

Instructions for Use

RUO


BCR/ABL e1a2 RNA Dilution Set

For use as reference or validation material to target *BCR-ABL1* t(9;22) e1a2 transcripts.

RUO This product is for Research Use Only; not intended for diagnostic procedures.

Manufactured in U.S.A.



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

Catalog #	Description	Quantity
REF 40850110	<i>BCR/ABL</i> e1a2 RNA Dilution Set	6 tubes containing 50 µL each

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1. Product Use

The *BCR/ABL* e1a2 RNA Dilution Set can be used as reference and validation material within RUO assays that target *BCR-ABL1* t(9;22) translocations: p190 e1a2 and may be used for the following:


- Routine testing controls for cDNA synthesis, amplification and detection
- Establishing a standard reference curve
- Sensitivity controls for specific target assays

2. Reagents

2.1. Dilution Set Components

Invivoscribe's *BCR/ABL* e1a2 RNA Dilution Set consists of RNA that has been extracted from established *BCR/ABL* e1a2 positive and *BCR/ABL* negative cell lines grown under standard cell culture conditions. Controls are adjusted to the final concentration specified in Table 1 with molecular grade water.

Table 1. *BCR/ABL* e1a2 RNA Dilution Set components

Component	Dilution	Concentration	Quantity	Volume	Target	Storage Conditions*
10 ⁻¹ e1a2 RNA	1:10	400 µg/mL	1	50 µL	<i>BCR-ABL1</i> t(9;22) p190 e1a2	 -85°C -65°C *
10 ⁻² e1a2 RNA	1:100	400 µg/mL	1	50 µL		
10 ⁻³ e1a2 RNA	1:1,000	400 µg/mL	1	50 µL		
10 ⁻⁴ e1a2 RNA	1:10,000	400 µg/mL	1	50 µL		
10 ⁻⁵ e1a2 RNA	1:100,000	400 µg/mL	1	50 µL		
e1a2 Negative RNA	n/a	400 µg/mL	1	50 µL	negative for <i>BCR/ABL</i> e1a2 transcript	

*Minimize the number of freeze-thaw cycles.

2.2. Warnings and Precautions

- **RUO** Invivoscribe's *BCR/ABL* e1a2 RNA Dilution Set is for Research Use Only. Not intended for diagnostic purposes.
- Establish standard operating procedures and instructions for using the Invivoscribe *BCR/ABL* e1a2 RNA Dilution Set in molecular assays.
- 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.

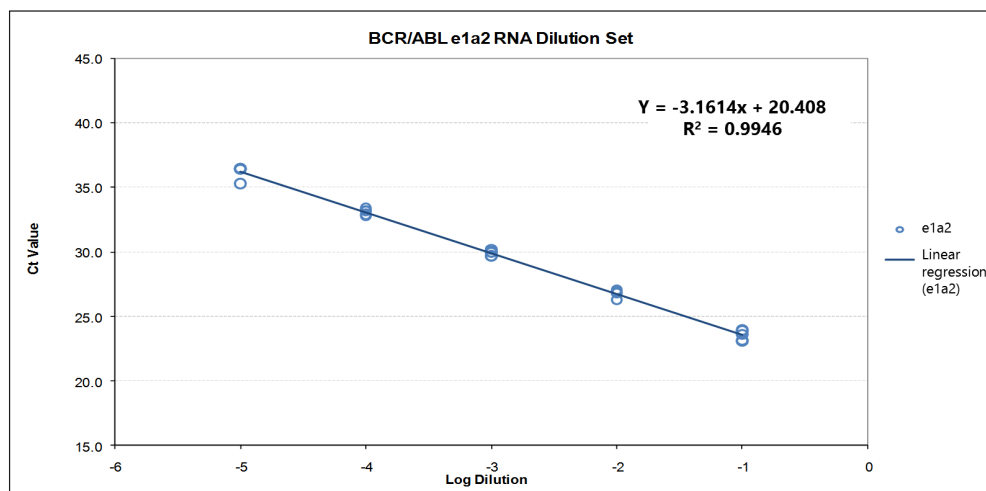
2.3. Storage and Stability

- Store all RNA material at -65°C to -85°C to maintain product integrity.
- The material contains date of manufacture on the label. Conduct appropriate stability testing to ensure the integrity of the material after aliquoting into single-use volumes.

3. Procedure

- 3.1. Allow the *BCR/ABL* e1a2 RNA Dilution Set to equilibrate to room temperature.
- 3.2. Vortex gently, then pulse-spin in a centrifuge (4 to 6 seconds) to collect the contents at the bottom of the tube.
- 3.3. Introduce each component of the *BCR/ABL* e1a2 RNA Dilution Set as an independent sample at the template addition step in the workflow.
- 3.4. Handle each component of the *BCR/ABL* e1a2 RNA Dilution Set similarly to nucleic acids extracted from routine samples and run in parallel with routine samples.

4. Interpretation of Results












This plot indicates the Ct values versus 10^{-1} , 10^{-2} , 10^{-3} , 10^{-4} and 10^{-5} dilutions of *BCR/ABL* e1a2 RNA Dilution Set (5 replicates).

- 4.1. Results generated by Invivoscribe's *BCR/ABL* e1a2 RNA Dilution Set may differ according to the molecular test method.
- 4.2. 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.
- 4.3. Once the validated size range is ascertained, the expected size range can be used to verify each subsequent run result of the *BCR/ABL* e1a2 RNA Dilution Set.

5. 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		

6. 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.

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7. Legal Notice

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

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