ZYMO RESEARCH

Quick-DNA/RNA™ HT - Dx

High-throughput, total nucleic acid purification system

Highlights

- High-throughput, magnetic-bead based purification of total nucleic acid (DNA/RNA) from any biological or clinical sample (e.g., host, plasma, serum, urine, cell culture media, blood, saliva, cellular suspensions, swab, fecal and biopsies).
- High-quality DNA/RNA is ready for Next-Gen sequencing, RT/qPCR, hybridization, etc.

Catalog Numbers or REF
R2150-E, R2151-E

Scan with your smart-phone camera to view the online protocol/video.

CE IVD

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Table of Contents

Product Contents

Quick-DNA/RNA™ HT – Dx	R2150-E (250 preps)	R2151-E (1000 preps)
DNA/RNA Buffer HT	100 ml	400 ml
Proteinase K (lyophilized)	20 mg	60 mg
Proteinase K Storage Buffer	1.2 ml (x3)	10 ml
HT MagBinding Beads	3 ml	12 ml
MagBead DNA/RNA Wash 1 (concentrate)	30 ml (x2)	120 ml (x2)
MagBead DNA/RNA Wash 2 (concentrate)	20 ml (x2)	80 ml (x2)
DNase/RNase-Free Water	30 ml	100 ml
Instruction Manual	1 pc	1 pc

- **Materials/Equipment Needed (user provided)**
  - ✓ Beta-mercaptoethanol (β-Me)
  - ✓ Isopropanol (99.5-100%)
  - ✓ Ethanol (95-100%)
  - ✓ Nuclease-free water
  - ✓ Vortex Mixer
  - ✓ Magnetic stand or separator
  - ✓ Liquid handler or robotic sample processor

- **Materials Available Separately (not provided)**
  - DNA/RNA Shield™ (2X concentrate) (R1200-25, 25 ml)
  - ZR-96 MagStand (P1005)
  - Collection Plate (C2002; capacity 1.2 ml/well)
  - 96-Well Block (P1001-2; capacity 2 ml/well)
  - Elution Plate (C2003; capacity 0.35 ml/well)
  - Cover Foil (C2007-4; 4 pack)
  - ZR BashingBead Lysis Tubes (S6003-50; 2.0 mm beads), (S6012-50; 0.1 & 0.5 mm beads), (S6014-50; 0.1 & 2.0 mm beads)
  - DNase I Set (E1010; 250 U DNase I (lyophilized) supplied with DNA Digestion Buffer, 4 ml)
  - DNA/RNA Prep Buffer (D7010-2-50, 50 ml)

Specifications

- **Sample Sources**

  Any biological sample (e.g., swabs, liquids, cells, tissue, etc.), and samples collected/stored in media (e.g., UTM, VTM, saline, PBS, DNA/RNA Shield™, PAXgene, RNAlater, RNAProtect, etc.)

- **Binding Capacity**

  5 µg DNA/RNA per 10 µl **HT MagBinding Beads**

- **Elution Volume**

  ≥ 15 µl **DNase/RNase-Free Water**

- **Purity**

  DNA/RNA is ready for Next-Gen Sequencing, RT/qPCR, etc.

- **Storage Temperature and Stability**

  ✓ Store all components (i.e., buffers/reagents, columns) at room temperature (15-30°C).
  ✓ Expiration dates for each of the unopened components are indicated on the individual component labels. These storage conditions apply to both opened and unopened components.
  ✓ Eluted DNA/RNA can be used immediately or stored frozen (-20/-80°C).

General Laboratory Warnings/Precautions

This assay is for *in vitro* diagnostic use. Nucleic acid extraction kits are designed for procedures of molecular diagnostic and can only be handled by personnel trained in molecular biology methods.

- ✓ This product is intended for professional use or for use in POC. DO NOT use if the product is visibly damaged.
- ✓ Wear gloves when handling specimens or reagents.
- ✓ Do not pipette by mouth.
- ✓ Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- ✓ Clean and disinfect spills of specimens by including the use of soap and water (i.e., 20% aqueous solution of Sodium Dodecyl Sulfate disinfectant (SDS)).
- ✓ Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.
- ✓ Decontaminate and dispose of all potentially infectious materials in accordance with local, state, and European regulations.

