

Instructions for Use

RNA Controls and Panels

RUO

For use as qualitative PCR controls.

RUO These products are for Research Use Only; not intended for diagnostic procedures.



 Storage Conditions: **-85°C to -65°C**

Catalog Number	Product Name	Quantity
REF 40870030	Sensitivity Panel - IVS-0003 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870110	Sensitivity Panel - IVS-0011 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870150	Sensitivity Panel - IVS-0015 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870200	Sensitivity Panel - IVS-0020 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870320	Sensitivity Panel - IVS-0032 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40890200	10 ⁻¹ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890210	10 ⁻² IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890220	10 ⁻³ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890230	10 ⁻⁴ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890240	10 ⁻⁵ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890250	10 ⁻⁶ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890920	10 ⁻¹ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890930	10 ⁻² IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890940	10 ⁻³ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890950	10 ⁻⁴ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890960	10 ⁻⁵ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40891730	10 ⁻¹ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891740	10 ⁻² IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891750	10 ⁻³ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891760	10 ⁻⁴ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40892810	10 ⁻¹ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892820	10 ⁻² IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892830	10 ⁻³ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892840	10 ⁻⁴ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892850	10 ⁻⁵ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892860	10 ⁻⁶ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 43100100	Proficiency Panel for <i>BCR/ABL</i> t(9;22) Translocation Assay	1 Panel – 10 Tubes - 100 µL each

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Table of Contents

1. PROPRIETARY NAME	3
2. PRODUCT USE	3
3. REAGENTS	4
3.1. RNA Sensitivity Panels.....	4
3.2. RNA Controls	4
3.3. Proficiency Panel for <i>BCR-ABL1</i> t(9;22).....	5
3.4. Warnings and Precautions.....	6
3.5. Storage and Stability.....	6
4. PROCEDURE	6
5. INTERPRETATION OF RESULTS	6
6. SYMBOLS	7
7. TECHNICAL AND CUSTOMER SERVICE	7
8. LEGAL NOTICE	7

1. Proprietary Name

Table 1. Proprietary Product Names

Catalog Number	Product Name	Quantity
REF 40870030	Sensitivity Panel - IVS-0003 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870110	Sensitivity Panel - IVS-0011 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870150	Sensitivity Panel - IVS-0015 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870200	Sensitivity Panel - IVS-0020 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40870320	Sensitivity Panel - IVS-0032 Clonal Control RNA	1 Panel – 7 Tubes - 100 µL each
REF 40890200	10 ⁻¹ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890210	10 ⁻² IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890220	10 ⁻³ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890230	10 ⁻⁴ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890240	10 ⁻⁵ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890250	10 ⁻⁶ IVS-0003 Clonal Control RNA	1 Tube - 100 µL
REF 40890920	10 ⁻¹ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890930	10 ⁻² IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890940	10 ⁻³ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890950	10 ⁻⁴ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40890960	10 ⁻⁵ IVS-0011 Clonal Control RNA	1 Tube - 100 µL
REF 40891730	10 ⁻¹ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891740	10 ⁻² IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891750	10 ⁻³ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40891760	10 ⁻⁴ IVS-0020 Clonal Control RNA	1 Tube - 100 µL
REF 40892810	10 ⁻¹ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892820	10 ⁻² IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892830	10 ⁻³ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892840	10 ⁻⁴ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892850	10 ⁻⁵ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 40892860	10 ⁻⁶ IVS-0032 Clonal Control RNA	1 Tube - 100 µL
REF 43100100	Proficiency Panel for <i>BCR/ABL</i> t(9;22) Translocation Assay	1 Panel – 10 Tubes - 100 µL each

2. Product Use

Inivoscribe's RNA Controls and Panels are intended for validation by the end user for use in molecular assays. These controls are specific to gene rearrangements, mutations, and/or translocations from human RNA, indicated in section 3: *Reagents*.

These products are for Research Use Only. Not intended for diagnostic purposes.


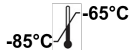




3. Reagents

3.1. RNA Sensitivity Panels

Invivoscribe RNA Sensitivity Panels are seven (7) member panels that consist of 100% clonal RNA extracted from a positive control cell line and 10^{-1} , 10^{-2} , 10^{-3} , 10^{-4} , 10^{-5} , and 10^{-6} dilutions of the positive clonal RNA diluted (v/v) into our standard negative control RNA, IVS-0035 Clonal Control RNA.

