3095-0020

chemagic™ DNA Blood200 kit (MSM I)

Instructions for use. Reagents for 960 extractions.

Manufacturer:
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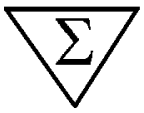
FOR *IN VITRO* DIAGNOSTIC USE

CE

revvity

SYMBOLS

	*In vitro* diagnostic medical device
	Batch code
	Packing number
	Catalog number
	Use by
	Temperature limitation
	Contains sufficient for <n> tests
	Consult instructions for use
	Manufacturer
	GHS07
	GHS02
	GHS08

This way up

Recyclable

Fragile, handle with care

Keep dry

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chemagic™ DNA Blood200 kit (MSM I)

INTENDED PURPOSE

The chemagic™ DNA Blood200 kit (MSM I) is intended for the extraction and purification of DNA from human whole blood for analysis by PCR based *in vitro* diagnostic test systems. The disorder and determination of analytes are dependent on the PCR based downstream assay. The product is intended to be used with an automated workflow by trained laboratory personnel.

SUMMARY AND PRINCIPLE

The chemagic DNA Blood200 kit (MSM I) is based on a magnetic bead technology platform proprietary to Revvity chemagen Technologie GmbH. Cells present in whole blood samples are lysed during the extraction process. The released nucleic acids bind to small magnetizable particles which are then magnetically separated from the sample material. During subsequent steps contaminants are removed and the purified nucleic acids are transferred into an elution buffer. The automated sample processing is performed using the chemagic Magnetic Separation Module I, MSM I (CMG-500) or the chemagic Magnetic Separation Module ND, MSM ND (CMG-533) with chemagic 96 Rod Head (CMG-536).

KIT CONTENTS

The kit contains reagents sufficient to perform 960 extractions.

The expiry date of the unopened kit is stated on the outer label. Do not use any component beyond the expiry date. Store at +2 to +25 °C.

Once opened, the kit components are stable for 60 days. Note: Recap the bottles tightly immediately after use to prevent evaporation.

The bottles may discolor during storage. The discoloration of the bottles has no effect on the functionality of the assay.

The kit contains following items:

Component	Quantity
Magnetic Beads B	1 bottle, 150 mL
Lysis Buffer B	1 bottle, 480 mL
Binding Buffer B	2 bottles, 550 mL
Wash Buffer BB	2 bottles, 700 mL
Wash Buffer BA	2 bottles, 700 mL
Wash Buffer E	2 bottles, 700 mL
Wash Buffer H	2 bottles, 700 mL
Elution Buffer	1 bottle, 240 mL
Lot-specific quality control certificate	1 pc

Reagents

Component	Stability and storage
Magnetic Beads B	+2 to +25 °C until expiry date stated on the bottle label.
Suspension of particles containing nanoparticular iron oxide encapsulated in a matrix of polyvinyl alcohol. Magnetic Beads (28.0 ± 0.5 mg/mL) bind the DNA during the extraction process.	
Lysis Buffer B  WARNING	+2 to +25 °C until expiry date stated on the bottle label. Avoid direct sunlight.
Ready-for-use aqueous buffer solution (pH 6.9–7.4) containing guanidinium chloride (15–25 %) and detergent. Lysis Buffer is used to lyse the blood cells in order to get the DNA in solution.	

Lysis Buffer B contains guanidinium chloride:
H315 Causes skin irritation.
H319 Causes serious eye irritation.
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.

Binding Buffer B +2 to +25 °C until expiry date stated on the bottle label.

DANGER

Ready-for-use Tris-HCl-buffered (pH 5.0–5.9) solution with sodium perchlorate (15–25 %) and ethanol (25–50 %). Binding Buffer is used to create the appropriate conditions to get the DNA bound to the Magnetic Beads.

Binding Buffer B contains sodium perchlorate and ethanol:
H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local regulations.

Wash Buffer BB +2 to +25 °C until expiry date stated on the bottle label.

DANGER

Ready-for-use Tris-HCl-buffered (pH 5.0–5.6) solution with sodium perchlorate (15–25 %) and ethanol (25–50 %). Used for removing non-DNA contaminants during washing step.

Wash Buffer BB contains sodium perchlorate and ethanol:
H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local regulations.

