IAB-UCTM

universal collection transport medium

by InActiv Blue

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version B.2 update: 03/07/2024

For in vitro diagnostic use only
For professional use only

CATALOGUE NUMBER

REF **UCTM_0003** IVD CE

PRODUCT DESCRIPTION

REF	product description	packaging
UCTM_0003	*3 mL of IAB–UCTM in a screw cap tube (flat bottom, freestanding)*	*50 tubes per package* *8x50 tubes per box* *or* *24x50 tubes per box*

SYMBOL GLOSSARY

symbols as defined in ISO 15223

- REF *catalogue number*
- LOT *batch code*
- *use-by date*
- *manufacturer*
- *distributor*
- *do not re-use*
- *consult instructions for use*
- 2°C 25°C *temperature limit*
- IVD *in vitro diagnostic medical device*
- *caution*
- *keep away from (sun)light*
- BIO *contains biological material of animal origin*
- *contains a medicinal substance*

symbol as defined in 2017/746 (IVDR)

- CE *CE marking*

TECHNICAL SUPPORT

URL: ***www.inactivblue.com***
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MANUFACTURER INFORMATION / DISTRIBUTOR

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INTENDED USE

IAB-UCTM is a universal medium intended for the collection and transport of naso- or oropharyngeal swabs for in vitro diagnostic testing on the presence of genetic material (i.e. viral RNA, human RNA/ DNA) by (RT-)qPCR or other molecular methods. IAB-UCTM can be used for collection, transport, and storage of specimens at temperatures between 4-25 °C.

SPECIMEN TYPES

Upper respiratory specimens collected by swab.

INTENDED USER

Sample collection:	Sampling with naso- or oropharyngeal swabs: medical doctors or healthcare providers in healthcare institutes or other medical environments.
Analysis of preserved sample	Analysis by approved medical labs.

GENERAL

- Certificate of analysis
  - *A certificate of analysis per lot is available upon request*
- Storage / disposal
  - *Store reagents between 2-25 °C*
  - *Keep away from direct (sun)light*
  - *Do not use after expiry date*
  - *Dispose in accordance with local regulations for disposal of medical devices / hazardous substances*
- Materials needed, but not provided
  - *Naso- or oropharyngeal swabs: it is advised to only use synthetic (flocked) fiber swabs with plastic or wire shafts and not to use calcium alginate or cotton swabs or swabs with wooden shafts as these may inhibit molecular tests. Ideally, the breakpoint of the swab is not higher than 8 cm (3.15 inch).*
- Warnings and precautions
  - *All human, organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting pathogens. Always wear protective clothing when handling specimens and reagents (e.g. gloves, lab coat, surgical mask, eye/face protection).*
  - *Do not use if the product is visibly damaged.*
  - *For specifics, consult the MSDS that is available upon request or can be downloaded from the website www.inactivblue.com.*

PRINCIPLES OF OPERATION AND COMPOSITION

IAB-UCTM is not considered as a diagnostic test but as specimen receptacle:

- *doctors or other healthcare providers collect patient sample according to nationally accepted guidelines, e.g. respiratory secrete by means of a swab (in Belgium: guidelines by Sciensano).*
- *the tube is hermetically closed, identified and sent to an analysis lab for testing, along with the necessary documentation.*

IAB-UCTM is a HEPES-buffered(*) salt solution with the following main components:

1. bovine serum albumin (BSA, 5 g/L)): to stabilize the sample
   BSA does not contain:
   - *lipoproteins (which can inhibit attachment and growth of some viruses)*
   - *antibodies (which can interfere with the diagnosis)*
2. gelatin: to obtain a certain preferred viscosity
3. gentamicin (10 mg /L) : antimicrobial agent to inhibit and prevent the overgrowth of the normal flora within a clinical sample, improving sample storage at room temperature
4. sucrose: as carbohydrate nutrient source

(*) IAB-UCTM is phosphate-free as this might interfere with PCR assays.