- Controls are adjusted to the final concentration specified in Table 2 with molecular grade water.

Table 2. RNA Sensitivity Panels

Catalog Number	Description	Concentration	Target	Storage Conditions*
 40870030	Sensitivity Panel - IVS-0003 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e13a2 (b2a2)	
 40870110	Sensitivity Panel - IVS-0011 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e14a2 (b3a2)	
 40870150	Sensitivity Panel - IVS-0015 Clonal Control RNA	400 µg/mL	<i>CBFB-MYH11</i> inv(16)	
 40870200	Sensitivity Panel - IVS-0020 Clonal Control RNA	400 µg/mL	<i>PML-RARα</i> t(15;17)(q22;q11)	
 40870320	Sensitivity Panel - IVS-0032 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p190 e1a2	

*Minimize the number of freeze-thaw cycles.

3.2. RNA Controls

Invivoscribe RNA Controls are extracted from established cell lines grown under standard cell culture conditions. These controls are available as several ready-to-use dilutions into a standard negative control, IVS-0035 Clonal Control RNA, as listed in the table below.

- Controls are adjusted to the final concentration specified in Table 3 with molecular grade water.

Table 3. RNA Controls


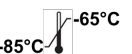














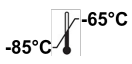
Catalog Number	Description	Concentration	Target	Storage Conditions*
 40890200	10^{-1} IVS-0003 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e13a2 (b2a2)	
 40890210	10^{-2} IVS-0003 Clonal Control RNA	400 µg/mL		
 40890220	10^{-3} IVS-0003 Clonal Control RNA	400 µg/mL		
 40890230	10^{-4} IVS-0003 Clonal Control RNA	400 µg/mL		
 40890240	10^{-5} IVS-0003 Clonal Control RNA	400 µg/mL		
 40890250	10^{-6} IVS-0003 Clonal Control RNA	400 µg/mL		
 40890920	10^{-1} IVS-0011 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e14a2 (b3a2)	
 40890930	10^{-2} IVS-0011 Clonal Control RNA	400 µg/mL		
 40890940	10^{-3} IVS-0011 Clonal Control RNA	400 µg/mL		
 40890950	10^{-4} IVS-0011 Clonal Control RNA	400 µg/mL		
 40890960	10^{-5} IVS-0011 Clonal Control RNA	400 µg/mL		
 40891730	10^{-1} IVS-0020 Clonal Control RNA	400 µg/mL	<i>PML-RARα</i> t(15;17)(q22;q11)	
 40891740	10^{-2} IVS-0020 Clonal Control RNA	400 µg/mL		
 40891750	10^{-3} IVS-0020 Clonal Control RNA	400 µg/mL		
 40891760	10^{-4} IVS-0020 Clonal Control RNA	400 µg/mL		

Table 3. RNA Controls

Catalog Number	Description	Concentration	Target	Storage Conditions*
REF 40892810	10 ⁻¹ IVS-0032 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p190 e1a2	 -85°C to -65°C
REF 40892820	10 ⁻² IVS-0032 Clonal Control RNA	400 µg/mL		
REF 40892830	10 ⁻³ IVS-0032 Clonal Control RNA	400 µg/mL		
REF 40892840	10 ⁻⁴ IVS-0032 Clonal Control RNA	400 µg/mL		
REF 40892850	10 ⁻⁵ IVS-0032 Clonal Control RNA	400 µg/mL		
REF 40892860	10 ⁻⁶ IVS-0032 Clonal Control RNA	400 µg/mL		

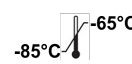
*Minimize the number of freeze-thaw cycles.

3.3. Proficiency Panel for *BCR/ABL* t(9;22) Translocation Assay

Inivoscribe Proficiency Panel for *BCR-ABL1* t(9;22) is a ten (10) member panel used to validate tests that identify *BCR-ABL1* t(9;22) translocations and is may be used with the *BCR/ABL* t(9;22) Translocation Assay Kits. This panel consists of 100% clonal control RNA extracted from three (3) *BCR-ABL1* positive cell lines as well as 10⁻² (1:100) and 10⁻⁴ (1:10,000) dilutions (v/v) of these positive RNAs diluted into a normal (*BCR-ABL1* negative) control RNA, IVS-0035 Clonal Control RNA. A sample of 100% IVS-0035 Clonal Control RNA is also included.

- Controls are adjusted to the final concentration specified in Table 4 with molecular grade water.

