

DNA Controls and Sensitivity Panels

For use as qualitative PCR controls.

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



 **Storage Conditions: 2°C to 8°C**
(DNA controls may be stored long term at -85°C to -65°C)

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1. Proprietary Name

Table 1. Proprietary Product Names

Catalog Number	Product Name	Quantity
REF 40860040	Sensitivity Panel - IVS-0004 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860070	Sensitivity Panel - IVS-0007 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860090	Sensitivity Panel - IVS-0009 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860100	Sensitivity Panel - IVS-0010 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860190	Sensitivity Panel - IVS-0019 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860210	Sensitivity Panel - IVS-0021 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40860300	Sensitivity Panel - IVS-0030 Clonal Control DNA	1 Panel – 6 Tubes - 100 µL each
REF 40880210	20% IVS-0004 Clonal Control DNA	1 Tube - 100 µL
REF 40880220	10% IVS-0004 Clonal Control DNA	1 Tube - 100 µL
REF 40880230	5% IVS-0004 Clonal Control DNA	1 Tube - 100 µL
REF 40880390	20% IVS-0007 Clonal Control DNA	1 Tube - 100 µL
REF 40880400	10% IVS-0007 Clonal Control DNA	1 Tube - 100 µL
REF 40880410	5% IVS-0007 Clonal Control DNA	1 Tube - 100 µL
REF 40880420	1% IVS-0007 Clonal Control DNA	1 Tube - 100 µL
REF 40880470	5% IVS-0008 Clonal Control DNA	1 Tube - 100 µL
REF 40880480	1% IVS-0008 Clonal Control DNA	1 Tube - 100 µL
REF 40880500	30% IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880510	20% IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880520	10% IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880530	5% IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880540	1% IVS-0009 Clonal Control DNA	1 Tube - 100 µL
REF 40880560	30% IVS-0010 Clonal Control DNA	1 Tube - 100 µL
REF 40880580	10% IVS-0010 Clonal Control DNA	1 Tube - 100 µL
REF 40880590	5% IVS-0010 Clonal Control DNA	1 Tube - 100 µL
REF 40881100	30% IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881110	20% IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881120	10% IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881130	5% IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881140	1% IVS-0019 Clonal Control DNA	1 Tube - 100 µL
REF 40881220	30% IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881230	20% IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881240	10% IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881250	5% IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881260	1% IVS-0021 Clonal Control DNA	1 Tube - 100 µL
REF 40881430	5% IVS-0024 Clonal Control DNA	1 Tube - 100 µL
REF 40881700	30% IVS-0029 Clonal Control DNA	1 Tube - 100 µL
REF 40881730	5% IVS-0029 Clonal Control DNA	1 Tube - 100 µL
REF 40881760	30% IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881770	20% IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881780	10% IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881790	5% IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881800	1% IVS-0030 Clonal Control DNA	1 Tube - 100 µL
REF 40881840	10% IVS-0031 Clonal Control DNA	1 Tube - 100 µL
REF 40881860	1% IVS-0031 Clonal Control DNA	1 Tube - 100 µL
REF 40900010	IVS-P001 Clonal Control DNA	1 Tube - 100 µL
REF 40900070	IVS-P002 Clonal Control DNA	1 Tube - 100 µL

2. Product Use

Inivoscribe's Research use Only (RUO) DNA controls and sensitivity 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 DNA indicated in section 3: *Reagents*.

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

3. Reagents

3.1. Cell Line DNA Controls

Cell Line DNA 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 (polyclonal) control as listed in the table below.

- DNA Clonal Controls are adjusted to the final concentration specified in Table 2 with 1/10th TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA), which provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg²⁺ concentrations required for robust amplification reactions.