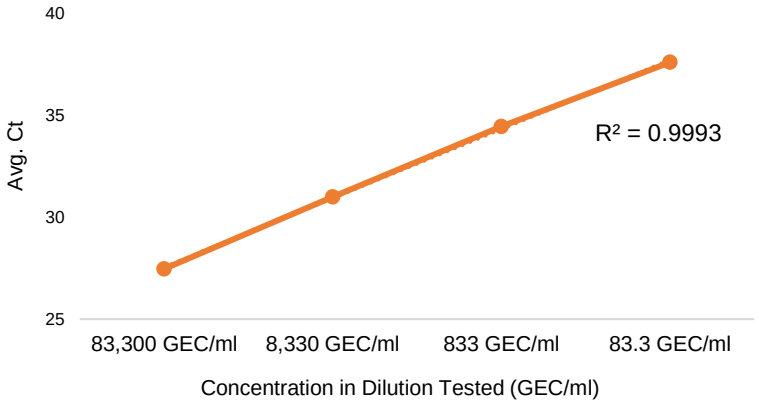
  Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet. Safety Data Sheets are available from Zymo Research Corp. Inquire directly.

Intended Use

The ***Quick*-DNA/RNA™ HT – Dx** kit is intended for rapid, high-throughput nucleic acid extraction (automated or manual) from any biological or clinical sample (e.g., swabs – nasal/nasopharyngeal, oropharyngeal, etc.; biological liquids – blood, plasma, serum, saliva, sputum, cells in suspension, etc.; tissue – needle biopsies, LCM, etc.) and/or samples stored in most collection matrices and devices (e.g., UTM, VTM, DNA/RNA Shield™, RNAlater, RNAProtect, etc.).

The kit is compatible with robotic-type sample processors (i.e, bead movers) in combination with sensitive downstream molecular amplification assays. High-quality DNA/RNA extracted with the ***Quick*-DNA/RNA™ HT-Dx** kit can be used for Next-Gen sequencing, RT/qPCR and more.

Limit of Detection Preliminary Assay from Biological Specimens using Automated Extraction



Concentration in Dilution	83,300 GEC/ml (5,000 GEC/rxn)	8,330 GEC/ml (500 GEC/rxn)	833 GEC/ml (50 GEC/rxn)	83.3 GEC/ml (5 GEC/rxn)	8.33 GEC/ml (0.5 GEC/rxn)
Avg. Ct	27.5	31.0	34.5	37.6	Not detected
Positive, n=5	5/5	5/5	5/5	5/5	0/5

Automated extraction of whole genome viral RNA (i.e., SARS-CoV-2) spiked in sputum/swab samples collected in DNA/RNA Shield™ was performed with the ***Quick*-DNA/RNA™ HT – Dx** kit, followed by quantification by RT-qPCR. Preliminary limit of detection (LoD) assay determined the lowest concentration for which 5/5 independent replicates tested positive.

Protocol

The protocol consists of: (I) Buffer Preparation, (II) Sample Preparation and (III) DNA/RNA Purification.

(I) Buffer Preparation

- ✓ Add 500 µl beta-mercaptoethanol (user supplied) per 100 ml **DNA/RNA Buffer HT**, (final 0.5% (v/v)).
- ✓ Add 20 ml (R2150-E) or 80 ml (R2151-E) of isopropanol to the **MagBead DNA/RNA Wash 1** concentrate.
- ✓ Add 30 ml (R2150-E) or 120 ml (R2151-E) of isopropanol to the **MagBead DNA/RNA Wash 2** concentrate.
- ✓ Reconstitute lyophilized **Proteinase K** at 20 mg/ml with **Proteinase K Storage Buffer** and mix by vortexing. Use immediately or store frozen aliquots:
  #R2150-E (**20 mg**), add 1.04 ml **buffer**
  #R2151-E (**60 mg**), add 3.12 ml **buffer**
- ✓ Optional: To prepare DNA/RNA Shield™ (1X)[1], dilute the 2X concentrate with an equal volume of nuclease-free water (user provided) (1:1) and mix well. Reagent is not provided (available separately, see page 14).

