



November 2023

# IGRA Control Set Instructions for Use



3 x 4 vials 1–4 (628022)

Version 1

**IVD**

For In Vitro Diagnostic Use

Human IFN- $\gamma$  unassayed quality control material

**REF**

628022



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## Intended Use

The IGRA Control Set contains human recombinant Interferon-gamma (IFN- $\gamma$ ), and is intended for use as an optional, unassayed quality control material for assays detecting IFN- $\gamma$ .

Laboratories can use the IGRA Control Set for routine monitoring of assay performance.

## Intended User

This kit is intended for use by diagnostic laboratories with trained staff.

# Description and Principle

## Summary and explanation

The IGRA Control Set product contains a set of four (4) lyophilized human recombinant Interferon-gamma (IFN- $\gamma$ ) controls. The IFN- $\gamma$  controls are provided in four (4) vials (IGRA Control Vial 1, IGRA Control Vial 2, IGRA Control Vial 3, and IGRA Control Vial 4).

# Materials Provided

## Kit contents

**IGRA Control Set**  
**Catalog no.**

**3 x 4 vials 1–4**  
**628022**

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Recombinant Human IFN- $\gamma$ , lyophilized (contains bovine casein, 0.01% w/v Thimerosal)

3 sets of vials 1–4

*IGRA Control Set Instructions for Use*

Available at [www.qiagen.com](http://www.qiagen.com)

# Materials Required but Not Provided

## Additional reagents

- Distilled or deionized water

## Equipment

- Calibrated variable volume pipets for delivery of 50–1000  $\mu\text{L}$  with disposable tips

# Warnings and Precautions

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative.

## Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at [www.qiagen.com/safety](http://www.qiagen.com/safety), where you can find, view, and print the SDS for each QIAGEN kit and kit component.

- All chemicals and biological materials are potentially hazardous.
- Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures.


## Emergency information

CHEMTREC

USA & Canada 1-800-424-9300



## Precautions

<p><b>CAUTION</b></p> 	<p>Dispose of materials in accordance with federal, state, and local (W2) regulations.</p>
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## Further information

- Thimerosal is used as a preservative in the IGRA Control Set. It may be toxic upon ingestion, inhalation, or skin contact.
- Do not use kit if any reagent bottle shows signs of damage or leakage prior to use.
- **Important:** Inspect vials prior to use. Do not use IGRA Control Set vials that show signs of damage or if the rubber seal has been compromised. Do not handle broken vials. Take the appropriate safety precautions to dispose of vials safely. It is recommended to use a vial de-crimper to open the IGRA Control Set vials to minimize risk of injury from the metal crimp cap.
- Discard unused reagents in accordance with local, state, and federal regulations.
- Do not use the IGRA Control Set after the expiration date.
- Correct laboratory procedures should be adhered to at all times.
- Make sure that laboratory equipment such as pipettes have been calibrated/validated for use.

## IGRA Control Vial 1



Contains: boric acid; Mixture of 2-methyl-1,2-thiazol-3(2H)-one and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Danger! May cause an allergic skin reaction. May damage fertility or the unborn child. Harmful to aquatic life with long lasting effects. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: Get medical advice/ attention. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

## IGRA Control Vial 2



Contains: boric acid; Mixture of 2-methyl-1,2-thiazol-3(2H)-one and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Danger! May cause an allergic skin reaction. May damage fertility or the unborn child. Harmful to aquatic life with long lasting effects. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: Get medical advice/ attention. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

### IGRA Control Vial 3



Contains: boric acid; Mixture of 2-methyl-1,2-thiazol-3(2H)-one and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Danger! May cause an allergic skin reaction. May damage fertility or the unborn child. Harmful to aquatic life with long lasting effects. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: Get medical advice/ attention. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

### IGRA Control Vial 4



Contains: boric acid; Mixture of 2-methyl-1,2-thiazol-3(2H)-one and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Danger! May cause an allergic skin reaction. May damage fertility or the unborn child. Harmful to aquatic life with long lasting effects. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection. IF exposed or concerned: Get medical advice/ attention. Store locked up. Dispose of contents/ container to an approved waste disposal plant.

# Reagent Storage and Handling

Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

## In-use stability

### IGRA Control Set reagents

Store IGRA Control Set kit at 2–8°C (36–46°F).

### Reconstituted and unused reagents

- For instructions on how to reconstitute the reagents, refer to Protocol: IGRA Control Set, page 13.
- The reconstituted IGRA may be kept for up to 28 days if stored at 2–8°C. Note the date the IGRA Control Set vials were reconstituted.

# Procedure: IGRA Control Set

## Important points before starting

- The IGRA Control Set must be brought to room temperature ( $22^{\circ}\text{C} \pm 5^{\circ}\text{C}$ ) before use. Allow at least 60 minutes for equilibration.

## Procedure



1. Equilibrate the set of four (4) vials to room temperature ( $17\text{--}27^{\circ}\text{C}$ ) for at least one hour prior to use.
2. Reconstitute each of the 4 vials with 0.25 mL of room temperature ( $17\text{--}27^{\circ}\text{C}$ ) distilled or deionized water and ensure complete resuspension by mixing with several gentle inversions to minimize frothing.
3. The IGRA Control Set may be included in a test run following the procedures as provided by the test kit manufacturer.
  - The reconstituted IGRA Control Set must be stored at  $2\text{--}8^{\circ}\text{C}$  and used within 28 days following resuspension of the vials.
  - The shelf life of the unopened IGRA Control Set is at least 24 months when stored between  $2\text{--}8^{\circ}\text{C}$ .








# Limitations

The IGRA Control Set is intended for use as an optional, unassayed quality control material for assays detecting IFN- $\gamma$ . Expected values for the IGRA Control Set Vials 1-4 must be established by the user laboratory.

# Symbols

The following symbols may appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
 $\Sigma$ <N>	Contains reagents sufficient for <N> reactions
	Use by
<b>IVD</b>	In vitro diagnostic medical device
<b>REF</b>	Catalog number
<b>LOT</b>	Lot number
<b>MAT</b>	Material number (i.e., component labeling)
<b>COMP</b>	Components
<b>CONT</b>	Contains

Symbol	Symbol definition
	Number
	Global Trade Item Number
Rn	R is for revision of the Instructions for Use and n is the revision number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Unique Device Identifier
	Warning/caution

# Contact Information

For technical assistance and more information, please see our Technical Support Center at [www.qiagen.com/Support](http://www.qiagen.com/Support) or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit [www.qiagen.com](http://www.qiagen.com)).



# Ordering Information

Product	Contents	Cat. no.
IGRA Control Set	Recombinant Human IFN- $\gamma$ (3 sets of vials 1–4)	628022

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

# Document Revision History

Revision	Description
R1, November 2023	Initial release

### Limited License Agreement for IGRA Control Set

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

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