



# **HYRIS**

## **bKIT™dqTACT MS**

### Instruction for Use (IFU)

REF: HR017X300  
HR017X260  
HR017X130

Version 1.3

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**INTENDED USE**

The **bKIT™ dqTACT MS** is a Real-Time RT-PCR assay intended for the qualitative detection of *CXCL10* mRNA in heparinized whole blood.

*CXCL10* mRNA is upregulated by monocytes in response to IFN-γ secreted by antigen-specific T cells, following stimulation with the Hyris specific-peptides pool of the **XTACT** product family.

The **bKIT™ dqTACT MS** used in combination with the specific-peptides Activation kit is intended to be used for basic research with the aim to collect information on cell-mediated immune (CMI) response in individuals.

The results of this test should not be used for diagnosis, treatment, or other patient management decisions.

Not to be used for diagnostic purposes.

For Research Use Only.

**SUMMARY AND EXPLANATION**

Long-term protection from viral infections is mediated by both the humoral (antibodies) and cellular immune pathways. While SARS-CoV-2-specific IgG and neutralizing antibody quantification are being used as clinical endpoints to determine immune protection, a precise measurement of cellular responses underlying virus protection also represents an important parameter of immune defence, which is rarely performed due to the technical challenges associated<sup>[1,2]</sup>.

The **bKIT™ dqTACT MS** is designed to detect the T cell immune responsivity through the measurement of *CXCL10* mRNA expression; *CXCL10* is a chemokine upregulated in monocytes and neutrophils in response to IFN-γ secreted by antigen-specific T cells. When the T cells are responsive to the specific pool of peptides, they upregulate IFN-γ secretion, stimulating monocytes to upregulate *CXCL10*.

The *CXCL10* mRNA is normalized to the expression of *ACTIN* mRNA, a housekeeping gene.

The **bKIT™ dqTACT MS** assay allows specimen processing based on a direct workflow (on peripheral whole blood samples).

**PRINCIPLE OF THE PROCEDURE**

The procedure allows detection of *CXCL10* mRNA in whole blood samples stimulated by specific pool of synthetic peptides specific for the antigen specific T cells (CMI). The sample stimulation occurs through a specific kit of the **XTACT** activation product line and subsequent analysis by RT-PCR. Monocytes and neutrophils produce *CXCL10* mRNA in a tightly regulated manner and in response to the IFN-γ secreted by antigen-specific T cells, and thus this gene serves as a proxy of T cell activation upon SARS-CoV-2 specific spike peptide stimulation of whole blood.<sup>[1]</sup>

No sample extraction is needed prior to the PCR amplification step. The technology is based on the TaqMan assay and works in duplex. *CXCL10* mRNA is detected by a sequence-specific primers and probe set.

Hyris primers / probes mixes:

*CXCL10*: targets human; molecule expressed by monocytes and neutrophils in response to T cell activation.<sup>[1]</sup>

*ACTIN*: targets human; control for sample normalization.

Probes are labelled with FAM and HEX fluorophores.

**Detection Channel**

Organism	Target region	Probe fluorophore	Excitation/emission	Detection channel
Homo sapiens	<i>ACTIN</i>	HEX	530/555 nm	Yellow
	<i>CXCL10</i>	FAM	470/510 nm	Green

## MATERIALS PROVIDED

### KIT DESCRIPTION

REF	Commercial name	Contents	Kit Size	Number of reactions
HR017X300	bKIT™ dqTACT MS	All in one Liquid reaction mix for <i>CXCL10</i> and <i>ACTIN</i> (FAM/HEX) detection. Positive Control Mix for <i>CXCL10</i> and <i>ACTIN</i> Negative Control.	<b>MASTER MIX IF:</b> 3x1000µL <b>PRIMER SET IF:</b> 3x50µL <b>ENHANCER IF:</b> 3x750µL  <b>POSITIVE CONTROL IF:</b> 1x120 µL <b>NEGATIVE CONTROL IF:</b> 1x150 µL	300 reactions
HR017X260			<b>MASTER MIX IF:</b> 2x1300µL <b>PRIMER SET IF:</b> 2x65µL <b>ENHANCER IF:</b> 2x975µL  <b>POSITIVE CONTROL IF:</b> 1x120 µL <b>NEGATIVE CONTROL IF:</b> 1x150 µL	260 reactions
HR017X130			<b>MASTER MIX IF:</b> 1x1300µL <b>PRIMER SET IF:</b> 1x65µL <b>ENHANCER IF:</b> 1x975µL  <b>POSITIVE CONTROL IF:</b> 1x120 µL <b>NEGATIVE CONTROL IF:</b> 1x150 µL	130 reactions