1 DNA/RNA Shield™ is a sample collection medium for storage and preservation of nucleic acids. It also inactivates pathogens and prevents viral infectivity. Specimens stored and transported in DNA/RNA Shield™ can be processed directly without reagent removal, using standard laboratory operating procedures, for the detection of nucleic acids with molecular amplification assays.

(II) Sample Preparation

✓ Perform all steps at room temperature (15-30°C).

Sample Input – Depending on the sample type, up to 200 µl can be processed per prep (see examples below).

Swabs		
Nasal/Nasopharyngeal	Oropharyngeal	Buccal/cheek
Vaginal	Fecal	

Stored in UTM, VTM, saline, PBS, DNA/RNA Shield™, etc.

Optional - To inactivate, store and preserve samples at room temperature, add 100 µl DNA/RNA Shield™ (2X concentrate)[1] to 100 µl sample (1:1). Mix well[2].

Liquids (I)		
Plasma	Serum	CSF
Cells in suspension		

Optional - To inactivate, store and preserve samples at room temperature, add 100 µl DNA/RNA Shield™ (2X concentrate)[1] to 100 µl sample (1:1). Mix well[2].

Liquids (II)		
Whole blood	Saliva	Sputum
Urine		

Recommended: To inactivate, lyse and preserve samples at room temperature, add 100 µl DNA/RNA Shield™ (2X concentrate)[1] to 100 µl sample (1:1). Mix well[2], centrifuge debris and process the cleared supernatant.

Tissue	
Tissue (< 5 mg)	Feces (< 20 mg)

LCM, needle biopsy or samples stored in media/device.

Recommended: To inactivate, lyse and preserve samples at room temperature, add 200 µl DNA/RNA Shield (1X)[1,3] and homogenize[4]. Mix well, centrifuge debris and process the cleared supernatant.

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1 At this point, samples in DNA/RNA Shield™ can be stored at ambient temperature (4-30°C) for a month, 7 days at 35°C, or long-term (> 1 year) at -20°C or below.
2 For all buffer additions and incubation steps, **mix well** for ≥1 minute by pipetting the beads up and down and/or by shaking (vortexing) at ~1,300 rpm. Optimization may be required.
3 To prepare DNA/RNA Shield™ (1X), dilute the **2X concentrate** with an equal volume of nuclease-free water (user provided) (1:1) and mix well.
4 For efficient homogenization of tough-to-lyse tissue samples, bead-beat with ZR BashingBead Lysis Tubes (S6003, S6012, S6014), sold separately.

(II) Sample Preparation (continued)

Proteinase K Treatment (optional)

✓ At this point, protein-rich samples e.g., plasma, serum, saliva, sputum, tissue, can be treated.

1. Add 1% **Proteinase K** (v/v) at 20 mg/ml[1] directly to a liquid sample. Mix well[2].
2. Incubate at room temperature for 15 minutes.

   Note: Up to 5% Proteinase K can be added to protein-rich samples (e.g., tissue). For example: Add 2-10 µl Proteinase K (20 mg/ml) to each 200 µl sample.

Transfer up to **200 µl** of the prepared sample into a new tube/well and proceed to **DNA/RNA Purification, page 8**.

1 For automation platforms with "dead volume" liquid handler dispensing, the lyophilized Proteinase K can be reconstituted to a working concentration of 4-20 mg/ml.
2 For all buffer additions and incubation steps, **mix well** for ≥1 minute, by pipetting the beads up and down and/or by shaking (vortexing) at ~1,300 rpm. Optimization may be required.

(III) DNA/RNA Purification

✓ Perform all steps at room temperature (15-30°C).