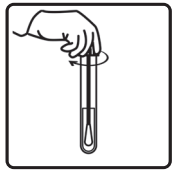
INSTRUCTIONS FOR USE

1 Make sure that you use the required personal protection. Follow the procedure for droplet protection: use gloves, coat, surgical mask, and eye protection (goggles or face shield). Identify the sample.

2 Collect the specimen with a suitable swab according to the instructions of the manufacturer of the swab. DO NOT PRE-WET the swab before touching the patient

3 While holding the swab, remove the cap from the test tube. Insert the swab into the test tube opening without touching the (outer) surface of the tube. Once the specimen is in the medium, spin around the swab.

4 Break off the swab shaft (or alternatively cut the swab handle) so that the breakpoint level corresponds with the test tube opening. Make sure that the breakpoint of the swab is not higher than the tube opening.



5 Hermetically close the tube by the screw cap. The sample is now stable for transport and storage prior to further processing in the laboratory. Samples can be stored at 4-25 °C up to three days (see performance characteristics below).

6 Samples should be analyzed in the laboratory within 3 days upon sample collection. If analysis is delayed, the specimen must be frozen. Invert tube 10 times to ensure that the complete inner surface of the tube (and swab) have been in contact with the buffer solution. Use validated laboratory procedures for PCR testing.

RESULTS AND PERFORMANCE

Performance characteristics:

- Stability of viral RNA in nasal swab sample: stability up to 72 hr, 4-25 °C (< 2 Cq higher on day 3 compared to day 0)
- Stability of human RNA in nasal swab sample: stability up to 72 hr, 4 °C (< 2 Cq higher on day 3 compared to day 0)
- Stability of human DNA in nasal swab sample: stability up to 72 hr, 4-25 °C (< 2 Cq higher on day 3 compared to day 0)
- Freeze/thaw stability (< 2 Cq later)
- Comparable performance as CE marked, commercially available UTM® (registered trademark of Copan group)

Table: Evaluation of clinical result for positive swab samples re-evaluated as a 10-fold dilution in IAB-UCTM or other commercially available CE marked UTM® on different platforms and storage conditions: all originally positive samples remained positive at day 0, 2 and 3.

platform	RNA extraction and RT-qPCR assays	storage temperature	nasal swab sample		IAB-UCTM	other CE marked UTM®
					evaluation on day 0 /2 /3	
Seegene STARlet *(Seegene)* ***and CFX96*** *(Bio-Rad)*	***STARMag 96 X 4 Universal Cartridge Kit*** *(Seegene)* ***and Allplex SARS-CoV-2/Flu A/Flu B/ RSV Assay*** *(Seegene)*	***20-25 °C***	**RSV:**	*strong positive*	+	+
				weak positive	+	+ (day 2) - (day3)
			influenza A:	*strong positive*	+	+
				weak positive	+	+
			SARS-CoV-2:	*strong positive*	+	+
				weak positive	+	+
Panther Fusion *(Hologic)*	***SARS-CoV-2/Influenza A/B/RSV assay***	***20-25 °C***	**RSV:**	*strong positive*	+	+
				weak positive	+	+
			influenza A:	*strong positive*	+	+
				weak positive	+	+
			SARS-CoV-2:	*strong positive*	+	+
				weak positive	+	+
geneXpert *(Cepheid)*	***Xpert Xpress SARS-CoV-2/Flu/RSV assay***	***4 °C***	**RSV:**	*strong positive*	+	+
				weak positive	+	+
			influenza A:	*strong positive*	+	+
				weak positive	+	+
			SARS-CoV-2:	*strong positive*	+	+
				weak positive	+	+

PRODUCT SPECIFICATIONS

The following quality control tests are performed before each batch release:

- chemical composition
- pH: 7.20-7.60
- osmolality: 280-310 mOsm/kg (release criteria: 280-300 mOsm/kg)
- sterility test (test method according to Ph Eur 2.6.1 /USP<71>): no growth
- functionality test: RT-qPCR that demonstrates:
  - *stable detection of a low concentration of viral RNA*
  - *no signs of PCR inhibition*

LIMITATIONS

IAB-UCTM is not intended to inactivate pathogens.

More details: www.inactivblue.com.