Table 2. Cell Line DNA Controls
























Catalog Number	Description	Concentration	Characteristics			Storage Conditions*
			Gene Rearrangement	Chromosome Translocation	Gene Mutation	
 40880210	20% IVS-0004 Clonal Control DNA	200 µg/mL	<i>TRB, TRG</i>	n/c	n/c	
 40880220	10% IVS-0004 Clonal Control DNA	200 µg/mL				
 40880230	5% IVS-0004 Clonal Control DNA	200 µg/mL				
 40880390	20% IVS-0007 Clonal Control DNA	200 µg/mL	<i>IGH, IGK, IGL</i>	<i>IGH-BCL2</i> t(14;18) Mbr	n/c	
 40880400	10% IVS-0007 Clonal Control DNA	200 µg/mL				
 40880410	5% IVS-0007 Clonal Control DNA	200 µg/mL				
 40880420	1% IVS-0007 Clonal Control DNA	200 µg/mL				
 40880470	5% IVS-0008 Clonal Control DNA [†]	200 µg/mL	<i>IGH_{DH-JH}, TRB, TRG</i>	n/c	n/c	
 40880480	1% IVS-0008 Clonal Control DNA [†]	200 µg/mL				
 40880500	30% IVS-0009 Clonal Control DNA	200 µg/mL	<i>TRB, TRG</i>	n/c	n/c	
 40880510	20% IVS-0009 Clonal Control DNA	200 µg/mL				
 40880520	10% IVS-0009 Clonal Control DNA	200 µg/mL				
 40880530	5% IVS-0009 Clonal Control DNA	200 µg/mL				
 40880540	1% IVS-0009 Clonal Control DNA	200 µg/mL				
 40880560	30% IVS-0010 Clonal Control DNA	200 µg/mL	<i>IGH, IGK, IGL</i>	<i>IGH-BCL1</i> t(11;14) [§]	n/c	
 40880580	10% IVS-0010 Clonal Control DNA	200 µg/mL				
 40880590	5% IVS-0010 Clonal Control DNA	200 µg/mL				
 40881100	30% IVS-0019 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	n/c	n/c	
 40881110	20% IVS-0019 Clonal Control DNA	200 µg/mL				
 40881120	10% IVS-0019 Clonal Control DNA	200 µg/mL				
 40881130	5% IVS-0019 Clonal Control DNA	200 µg/mL				
 40881140	1% IVS-0019 Clonal Control DNA	200 µg/mL				

Table 2. Cell Line DNA Controls

Catalog Number	Description	Concentration	Characteristics			Storage Conditions*
			Gene Rearrangement	Chromosome Translocation	Gene Mutation	
REF 40881220	30% IVS-0021 Clonal Control DNA	200 µg/mL	<i>TRG, TRB, TRD</i>	n/c	n/c	
REF 40881230	20% IVS-0021 Clonal Control DNA	200 µg/mL				
REF 40881240	10% IVS-0021 Clonal Control DNA	200 µg/mL				
REF 40881250	5% IVS-0021 Clonal Control DNA	200 µg/mL				
REF 40881260	1% IVS-0021 Clonal Control DNA	200 µg/mL				
REF 40881430	5% IVS-0024 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	n/c	n/c	
REF 40881700	30% IVS-0029 Clonal Control DNA	200 µg/mL	<i>IGH, IGK, IGL</i>	n/c	n/c	
REF 40881730	5% IVS-0029 Clonal Control DNA	200 µg/mL				
REF 40881760	30% IVS-0030 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	<i>IGH-BCL2</i> t(14;18) mcr	n/c	
REF 40881770	20% IVS-0030 Clonal Control DNA	200 µg/mL				
REF 40881780	10% IVS-0030 Clonal Control DNA	200 µg/mL				
REF 40881790	5% IVS-0030 Clonal Control DNA	200 µg/mL				
REF 40881840	10% IVS-0031 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	<i>IGH-BCL2</i> t(14;18) mcr	n/c	
REF 40881860	1% IVS-0031 Clonal Control DNA	200 µg/mL				

Note: n/c is used to indicate that the control has not been fully characterized; there may be additional rearrangements, translocations or mutations associated with the control.

*Minimize the number of freeze-thaw cycles.

†This control does not contain a complete *IGHV_H-J_H* rearrangement and may only be suitable for *IGH_{D_H-J_H}* rearrangements.

§*IGH-BCL1* was previously referred to as *BCL1/J_H*


3.2. Plasmid DNA Controls

Inivoscribe plasmid DNA Controls are engineered to test positive for a specific chromosome translocation or mutation using our assay master mixes and extensively tested to ensure quality and reproducibility.

- Plasmid DNA controls are adjusted to the final concentration specified in Table 3. with 1/10th TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA), which provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg²⁺ concentrations required for robust amplification reactions.

Note: These controls are assay-specific and may not generate products with other assays.