Table 4. Components of the Proficiency Panel for *BCR/ABL* t(9;22) Translocation Assay (**REF** 43100100)

Quantity	Description	Concentration	Target	Storage Conditions*
1 Tube – 100 µL	IVS-0003 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e13a2 (b2a2)	 -85°C to -65°C
1 Tube – 100 µL	10 ⁻² IVS-0003 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	10 ⁻⁴ IVS-0003 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	IVS-0011 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p210 e14a2 (b3a2)	
1 Tube – 100 µL	10 ⁻² IVS-0011 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	10 ⁻⁴ IVS-0011 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	IVS-0032 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> t(9;22) p190 e1a2	
1 Tube – 100 µL	10 ⁻² IVS-0032 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	10 ⁻⁴ IVS-0032 Clonal Control RNA	400 µg/mL		
1 Tube – 100 µL	IVS-0035 Clonal Control RNA	400 µg/mL	<i>BCR-ABL1</i> Negative	

*Minimize the number of freeze-thaw cycles.

3.4. Warnings and Precautions

- **RUO** Invivoscribe's RNA Controls and Panels are for Research Use Only. Not intended for diagnostic purposes.
- Establish standard operating procedures and instructions for using the Invivoscribe RNA Controls or Panels in molecular assays.
- Reagents are stable until the labeled expiration date when stored and handled as directed. Do not use reagents beyond their expiration date.
- Perform all quality control requirements in conformance with local, state and/or federal regulations or accreditation requirements.
- Wear appropriate personal protective equipment and follow good laboratory practices and universal precautions when working with specimens.
- Handle specimens in approved biological safety containment facilities and open only in certified biological safety cabinets.
- Use extreme care to avoid the contamination of reagents with samples, controls or amplified materials. Closely monitor all reagents for signs of contamination (*e.g.*, negative controls giving positive signals). Discard reagents suspected of contamination.
- To minimize contamination, wear clean gloves when handling samples and reagents and routinely clean work areas and pipettes prior to doing PCR.
- Autoclaving does not eliminate nucleic acid contamination.
- Follow uni-directional workflow in the PCR laboratory; begin with master mix preparation, move to specimen preparation, then to amplification, and finally to detection. Do not bring amplified nucleic acid into the areas designated for master mix or specimen preparation.
- Dedicate all pipettes, pipette tips, and any equipment used in a particular area to that area of the laboratory.
- Use sterile, disposable plasticware whenever possible to avoid RNase, DNase, and cross-contamination.

3.5. Storage and Stability

- When stored at the intended storage conditions, Invivoscribe's RNA Controls and Panels are stable until the expiration date indicated on the vial label.

4. Procedure










- 4.1. Allow the RNA Control or Panel to equilibrate to room temperature.
- 4.2. Vortex gently, then pulse-spin in a centrifuge (4 to 6 seconds) to collect the contents at the bottom of the tube.
- 4.3. Introduce the RNA Control or Panel as an independent sample at the template addition step in the workflow.
- 4.4. Handle the RNA Control or Panel similarly to nucleic acids extracted from routine samples and run in parallel with routine samples.

5. Interpretation of Results

- 5.1. Results generated by Invivoscribe's RNA Controls and Panels may differ according to the molecular test method.
- 5.2. To establish a baseline performance, incorporate results from multiple runs under different conditions (*e.g.*, operator, run, day) to determine a valid size range specific to the assay used.
- 5.3. Once the validated size range is ascertained, the expected size range can be used to verify each subsequent run result of the RNA Control or Panel.

6. Symbols

The following symbols are used in labeling for Invivoscribe products.

	Storage Conditions		Expiration Date
	Catalog Number		Authorized Representative in the European Community
	Reagent Volume		Manufacturer
	Lot Number		Consult Instructions for Use
	Research Use Only		

7. Technical and Customer Service


Technical and Customer Service Representatives are available Monday through Friday to answer phone, e-mail or website inquiries. Please do not hesitate to contact sales@invivoscribe.com for assistance evaluating controls to suit your testing needs.

Contact Information

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Authorized Representative and EU Technical Assistance

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Customer Service: sales-eu@invivoscribe.com
Website: www.invivoscribe.com
Business Hours: 9:00AM – 5:00PM CET/CEST

8. Legal Notice

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This product is for Research Use Only; not for use in diagnostic procedures.

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