Wash Buffer BA +2 to +25 °C until expiry date stated on the bottle label.

DANGER

Ready-for-use Tris-HCl-buffered (pH 5.0–5.6) solution with sodium perchlorate (15–25 %) and ethanol (25–50 %). Used for removing non-DNA contaminants during washing step.

Wash Buffer BA contains sodium perchlorate and ethanol:
H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local regulations.

Wash Buffer E +2 to +25 °C until expiry date stated on the bottle label.

DANGER

Ready-for-use solution contains ethanol 50–75 %. Used for removing last traces of non-DNA contaminants during washing step.

Wash Buffer E contains ethanol:
H225 Highly flammable liquid and vapor.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/container in accordance with local regulations.

Wash Buffer H	+2 to +25 °C until expiry date stated on the bottle label.
Ready-for-use ultra-filtered water solution. Used for removing possible residuals of ethanol.	
Elution Buffer	+2 to +25 °C until expiry date stated on the bottle label.
Ready-for-use 10 mM Tris-HCl-buffered (pH 7.8–8.4) solution.	

MATERIALS REQUIRED BUT NOT SUPPLIED WITH THE KIT

The chemagic DNA Blood200 kit (MSM I) requires the following items, which are available from Wallac Oy or Revvity, Inc. and its distributors:

- chemagic Magnetic Separation Module I, MSM I (prod. no. CMG-500) or chemagic Magnetic Separation Module ND, MSM ND (prod. no. CMG-533) with chemagic 96 Rod Head (prod. no. CMG-536)
- chemagic consumables (tips, deep well plates and low well plates for chemagic, prod. no. 4155-0010)

Additional required items:

- pipettes and pipette tips with aerosol barriers

Additional optional items:

- chemagic Stand 96 (prod. no. CMG-301)

SPECIMEN COLLECTION AND HANDLING

Human whole blood samples (200 µL), fresh or stored typically for a maximum of one week at +2 to +8 °C should be used. The recommended blood stabilizers are EDTA or citrate. The use of heparin stabilized blood samples can cause inhibition problems in PCR and is therefore not recommended.

The white blood cell count in the whole blood sample decreases during storage. Storing the samples may cause a poor yield of the DNA extraction.

The extraction efficiency using other types of sample material has not been determined.

Specimen Stability

The influence of storage time and temperature was studied[1] using several whole blood specimens collected from healthy donors to collection tubes containing either EDTA or citrate as an anticoagulant. Samples were stored at +2 to +8 °C up to 10 days. Extracted DNA samples were replicated in IVD-registered PCR assay and samples were tested by a commercially available downstream assay kit for detecting Fragile X syndrome using recommended reference samples by the National Institute for Biological Standards and Control (NIBSC). No clinically significant deviation was observed on results.

WARNINGS AND PRECAUTIONS

The product is intended to be used by trained laboratory personnel.

To minimize irregularities in diagnostic results, the product is intended to be used with an internal control as well as positive and negative controls throughout the process of sample preparation, and sample amplification and detection according to the downstream assay used.

Handle all patient specimens as potentially infectious. Nevertheless all recommended precautions for the handling of blood derivatives should be observed. Please refer to the U.S. Department of Health and Human Services publication "Biosafety in Microbiological and Biomedical Laboratories" or any other local or national regulation.

Lysis Buffer B contains guanidinium chloride and causes skin irritation and serious eye irritation. **Wash Buffer BB, Wash Buffer BA and Binding Buffer B contain sodium perchlorate and ethanol** and are highly flammable liquids and vapors, cause serious eye irritation and may cause damage to organs through prolonged or repeated exposure. **Wash Buffer E contains ethanol** and is highly flammable liquid and vapor. See specific precautions from the section “KIT CONTENTS”.

To avoid injuries working with the kit components, always wear safety glasses, disposable gloves, and protective clothing. For detailed information, please refer to the corresponding safety data sheets (SDS).

Follow local regulations for handling of ethanolic solutions.

Disposal of all waste should be in accordance with local regulations.

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (IVDR; EU 2017/746/EU); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is stated on the cover page of these instructions for use.

[1] Study performed at Wallac Oy, Turku, Finland.

PROCEDURE

Extraction protocol using the chemagic Magnetic Separation Module I (MSM I)

The duration of the automated extraction protocol is approximately 60 minutes.