Table 3. Plasmid DNA Controls

Catalog Number	Description	Concentration	Target	Storage Conditions*
REF 40900010	IVS-P001 Clonal Control DNA	200 pg/mL	<i>FLT3</i> TKD D835 mutation positive control for the <i>FLT3</i> D835 master mix (REF 24120020)	
REF 40900070	IVS-P002 Clonal Control DNA	1600 pg/mL	<i>IGH-BCL2</i> t(14;18) (3' Mbr-J _H) positive control for the <i>BCL2/J_H</i> Tube B master mix (REF 23090060)	


*Minimize the number of freeze-thaw cycles.

3.1. DNA Sensitivity Panels

Invivoscribe DNA Sensitivity Panels consist of 100% clonal DNA extracted from a positive control cell line and 30%, 20%, 10%, 5%, and 1% dilutions of the positive clonal DNA diluted (v/v) into our standard negative control DNA, IVS-0000 Polyclonal Control DNA.

- DNA Sensitivity Panels are adjusted to the final concentration specified in Table 4 with 1/10th TE (1 mM Tris-HCl (pH 8.0), 0.1 mM EDTA), which provides sufficient buffering capacity and EDTA to protect the DNA controls without interfering with the Mg²⁺ concentrations required for robust amplification reactions.

Table 4. DNA Sensitivity Panels

Catalog Number	Description	Concentration	Characteristics		Storage Conditions*
			Gene Rearrangement	Chromosome Translocation	
REF 40860040	Sensitivity Panel - IVS-0004 Clonal Control DNA	200 µg/mL	<i>TRB, TRG</i>	n/c	
REF 40860070	Sensitivity Panel - IVS-0007 Clonal Control DNA	200 µg/mL	<i>IGH, IGK, IGL</i>	<i>IGH-BCL2</i> t(14;18) Mbr	
REF 40860090	Sensitivity Panel - IVS-0009 Clonal Control DNA	200 µg/mL	<i>TRB, TRG</i>	n/c	
REF 40860100	Sensitivity Panel - IVS-0010 Clonal Control DNA	200 µg/mL	<i>IGH, IGK, IGL</i>	<i>IGH-BCL1</i> t(11;14) [§]	
REF 40860190	Sensitivity Panel - IVS-0019 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	n/c	
REF 40860210	Sensitivity Panel - IVS-0021 Clonal Control DNA	200 µg/mL	<i>TRG, TRB, TRD</i>	n/c	
REF 40860300	Sensitivity Panel - IVS-0030 Clonal Control DNA	200 µg/mL	<i>IGH, IGK</i>	<i>IGH-BCL2</i> t(14;18) mcr	

Note: n/c is used to indicate that the control has not been fully characterized; there may be additional rearrangements, translocations or mutations associated with the control.

*Minimize the number of freeze-thaw cycles.

[§]*IGH-BCL1* was previously referred to as *BCL1/J_H*

3.2. Warnings and Precautions

- **RUO** Invivoscribe's DNA Controls and Sensitivity Panels are for Research Use Only. Not intended for diagnostic purposes.
- Establish standard operating procedures and instructions for using the Invivoscribe DNA Controls or Sensitivity 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 DNA 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 DNA 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 plastic ware whenever possible to avoid RNase, DNase, or cross-contamination.

3.3. Storage and Stability

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

4. Procedure









- 4.1. Allow the DNA Control or Sensitivity 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 DNA Control or Sensitivity Panel as an independent sample at the template addition step in the workflow.
- 4.4. Handle the DNA Control or Sensitivity 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 DNA Control and Sensitivity 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 DNA Control or Sensitivity 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

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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Customer Service: sales@invivoscribe.com
Website: www.invivoscribe.com
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8. Legal Notice

Invivoscribe, Inc. (Invivoscribe®) is committed to providing the highest quality products. Invivoscribe® warrants that the products meet or exceed the performance standards described in the Instructions For Use, as to products with such an insert. If a product is covered by product specifications and does not perform as specified, our policy is to replace the product or credit the full purchase price. No other warranties of any kind, expressed or implied, are provided by Invivoscribe®. Invivoscribe® liability shall not exceed the purchase price of the product. Invivoscribe shall have no liability for direct, indirect, consequential or incidental damages arising from the use, results of use, or inability to use its products; product efficacy under purchaser controlled conditions in purchaser's laboratory must be established and continually monitored through purchaser defined and controlled processes including but not limited to testing of internally validated positive, negative, and blank controls every time a sample is tested. Ordering, acceptance and use of product constitutes purchaser acceptance of sole responsibility for assuring product efficacy and purchaser agreement to the limitation of liability set forth in this paragraph.

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

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