

RheumaKit

Thank you for using RheumaKit. Please read this document carefully before use.

Storage and handling conditions

This product contains biopsy collection vials filled with an RNA-preserving solution containing ammonium sulfate. Dispose of in accordance with local regulations.



Intended Use

This product is a synovial biopsy receptacle and transportation kit intended to be used in conjunction with RheumaKit services. RheumaKit is a solution for early differential diagnostic of patients with undifferentiated arthritis. Undifferentiated arthritis describes a condition in which synovial inflammation is present in one or more joints, and no definite diagnosis can be made using presently available diagnostic criteria.

Kit content

You received the kit illustrated below, which is composed of a covering sheet with RheumaKit branding, wrapped around a UN3373 validated packaging (i.e. validated for air transportation). This box contains:

- 2 biopsy collection vials (one for use, the other for backup), each filled with 1.5ml of rna-preserving solution (see warnings & precautions on the right). Those vials display the following symbol:



- 1 liquid-absorbing device (very small bag with powder inside)
- 1 Cibesmed low-pressure protective bag
- 1 list of instructions (this document)
- 1 return form
- 1 TNT "medpack sleeve / overpack" including a return label
- 1 patient consent form
- 1 set of extra labels displaying the Kit ID number

Sampling procedure

The RNA extraction and hybridization procedure must be performed using synovial biopsies from a joint with synovitis, (visually assessed or through ultrasound imaging) from a patient with undifferentiated arthritis (see intended use).

At least 5 and up to 10 different synovial biopsy fragments are needed, in order to decrease the risk of biases in gene expression profiles related to the potential heterogeneous distribution of synovial inflammation.

All fragments should be immersed immediately after sampling in one of the two delivered biopsy collection vials. They contain an RNA-stabilizing solution. A total of 5 to 10mg of synovial tissue are required in order to extract enough total RNA for the procedure. This amount is easily obtained when 4 to 6 biopsy specimens are collected by needle arthroscopy, likely 8 to 10 if harvested via an ultrasound-guided approach. Surgical biopsy fragments can be used as well ; however, each biopsy fragment may not exceed 5 mm in each dimension, before immersion in the RNA stabilizing solution. In any case the total volume of the fragments should not exceed one fifth of the volume of the delivered RNA stabilizing solution (i.e. one fifth of 1.5 cm³). Do not split the specimens into the two vials. However, we recommend that the procedure be repeated and the same amount of tissue be stored in the second, backup vial. This second vial is present in the kit in case a problem occurs with the first one during transportation or QC.

The fragments in the biopsy collection vial (and the backup vial) should be stored at 4°C before shipment. They should not be frozen. They need to be shipped as soon as possible (max 48h at 4°C), using the pre-paid packaging material delivered with the kit (see shipping procedure section).

Please do not perform biopsy on a Friday, nor the day before a holiday in Belgium, nor the day before a laboratory closing day, which can be checked on <http://dnalytcs.com/rheumatology-rheumakit/lab-availability>
In case of doubt please contact DNalytcs at customer-support@rheumakit.com.

Shipping procedure

1. Fill the return form provided within the box
2. Insert the box in the TNT medpack sleeve / overpack which includes already a return label.
3. Store again the box at 4°C until shipment.
4. To arrange the return journey of your sample to our facilities, call the carrier at the number mentioned on the upper face of the cardboard box, before the time mentioned next to the phone number. This shipping is prepaid. During your phone call, a reference number will be given to you in order to track the pick up procedure. Write it down and keep it.
5. The kit will be picked up at your address on the same day. Leave the box at 4°C as long as possible.

Warnings & precautions

Enhance quality: When sampling the biopsies, take care not sampling tissues containing mostly fat. Meet the temperature requirements along the entire process.

Backup: When possible, repeat the sampling procedure and fill the second (backup) biopsy collection vial with an additional series of biopsies, also summing up to 5-10mg. Store this second vial at 4°C too. It should be kept until the gene expressions have been produced by our laboratory on your first sample. A confirmation email will be sent to you when the first sample has been processed. If it passes the quality control, the second sample becomes useless. In case of quality control issue with the first sample, the second sample can be sent to our facilities (detailed instructions will follow in this case).

Avoid mixing patient samples:

1. Do not put samples from different patients within the same vial.
2. Do not use the second vial for another patient's sample

Avoid contaminating the fragments put in the vial(s) with pathogens. The following hazard and precautionary statements apply to the rna-preserving solution contained in the two biopsy collection vials provided with this kit.

Hazard statements

- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H335 - May cause respiratory irritation



Precautionary statements

- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P337 + P313 - If eye irritation persists: Get medical advice/attention
- P332 + P313 - If skin irritation occurs: Get medical advice/attention
- P264 - Wash hands thoroughly after handling

Support

Should you have any question, please send an email to customer-support@rheumakit.com, specifying your name and kit ID number.

Disclaimer

RheumaKit is a trademark of DNalytcs SA. All the disclaimers and general terms and conditions displayed on <http://www.rheumakit.com> apply to this kit and its related services.



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