The MASTERMIX IF contain Reverse Transcriptase, DNA polymerase, RNase Inhibitor, buffer, dNTPs. PRIMERSET IF contain fluorescent probes and corresponding forward and reverse primers specific for detection of *CXCL10* and *ACTIN*.

Component	Cap Color	LABEL
MASTER MIX IF	Crystal blue	Blue
PRIMER SET IF	Blue	Blue
ENHANCER IF	Pink	White
POSITIVE CONTROL IF	Red	Red
NEGATIVE CONTROL IF	Green	Green

**MATERIALS REQUIRED BUT NOT PROVIDED (available separately from Hyris)**

REF	Commercial name	Description	Size
<b>Instruments</b>			
bCUBE 2.0	HYRIS bCUBE™	Miniaturized Thermal Cycler for PCR.	1 Instrument
H0001	HYRIS bCUBE™3	Miniaturized Thermal Cycler for PCR.	1 Instrument
<b>Consumables</b>			
HyCT16.01	HYRIS 16-well cartridges	Disposable 16-well cartridges for HYRIS bCUBE™ Material: Ultra-pure polypropylene and aluminium	1 pack contains 25 cartridges
HyCT36.01	HYRIS 36-well cartridges	Disposable 36 well cartridges for HYRIS bCUBE™ Material: Ultra-pure polypropylene and aluminium	1 pack contains 25 cartridges
<b>Software</b>			
bAPP	HYRIS bAPP™	Graphical User Interface (GUI). Works on smartphones, tablets, laptops, and PCs using any major operating systems	-
<b>Other reagents</b>			
R-XTACT(SCV2).01-50	XTACT (SCV2)	A set of reagents intended to activate the T cells with specific peptides pool of the of the SARS-CoV-2 virus	50 reactions
R-XTACT(SCV3)-50	XTACT(SCV3)	A set of reagents intended to activate the T cells with specific peptides pool of the of the SARS-CoV-2 virus	50 reactions
R-XTACT(SCV4)-50	XTACT(SCV4)	A set of reagents intended to activate the T cells with specific peptides pool of the of the SARS-CoV-2 virus	50 reactions
HR014X050	XTACT(SCV2_P5)	A set of reagents intended to activate the T cells with specific peptides pool of the of the SARS-CoV-2 virus	50 reactions

**OTHER MATERIALS REQUIRED BUT NOT PROVIDED (available separately from Hyris)**

REF	Commercial name	Description	Note
Sk.1x-Acc.01	Starter accessories kit	<ul style="list-style-type: none"> <li>● 3 x Precision pipettes (10µL, 100 µL, 1000 µL)</li> <li>● 1 x Mini centrifuge</li> <li>● 1 x Mini vortex</li> </ul>	Customizable on the basis of Laboratory needs.

**MATERIALS REQUIRED BUT NOT SUPPLIED**
**Hardware**

- PC, tablet, smartphone with google chrome or a compatible browser
- Refrigerator from 2 to 8°C for thaw operation (or fridge bag also for transport)
- Freezer from -10 to -30 °C for storage
- Racks for 1.5 mL micro-centrifuge tubes
- Micropipette 200 µL
- PPE such as (but not limited to) respiratory protection (face mask), safety goggles, full length (elastic) sleeved lab coat and suitable disposable gloves. Racks suitable for 1.5 mL tubes