1. Add 400 µl **DNA/RNA Buffer HT** to each 200 µl sample[1] (2:1) and mix well[2].
2. Add 10 µl **HT MagBinding Beads** and mix well[2] for 10 minutes.
3. Transfer the plate/tube to a magnetic stand[3] until beads have pelleted, then aspirate[4] and discard the cleared supernatant.
4. Add 250 µl **MagBead DNA/RNA Wash 1** and mix well[2]. Pellet the beads[3,4] and discard the supernatant.
5. Add 250 µl **MagBead DNA/RNA Wash 2** and mix well[2]. Pellet the beads[3,4] and discard the supernatant.
6. Add 250 µl ethanol (95-100%) and mix well[2]. Pellet the beads[3,4] and discard the supernatant.
7. Add 250 µl of ethanol (95-100%) and mix well[2]. Then transfer the sample (beads and liquid) to a new plate/tube (not provided). Pellet the beads[3,4] and discard the supernatant.

   Optional: At this point, DNase I treatment can be performed (see Appendices, page 9).
8. Dry the beads for 10 minutes.
9. To elute DNA/RNA from the beads, add 30 µl **DNase/RNase-Free Water** and mix well[2].

   Alternatively, for highly concentrated DNA/RNA use ≥ 15 µl volume.
10. Transfer the plate/tube to a magnetic stand[3] until beads have pelleted, then aspirate[4] and dispense the eluted DNA/RNA to a new plate/tube.

    The eluted DNA/RNA[5] can be used immediately or stored frozen.

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1 Up to 200 µl sample (including the volume of DNA/RNA Shield™, if added) can be processed per prep.
2 For all buffer additions and incubation steps, **mix well** for ≥1 minute, by pipetting the beads up and down and/or by shaking (vortexing) at ~1,300 rpm. Optimization may be required.
3 Use a strong-field magnetic stand or separator (e.g., ZR-96 MagStand, P1005; sold separately) until beads have pelleted.
4 Some beads will adhere to the sides of the well. When removing the supernatant, aspirate slowly to allow these beads to be pulled to the magnet as the liquid level is lowered.
5 It is recommended to titrate the DNA/RNA eluate for downstream applications (i.e., RT/qPCR, etc.).

Appendices

Automation Scripts

The ***Quick*-DNA/RNA™ HT - Dx** (R2150-E, R2151-E) is compatible with automated platforms*. For automation scripts and related technical support, email automation@zymoresearch.com. In the subject line, please include "Automation Scripts", instrument used and the product catalog number.

DNase I Treatment

✓ For DNA-free RNA, DNase I treatment can be performed using DNase I Set (E1010; 50 reactions) and DNA/RNA Prep Buffer (D7010-2-50), materials sold separately.

For each sample to be treated, prepare **DNase I Reaction Mix** in an RNase-free tube (not provided) and mix by gentle inversion:

DNase I Reaction Mix	
Nuclease-free water (user provided)	40 µl
DNA Digestion Buffer	5 µl
DNase I (reconstituted; 1 U/µl)[1]	5 µl

1. Add 50 µl **DNase I Reaction Mix** to the beads and mix gently for 10 minutes.
2. Add 500 µl **DNA/RNA Prep Buffer** and mix well[2] for 10 minutes. Pellet the beads[3,4] and discard the supernatant.
3. Add 250 µl ethanol (95-100%) and mix well[2]. Pellet the beads[3,4] and discard the supernatant.
4. Add 250 µl of ethanol (95-100%) and mix well[2]. Then transfer the sample (beads and liquid) to a new plate/tube (not provided). Pellet the beads[3,4] and discard the supernatant.
5. Proceed with step 8 in DNA/RNA Purification, page 8.

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*For automation platforms with "dead volume" liquid handler dispensing, additional reagents are available separately.
1 Prior to use, reconstitute lyophilized 250 U DNase I (E1009-A) to 1U/µl (final concentration) with 275 µl nuclease-free water (user provided), mix by gentle inversion and store frozen aliquots.
2 For all buffer additions and incubation steps, **mix well** for ≥1 minute, by pipetting the beads up and down and/or by shaking (vortexing) at ~1,300 rpm. Optimization may be required.
3 Use a strong-field magnetic stand or separator (e.g., ZR-96 MagStand, P1005; sold separately) until beads have pelleted.
4 Some beads will adhere to the sides of the well. When removing the supernatant, aspirate slowly to allow these beads to be pulled to the magnet as the liquid level is lowered.