The protocol is suitable for processing up to 96 samples in parallel (see protocol steps below). For detailed instructions on the use of the chemagic Magnetic Separation Module I (MSM I) or the chemagic Magnetic Separation Module ND (MSM ND), please refer to the respective instrument manual.

Samples and reagents must be brought to room temperature (+19 to +25 °C) before use.

NOTE: Recap the bottles tightly immediately after use. Binding Buffer B, Wash Buffer BB, Wash Buffer BA and Wash Buffer E contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

Processing Steps in Detail

Preparing Steps

1. Check all kit components for integrity. In case of damage, contact your supplier.

2. Before prefilling the plates mark each plate with material in position.

3. Prefill the plates (using a multichannel pipette or a dispensing system) as described in the table in section “Protocol Steps”. **Please pay special attention to the prefilling order (Protocol Steps in tracking system positions 4–8).** The process has to be started as soon as possible, at the latest 30 minutes after prefilling of the solutions to avoid evaporation of the solutions.

NOTE: The run must be started immediately after adding the Lysis Buffer B to the sample wells. Hesitation may result in low yield and purity.

Protocol Steps

Position in tracking system	Material in position	Protocol step in detail
		Select the protocol '**chemagic DNA Blood200 IVD 131216.che**' and press [insert IDs] button. Follow the instructions given in the software. If the enhanced functions are deactivated, continue without pressing [insert IDs] button.
1	Rack with disposable tips	Use Disposable tips according to the positions of the samples.
2	Low well plate 150 µL Magnetic Beads B	Prefill **before starting the run** according to the positions of the samples. **Magnetic bead suspension needs to be thoroughly resuspended by mixing.**
3	Deep well plate 200 µL Blood (sample) 500 µL Lysis Buffer B	Dispense up to 96 wells of the Sample Plate with 200 µL blood. Add Lysis buffer to the wells containing sample and **start the run immediately.**
		Check all plates for accurate positioning and fitting. Close the cover and start the process by pressing [Start] button. Subsequently the lysate will be mixed automatically. **The process has to be started as soon as possible, at the latest 30 minutes after prefilling of the solutions** to avoid evaporation of the solutions.
3	1050 µL Binding Buffer B	After the lysis has been completed the protocol will be interrupted (external processing). Remove the Sample Plate from the tracking system (as indicated in pop up window). Follow the instructions given in the software and add 1050 µL Binding Buffer B to each lysate. Return the Sample Plate back to **position 3** on the tracking system, close the cover and confirm to continue with the automated extraction process. Continue the process immediately after addition of the Binding Buffer B. Hesitation may result in low yield and purity.
4	Deep well plate 1000 µL Wash Buffer BB	Prefill **before starting the run** according to the positions of the samples.
5	Deep well plate 1000 µL Wash Buffer BA	Prefill **before starting the run** according to the positions of the samples.
6	Deep well plate 1000 µL Wash Buffer E	Prefill **before starting the run** according to the positions of the samples.
7	Deep well plate 1000 µL Wash Buffer H	Prefill **before starting the run** according to the positions of the samples.
8	Deep well plate 100 µL Elution Buffer	Prefill **before starting the run** according to the positions of the samples.
9	Deep well plate Empty	Empty deep well plate is for used Disposable tips to be discarded.

PROCEDURAL NOTES

1. A thorough understanding of this package insert and the chemagic Magnetic Separation Module I (MSM I) or chemagic Magnetic Separation Module ND (MSM ND) instrument manual is necessary for successful use of the chemagic DNA Blood200 kit (MSM I).

2. Do not use kit reagents after the expiry date printed on the kit label. Once opened, the reagents can be used for up to 60 days.

3. Any deviation from the protocol may affect the results.

4. The amount of DNA obtained can be quantified using an independent method, e.g. UV measurement.

LIMITATIONS OF THE PROCEDURE

In some cases traces of Magnetic Beads B may be left in the eluate. Though such particles will usually not interfere with PCR or most downstream applications, an additional separation step either using centrifugation or a magnetic separator (e.g. chemagic Stand 96, prod. No. CMG-301) is recommended, in order to separate any traces of particles. For UV measurement, traces of Magnetic Beads may cause a higher background and a separation step should be done prior to quantitation.