**Consumables**

- Sterile DNase/RNase free, filter tips 10µL
- Sterile DNase/RNase free, filter tips 100µL
- Sterile DNase/RNase free, filter tips 200µL
- Sterile DNase/RNase free, filter tips 1000µL
- 2mL Sterile, nonpyrogenic, RNase DNase free, polypropylene microcentrifuge tubes
- RNase AWAY™ (Thermo Scientific Cat# 7002PK) or equivalent for surface decontamination

**KIT STORAGE HANDLING AND STABILITY**

**Unopened/Once opened kit**

- HYRIS bKIT™ dqTACT MS kit storage is -20°C (between -10°C and -30°C);
- HYRIS bKIT™ dqTACT MS is stable at -20°C until the expiration date reported on the label of outer box

Allow the reagents to thaw before use at the recommended temperature between 2°C and 8°C.  
Avoid frequent thaw cycles

**SPECIMEN COLLECTION, TRANSPORT AND STORAGE**

The HYRIS bKIT™ dqTACT MS is designed to work with whole blood specimens collected with sodium or lithium heparin tubes. Proper specimen collection, storage, and transport are critical for this test. Inadequate specimen collection, handling and/or transport may yield a false result. Handle specimens as if they can transmit infection agents.

The HYRIS bKIT™ dqTACT MS has been validated under the following condition: sodium or lithium heparinized whole blood sample.

Table 1 are reports the compatible collection and transport systems validated with the HYRIS bKIT™ dqTACT MS.

Compatible collection and transport systems	Brand and model	REF
6ml single sterile tube for blood collection coated with lithium-heparin	BD (Vacutainer®)	368886

Table 1 - list of all validated collection methods

**Specimen stability**

Whole blood is stable prior the stimulation at room temperature up to 6-8 hours after collection. Whole blood must be stimulated with the products of the family XTACT (SCVx) within 6-8 hours from collection. Whole blood samples must be stimulated prior the analysis with the bKIT™ dqTACT MS.

After the overnight incubation, the stimulated samples must be immediately tested with the bKIT™ dqTACT MS or immediately stored at -80°C after the dilution with Buffer A as specified in the activation kit instruction for use.

## WARNINGS AND PRECAUTIONS

- For research use only;
- For Professional User;
- Wear personal protective equipment, such as (but not limited to) gloves, and lab coats when handling kit reagents and equipment. Wash hands thoroughly when finished performing the test;
- Do not pipette by mouth
- Do not smoke, drink, eat, handle contact lenses, or apply make-up in areas where kit reagents and/or human specimens are being used;
- Dispose of unused kit reagents and human specimens as hazardous waste for incineration according to local, state, and federal regulations;
- Treat all human specimens and all consumables that have come into contact with the samples included the cartridge as capable of transmitting infectious agents;
- Contamination of patient specimens or reagents can produce erroneous results. Use good laboratory practices and control workflow;
- Only use the protocol described in this insert. Deviations from the protocol or the use of times or temperatures other than those specified may give erroneous results;
- Assay setup should be performed at room temperature (approximate range 18 to 25°C);
- Do not use kits or reagents beyond their expiration dates.
- Do not use the test product if the primary or secondary packaging has been visually compromised.
- Use calibrated micro pipettes to transfer sample and reaction mix;
- Use only the aluminum adhesive black seals provided with the HYRIS **bCUBE™** cartridges to seal the cartridge;
- Avoid touching the adhesive side of the aluminum foil that will be in contact with the HYRIS **bCUBE™** cartridge;
- To prevent potentially erroneous results, make sure that the sample and reagents are added to the appropriate input wells;
- Initiate the run within ten (10) minutes from cartridge loading;
- Do not attempt to remove the adhesive foil cover from the cartridge after use or attempt to re-use a cartridge or reagents that have been used in previous runs;
- Protect reagents from direct sources of light;
- Safety Data Sheets (SDS) are provided for each reagent upon request;
- If the kit packaging or its contents appear to be broken or damaged do not use and contact Hyris Srl (support@hyris.net).