Clinical Performance

Limit of Detection (LoD) – Analytical Sensitivity

The LoD study was performed to determine the lowest concentration of viral RNA copies (i.e., SARS-CoV-2) that can be recovered from a biological specimen with greater than or equal to 95% accuracy. The ***Quick*-DNA/RNA™ HT - Dx** kit was used in automated and manual viral RNA extraction, and SARS-CoV-2 detection/analysis was performed with the *Quick* SARS-CoV-2 rRT-PCR Kit and the Bio-Rad CFX96 Touch Real-Time PCR Detection System (Bio-Rad CFX Maestro 1.1 software version 4.1.2433.1219).

For clinical matrix (input), negative sputa samples collected and stored in DNA/RNA Shield™ reagent combined with throat swabs collected in DNA/RNA Shield™ Collection Tubes, were spiked with SARS-CoV-2 (strain Muc-IMB-1) whole genome RNA. The whole genome RNA was obtained from the SARS-CoV-2 virus isolated from a COVID-19 positive patient specimen at the University of Freiburg, Germany.

20 replicates were independently processed by automated and manual extraction with the ***Quick*-DNA/RNA™ HT - Dx** kit for LoD determination and quantified by RT-qPCR. The lowest concentration at which all 5 replicates were positive in a preliminary LoD study (i.e., 83 GEC/ml) was used as a starting point for the confirmatory LoD study (see data, page 4). Testing of 83 GEC/ml (increasing by factor 2) were tested until ≥ 19/20 replicates tested positive.

The final LoD for both the manual and automated extraction methods was determined to be 250 GEC/ml (15 GEC/rxn) (see data, page 11).

Limit of Detection Validation Assay from Biological Specimens using Automated Extraction

Automated Extraction						Manual Extraction			
Replicate	250 GEC/ml (15 GEC/rxn)	167 GEC/ml (10 GEC/rxn)	83 GEC/ml (5 GEC/rxn)	Lowest concentration w/ at least 19/20 (95%) positive	Confirmatory Limit of Detection (LoD)	Replicate	250 GEC/ml (15 GEC/rxn)	Lowest concentration w/ at least 19/20 (95%) positive	Confirmatory Limit of Detection (LoD)
	Ct	Ct	Ct	250 GEC/ml (15 GEC/rxn)	**250 GEC/ml (15 GEC/rxn)**		Ct	250 GEC/ml)(15 GEC/rxn)	**250 GEC/ml(15 GEC/rxn)**
1	33.5	35.0	34.0			1	35.3		
2	33.6	33.3	34.6			2	35.9		
3	33.3	33.3	33.5			3	35.8		
4	34.1	35.1	**NA**			4	34.8		
5	33.5	**NA**	34.2			5	**NA**		
6	34.2	33.6	35.1			6	35.0		
7	33.6	34.5	**NA**			7	34.8		
8	34.0	34.1	35.5			8	37.0		
9	33.7	34.7	36.7			9	36.6		
10	33.7	35.0	35.4			10	34.6		
11	34.1	33.1	**NA**			11	35.7		
12	34.2	**NA**	35.2			12	36.4		
13	33.1	34.3	35.3			13	34.0		
14	34.5	36.1	34.9			14	35.0		
15	33.6	35.6	34.5			15	36.2		
16	33.4	33.2	35.7			16	36.2		
17	34.6	35.5	**NA**			17	34.5		
18	33.0	**NA**	37.8			18	38.2		
19	33.6	35.2	**NA**			19	35.5		
20	34.6	33.4	34.8			20	33.2		
Call Rate	20/20	17/20	15/20			**Call Rate**	19/20		

