimen could potentially be infectious and should be handled according to local and national guidelines [2].

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STEP 3: Transfer specimen to Specimen Transport Buffer	• Transfer the collected specimen to the vial containing Specimen Transport Buffer and tighten the screw cap to seal the vial.
STEP 4: Place specimen in Specimen Shipping Bag	• Place the vial containing the specimen inside the Specimen Shipping Bag. ⚠ **CAUTION - RISK OF DAMAGE TO SPECIMEN** Ensure that the screw cap of the vial containing the specimen is tightened to avoid leakage of the specimen during shipment.
STEP 5: Seal Specimen Shipping Bag	• Seal the Specimen Shipping Bag by following the instructions printed on the back of the bag.
STEP 6: Prepare shipping box	• Place the Specimen Shipping Bag containing the specimen inside the cooled or activated shipping box together with the signed IndiTreat® Requisition Form. • If the IndiTreat® Shipping Container is used, follow the procedure for activating the cooling element. • If a third party shipping container is used, ensure that the box is cold prior to placing the specimen in the shipping container. ⚠ **CAUTION - RISK OF DAMAGE TO SPECIMEN** **DO NOT** use a shipment box at freezing temperature as the specimen quality and viability will be compromised. The shipping box must be able to maintain 2-8C° for a minimum of 24 hours for shipment. 2cureX recommends using the IndiTreat® Shipping Container box.
STEP 7: Activate temperature logger	• Activate the temperature logger by pressing the START button for **5 seconds** until the LED display flashes green and the LCD display is activated. 

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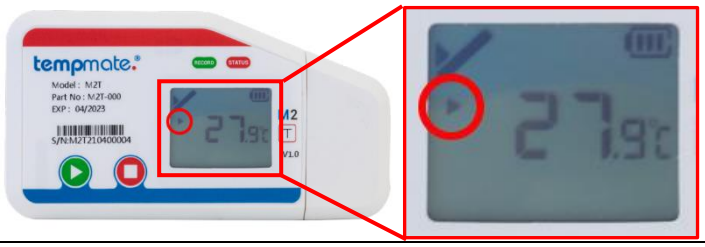
	• Once activated, the display will show a small “play” triangle in the LCD display as shown below. • DO NOT press the STOP button for more than 5 seconds, as this will stop the temperature recording. 
STEP 8: Seal shipping box	• Place the activated temperature logger inside the shipping box and seal the box. • **IMPORTANT!** Before sealing the cooled shipment box make sure that your shipment contains the requisition form, sealed specimen and activated temperature logger.
STEP 9: Ship shipping box containing specimen to IndiTreat® testing facility	• Ship the shipment to your IndiTreat® testing facility. The specimen must arrive at the testing facility within 24 hours.

Control procedure

The IndiTreat® Specimen Collection Kit includes a temperature logger device to monitor the temperatures that the specimen has been exposed to during shipment. When the specimen arrives at the IndiTreat® testing facility, the temperature logger is used to verify that the specimen temperature has been kept at the specified temperature interval.

Performance characteristics

The vial containing IndiTreat® Specimen Buffer is designed to have enough head space to submerge the specimen in the buffer. The vial also has enough buffer to avoid the specimen drying out during storage and transportation.

The IndiTreat® Specimen Buffer is serum-free and is optimized to maintain specimen integrity and to reduce necrosis and apoptosis during specimen storage and transportation. The buffer supports mitochondrial metabolism and is acid/base-balanced as required for human cellular functionality. The

buffer supports cellular viability of the specimen for more than 24 hours and is stable at temperatures between 2°- 8°C.

Support

For technical support and other product-related inquiries, please contact your local distributor or contact 2cureX Support directly: support@2cureX.com

Any serious incidents by user occurred in relation to product use shall be reported to 2cureX and the competent authority of the Member State where the user is established.

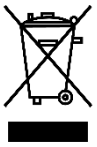
Ordering information

Item product reference code	Description
2CX-SCK-01	IndiTreat® Specimen Collection Kit
2CX-SC-01	IndiTreat® Shipping Container

Contact your local distributor for ordering or contact 2cureX (email: customerservice@2curex.com

2cureX complies with the IVD regulation and is certified according to ISO 13485 [3,4].

LABELING SYMBOLS

	Manufacturer		In vitro diagnostic product
	Caution or warning		Product reference code
	Temperature limitations		LOT number
	Expiry date		Do not re-use
	Keep away from exposure to direct sunlight		WEEE (Waste Electrical and Electronic Equipment)
	Consult online Instructions For Use		EU conformity mark

References

1. (EU) 2018/849 Waste from Electrical and Electronic Equipment (WEEE)
2. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline –Fourth Edition. CLSI document M29-A4E. 2014
3. 2017/746/EU IVD European Regulation
4. ISO13485:2016 Medical Device Standard