## OPERATING PROCEDURE

The following operating procedure is intended for the direct amplification test (on heparinized whole blood sample). The test can also be performed using purified nucleic acid. Contact Hyris support center ([support@hyris.net](mailto:support@hyris.net)) for the operating procedure on this matrix (extracted RNA protocol).

### 1. SAMPLE TREATMENT – DIRECT AMPLIFICATION WORKFLOW ONLY

Before the sample preparation:

- Prepare the working area cleaning all the instruments and surfaces
- Mix well the tubes containing the activated blood already mixed with Buffer A with a vortex for 5s at 3000 rpm

**WARNING:** samples should be prepared as outlined in the Instructions for Use of the HYRIS stimulation kit from the Activation kit product line.

#### Further dilution of samples

Some samples may contain a higher concentration of interferents (e.g. lactoferrin and hemoglobin) than those tolerated by the direct amplification detection kit; these samples can be quantified by higher dilution and measured again with the chosen **bKIT™ dqTACT MS** line kit. It is not necessary to collect and stimulate a fresh blood sample.

To enable measurement of such samples, it is recommended to make an additional 1:5 dilution of the stimulated sample already resuspended in Buffer A by using the Dilution Buffer contained in the Buffer A box as described below:

- a. Set the ID number and the pool type on new 1.5 mL tubes for each sample.
- b. Dispense 160  $\mu$ L of Dilution Buffer
- c. Add 40  $\mu$ L of the overnight stimulated blood previously diluted 1:4 in Buffer A
- d. Store the aliquot of samples diluted in BUFFER A at -80°C immediately after the use

- e. Thoroughly mix the tubes for 10 seconds with a vortex at 3200 rpm
- f. Immediately proceed to analysis with the bKIT™ dqTACT MS

To improve the detection signal, additional 1:5 dilution with Dilution Buffer can also be performed on frozen (-80°C) stimulated samples already resuspended in Buffer A.

**Error! Reference source not found.** summarizes the volumes to use for the additional sample dilution:

Sample ID	Stimulated blood treated with buffer A (µL)	Dilution Buffer (µL)	Final volume in 1.5 mL tube (µL)
1 POOL ONE	40	160	200
1 POOL NEG	40	160	200
....	....	....	....
n POOL ONE	40	160	200
n POOL NEG	40	160	200

Table 2– Volumes to use for the dilution step in Dilution Buffer

## 2. REACTION MIX PREPARATION

- a. Allow the reagents to thaw at 2-8°C. Gently mix tubes when thawed and spin to collect contents at the bottom of the vial.
- b. Setup a new tube of 2 mL writing on the cap **REACTION MIX**
- c. Mix well the **ENHANCER IF** with a vortex at 3000rpm for 10s. If solid or floating particles are present heat at 65°C up to 3 minutes and vortex again until the solution is totally clear
- d. Mix for 4s the **MASTER MIX IF** a vortex (3000rpm)
- e. Briefly mix the **PRIMER SET IF** and spin down with a minicentrifuge
- f. Based on the number of reaction calculate the volume of each component of the **REACTION MIX** using the following formula

$$V=R*10 \mu\text{L (MASTER MIX IF)} + R*7.5 \mu\text{L (ENHANCER IF)} + R*0.5 \mu\text{L (PRIMER SETIF)}$$

V = final volume (µL) of the assembled **REACTION MIX**

R = number of reactions to be assessed

**WARNING:** calculate the volume of each component of the **REACTION MIX** with a minimum excess of 2 reactions

Reactions are intended as the number of wells to be loaded.

Keep the **ENHANCER IF** at room temperature after thaw for the entire procedure of the **REACTION MIX** preparation.