*NA = no amplification

Summary								
Target Level	Method	Valid Results	SARS-CoV-2 N (all targets) Positive			Internal Control Positive		
			n	Avg. Ct	Detection Rate	n	Avg. Ct	Detection Rate
250 GEC/ml (15 GEC/rxn)	Automated	20	20	33.8	**100%**	20	28.3	**100%**
167 GEC/ml (10 GEC/rxn)	Automated	20	17	34.4	**85%**	20	28.2	**100%**
83 GEC/ml (5 GEC/rxn)	Automated	20	15	35.1	**75%**	20	28.2	**100%**
250 GEC/ml (15 GEC/rxn)	Manual	20	19	35.5	**95%**	19	27.2	**95%**

Label Legend

	Authorized representative in the European community/European Union
	CE IVD vertical
	CE IVD horizontal
	Do not-reuse
	Warning
	*In vitro* diagnostic medical device
	Lot number
	Manufacturer
	Reference **or** Catalogue number
	Consult instructions for use
	Temperature limit
	Unique device identifier
	Use-by-date
	Contains sufficient for < n > preps or reactions

Troubleshooting Guide

Problem	Possible Causes and Suggested Solutions
RNA degradation	To prevent RNA degradation: Immediately collect and lyse fresh sample into a stabilization reagent (i.e., DNA/RNA Shield™) to ensure nucleic acid stability. Homogenized samples in DNA/RNA Shield™ can be stored frozen for later processing.
Low nucleic acid content and/or low sensitivity in downstream application	Incomplete deproteinization due to high-protein content in the sample (blood, plasma/serum, tissue etc.): - Increase the volume of DNA/RNA Shield™ to the sample. - Perform Proteinase K treatment (see Sample Preparation, page 7). Increase binding time: At all binding steps, increase binding time for an additional ≥10 minutes (e.g., 30 minutes). Depending on the amount of biomass, more time may be required to allow nucleic acids to be sufficiently bound to beads. Inefficient washing of beads: -Shaking/Mixing: Mix well for ≥1 minute, by pipetting up and down and/or by shaking (vortexing) at high speed. Make sure that the beads are resuspended throughout the bind, wash and elution steps. Optimization may be required. Increase eluate input: -Titrate the DNA/RNA eluate for downstream applications (i.e., RT/qPCR).
DNA contamination	To remove DNA: - Perform DNase I treatment during the purification (page 8) or perform DNase I treatment post-purification (#R1082), then clean-up the treated sample.

For technical assistance, please contact 1-888-882-9682 or email tech@zymoresearch.com

Ordering Information

Product Description	Catalog No.	Size
***Quick*-DNA/RNA™ HT - Dx**	R2150-E	250 preps
***Quick*-DNA/RNA™ HT - Dx**	R2151-E	1000 preps

Individual Kit Component	Catalog No.	Amount
DNA/RNA Buffer HT	R2150-1-100	100 ml
Proteinase K Set supplied w/ Storage Buffer	D3001-2-20 D3001-2-60	20 mg 60 mg
MagBead DNA/RNA Wash 1 (concentrate)	R2130-1-30 R2130-1-120	30 ml 120 ml
MagBead DNA/RNA Wash 2 (concentrate)	R2130-2-20 R2130-2-80	20 ml 80 ml
HT MagBinding Beads	R2150-2-3 R2150-2-12	3 ml 12 ml
DNase/RNase-Free Water	W1001-30 W1001-100	30 ml 100 ml
DNA/RNA Shield™ (2X concentrate)	R1200-25 R1200-125	25 ml 125 ml

Notes

Notes

100% satisfaction guarantee on all Zymo Research products, or your money back.

Zymo Research is committed to simplifying your research with quality products and services. If you are dissatisfied with this product for any reason, please call 1(888) 882-9682.

Integrity of kit components is guaranteed for up to one year from date of purchase.
Reagents are routinely tested on a lot-to-lot basis to ensure they provide the highest performance and reliability.

Some reagents included with this kit are irritants. Wear protective gloves and eye protection. Follow the safety guidelines and rules enacted by your research institution or facility.

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