See table **Table 3** for an example of volume already calculated

Number of reactions (R)	MASTER MIX IF	ENHANCER IF	PRIMER SET IF
10	100 µL	75 µL	5 µL
20	200 µL	150 µL	10 µL
30	300 µL	225 µL	15 µL
40	400 µL	300 µL	20 µL
50	500 µL	375 µL	25 µL
60	600 µL	450 µL	30 µL

**Table 3 – volume calculation for standard number of reactions**

- g. Transfer the correct volume of each component of the **REACTION MIX** into the tube of 2 mL previously prepared: **MASTER MIX IF + ENHANCER IF+ PRIMER SET IF**
- h. Vortex the **REACTION MIX** at 3000 rpm for 5 sec

**3. ANALYSIS SETUP**

- 1. Log in to HYRIS bAPPTM (<https://bapp2.HYRIS.net>) with username and password.
- 2. Initialize a new analysis from the Analysis menu by clicking on "Create analysis".
- 3. Fill in the "General Information" page:
  - I. - Description (lot of the kit)Analysis Name
  - II. bKIT LOT Number
  - III. description
- select global recipe, then from the dropdown menu select Type "**Immunology**", and bKITs other
- Press continues to proceed with the sample name/ID insertion.

**4. CARTRIDGES SET UP**

The following set up refers to a specific kit from the HYRIS **XTACT** family (HR014X050). The specific setup can be found in the Instruction for Use of each Activation kit or alternatively in the "Loading Wizard Procedure" section of the bAPP.

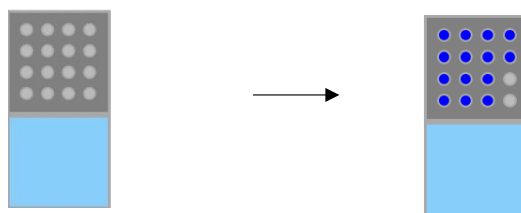
- Select the cartridge type between 16- and 36-well layouts.
- For each sample, scan or type the sample ID in the "Sample Name" field.
- When finished entering the IDs, press "Continue".
- Check the position of the samples on the cartridge layout.
- Save the initialized analysis for later by dragging the selector above the "Finish" button.

**WARNING:** Two wells in the last row are reserved for controls, they should not be modified.

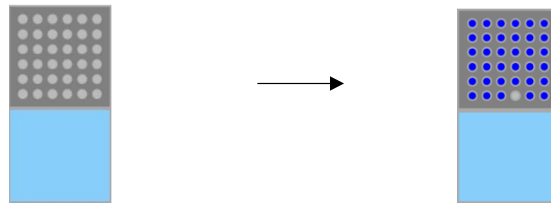
- I. The well in **Red** is reserved for the Positive controls (Pos Ctrl).
- II. The well in **Green** is reserved for the Negative controls (Neg Ctrl).

**5. CARTRIDGE LOADING**

**WARNING:** The following example of loading layout refer to the T Cell activation kit **XTACT (SCV2\_P5)** [REF: HR014X050] load 18 µL of **REACTION MIX** in each well highlighted in **BLUE** as shown in **Figure 1** for 16 well cartridge and in **Figure 2** for 36 well cartridge.



**Figure 1 – Reaction Mix loading on 16 well cartridge**



**Figure 2 - Reaction Mix loading on 36 well cartridge**  
 Grey wells represent empty wells, whereas blue wells indicate wells filled with the Reaction Mix.

**SAMPLES AND CONTROLS LOADING**

- a. Load each sample as following:
  - o Load 2 µL of sample (or extracted RNA) treated with peptides pool (ex POOL ONE) into corresponding well
  - o Load 2 µL of Pool NEG treated sample (or its extracted RNA) into corresponding well
- b. Load 2 µL of **Positive Control** into corresponding well
- c. Load 2 µL of **Negative Control** into corresponding well

**CARTRIDGE SEALING AND LOADING**

- a. Carefully seal the cartridge with adhesive aluminum film included into the cartridge packaging.
- b. Load the cartridge onto the HYRIS bCUBE™

**WARNIGN:** DO NOT USE any seal not included into the HYRIS Cartridges packaging  
 DO NOT LOAD the cartridge onto the HYRIS bCUBE without the adhesive aluminum seal

**6. RUN THE ANALYSIS**

- a. Open the menu “Analyses” of the HYRIS bAPP
- b. Select the analysis
- c. Click on the “Run Analysis” button
- d. Select the bCUBE S/N
- e. Click on **SEND**

At the end of the analysis remove the cartridge from the bCUBE and dispose according to local, state, and federal regulations.

The procedure is also reported on the User Smart Guide, available on HYRIS Help Center [supporthyris.net](http://supporthyris.net)

**OPERATING PROCEDURE FOR OTHER INSTRUMENTS**

This procedure and protocol designed for the use of the bKIT™ dqTACT MS with the Real-Time PCR system:

- Bio-Rad CFX 96™  
 QuantStudio 5 (Thermo scientific)

Read the manual provided by the manufacturer of the instrument to set the protocol

**THERMAL PROTOCOL SETTING**

Set the thermal protocol on the chosen Real-Time PCR System

Probe fluorophore	Excitation/emission	Target region
HEX	530/555 nm	ACTIN
FAM	470/510 nm	CXCL10

Step	Step type	Temperature (°C)	Duration	Cycles	Acquisition
1	Constant temperature step	53 °C	15 min	-	-
2	Constant temperature step	95°C	5 min	-	-
3	Denaturation	95°C	15 sec	45	-
4	Annealing/Extension	60°C	30 sec		yes
5	GOTO Step 3, 44 more times				

### PLATE LOADING

**WARNING:** The following example of loading layout refer to the T Cell activation kit XTACT (SCV2\_P5) [REF: HR014X050]

### REACTION MIX LOADING

Load 18 µL of **REACTION MIX** in all designed well for the samples and controls analysis.

### SAMPLES AND CONTROLS LOADING

- Load each sample as following:
- Load 2 µL of each sample (or extracted RNA) treated with peptides (ex POOL ONE) into the corresponding well
- Load 2 µL of POOL NEG treated sample (or its extracted RNA) into the corresponding well
- Load 2 µL of **Positive Control** into corresponding well
- Load 2 µL of **Negative Control** into corresponding well

### RUN THE ANALYSIS

Run the analysis following the manufacturer's guidelines.

### QUALITY CONTROL PROCEDURES

A negative control and a positive control are run in parallel for each test cartridge to evaluate the validity of each run.

#### Positive Control

A **positive template control** is needed as the reference control to ensure that the entire one step RT-PCR process works properly and as the reference for the samples. The positive control does not contain any infectious agent. The positive control must be tested in every run.

#### Negative Control (NTC)

A "**no template control**" (NTC) is needed to detect any false amplification as well as contamination of the sample/reaction mix and is used for each run.

CONTROL TYPE	Used to monitor	TARGET	CHANNEL	Ct CUTOFF
<b>POSITIVE CONTROL</b>	Substantial reagent failure including primer and probe integrity	<i>CXCL10</i>	FAM	Valid for Ct<35
		<i>ACTIN</i>	HEX	
<b>NEGATIVE CONTROL</b>	Detect any false amplification as well as contamination of the sample/reaction mix .	<i>CXCL10</i>	FAM	Valid for Ct >45
		<i>ACTIN</i>	HEX	

Table 4 – Positive control expected results and Ct values

### QUALITY CONTROL CHECK ON HYRIS bAPP™

HYRIS bAPP™ perform the quality check of controls automatically prior to result interpretation. Controls results are listed as **PASS** or **FAIL**. If the controls are **FAIL**, the specimen results cannot be interpreted, and the software will show "**INVALID TEST**" as result. The interpretative algorithm uses the Ct cutoff values reported in the **Error! Reference source not found.**

**QUALITY CONTROL CHECK ON OTHER SOFTWARE**

Result information are shown on the software of the instruments **Bio-Rad Maestro** or **Design and Analysis software (Thermo)**.

All test controls have to be examined prior to result interpretation. Controls results could be PASS or FAIL. according to the cutoff values reported in **Table 5**

If the controls are not valid (**FAIL**), the specimen results cannot be interpreted, and the test must be repeated.

SAMPLE	TARGET	Ct CUTOFF
SAMPLE	<i>CXCL10</i>	Valid for Ct ≤42
	<i>ACTIN</i>	Valid for Ct ≤33

Table 5 – bKIT™ dqTACT MS sample Ct cutoff values

**DATA EXPORT AND ANALYSIS FOR HYRIS bGATE INTERPRETATION**

**Bio-Rad**

- Open the analysis on Biorad CFX.96 maestro click on export button
- Select export all data sheet
- Click on the .csv button to export data into the folder bgate

Follow the procedure for data importation on Hyris bGATE specific for your use (manual loading or fully automated loading)

**QuantStudio 5**

- Open the analysis on the Design and Analysis software
- Click on analyze button
- Click on action button
- Click on export button, then select csv format
- Browse the folder bgate, then click on export

Follow the procedure for data importation on Hyris bGATE specific for your use (manual loading or fully automated loading)

**DATA EXPORT AND ANALYSIS FOR MANUAL INTERPRETATION**

This procedure are defined for the use of the **bKIT™ dqTACT MS** with the Real-Time PCR system:

- Bio-Rad CFX 96TM
- QuantStudio 5 (Thermo scientific)

To interpret the results, follow these steps:

- a. Download the Excel report file
- b. Download the results interpretation file, for instance “**dqTACT for XTACT (SCV2) interpretation\_V xx.xlsx**”.
- c. Add Ct values into the “Data insertion” sheet of the **interpretation** file copying the FAM and HEX Ct values of each sample from the analysis report file.
- d. Copy the FAM and HEX Ct values from the report Excel sheet into the "Data insertion" tab of the Immunofinder dqTACT MS Interpretation file.
- e. The "Interpreted Result" tab will display the final result.

For *CXCL10* relative mRNA expression the delta-delta Ct method ( $2^{-\Delta\Delta Ct}$ ) is applied. The difference between spike stimulated and NEG stimulated samples must be > 0.003 to be considered REACTIVE to the stimulation peptides pool, for instance SARS-CoV-2 peptides pool.

## INTERPRETATION OF RESULTS

After quality check of controls a valid sample is interpreted as indicated in Table 6

bKIT™ dqTACT MS RESULTS			
bAPP RESULTS	Threshold value Direct amplification	Threshold value <i>Extracted RNA</i>	INTERPRETED RESULTS
NOT REACTIVE	< 0.001	< 0.05	NOT REACTIVE to specific-peptides pool stimulation
REACTIVE	> 0.003	> 0.05	REACTIVE to specific-peptides pool stimulation
BORDERLINE REACTIVITY	$0.001 \leq x \leq 0.003$	-	BORDERLINE REACTIVITY to specific-peptides pool stimulation
INCONCLUSIVE	-	-	INCONCLUSIVE the <i>ACTIN</i> Ct in the specific-peptides POOL and/or POOL NEG treated sample is over the Ct Cut-off
INVALID	-	-	INVALID One of the controls DOES NOT exhibit the expected performance and the analysis CAN NOT be consider valid. Repeat the analysis

Table 6 - bKIT™ dqTACT MS interpretation table result

If the inconclusive and invalid result persist, contact Hyris technical support at [support@hyris.net](mailto:support@hyris.net). Protocol and data interpretation have been described according to Schwartz et al., 2022.









## LIMITATIONS

1. For research use only.
2. For Professional User
3. This test is a qualitative test and does not provide quantitative value of the T CELLS responsivity.

## BIBLIOGRAPHY

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**SYMBOLS DESCRIPTION**

SYMBOL	DESCRIPTION
	LOT
	Catalogue Number
	Expiration date
	Manufacturer
	Refer to the instructions for Use/functioning.
	Content sufficient for <n> test
	Temperature range recommended
	Do not use if the packaging is broken

Ordering information	Technical assistance	
E-mail: <a href="mailto:office@hyris.net">office@hyris.net</a>	E-mail: <a href="mailto:support@hyris.net">support@hyris.net</a>	E-mail: <a href="mailto:info@hyris.net">info@hyris.net</a>
Phone: +39.02.82951302	Phone: +39.02.82951302	

 Visit our website: <https://www.hyris.net>

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