Extracted DNA should be used immediately after extraction in the desired *in vitro* diagnostic test.

The DNA yield strongly depends on blood characteristics, e.g. low leukocyte count results in a decreased DNA yield.

PERFORMANCE CHARACTERISTICS

The performance of the chemagic DNA Blood200 kit (MSM I) was established by conducting DNA extractions for whole blood specimens from healthy donors. The mean yield for each specimen was calculated and plotted against the white blood cell count. Table 1 shows the descriptive statistics of the specimen means and the DNA yields are presented in figures 1 and 2 using both EDTA and citrate sample tubes. Note: The DNA yield is also effected by the sample dilution caused by the used sample tube (the volume of preservative is different in EDTA and citrate sample tubes).

The results on the purity of the extracted DNA are presented in figure 3.

Table 1. The descriptive statistics of the specimen results

Variable	N	Missing	Median	Mean	Minimum	Maximum
Citrate Yield (ng)	41	0	5.31	5.27	3.30	7.42
EDTA Yield (ng)	41	0	5.89	6.04	4.14	8.23

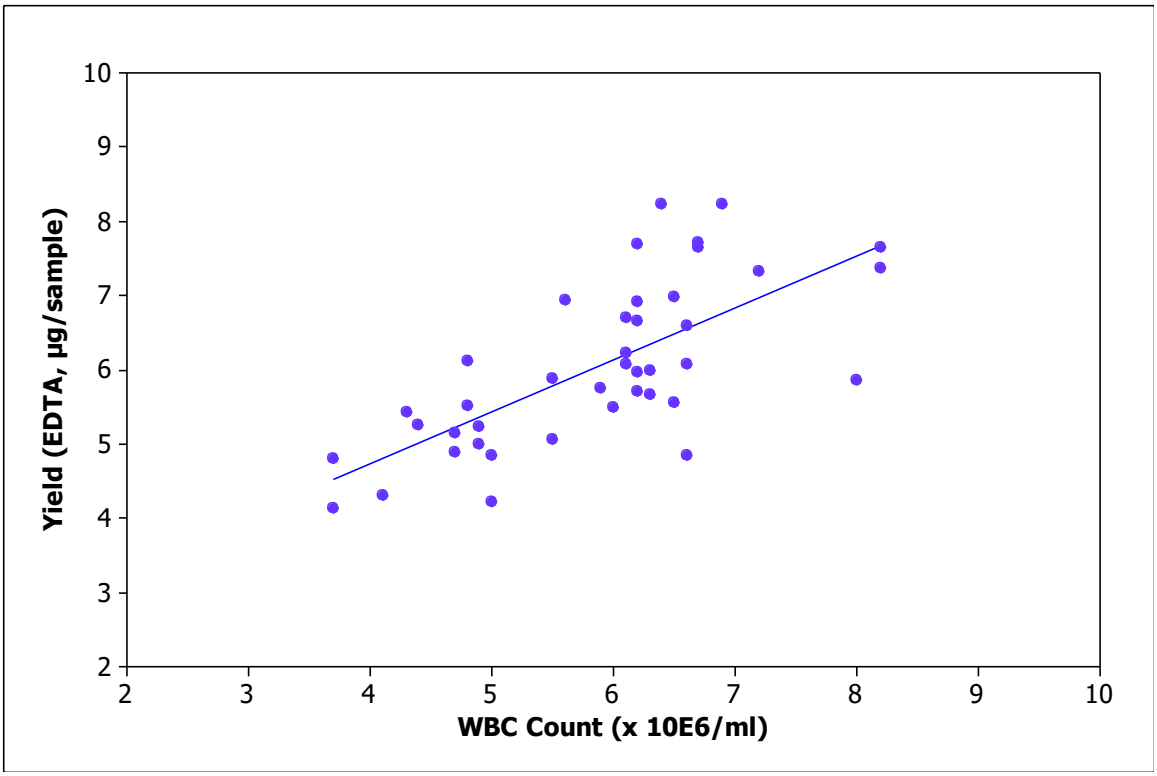

Figure 1. The DNA yield (EDTA tubes, 41 specimens) from 200 µL sample volume. White blood cell counts of healthy donors were determined and were in the range 2.9 - 8.2 x 10e6 cells/mL.

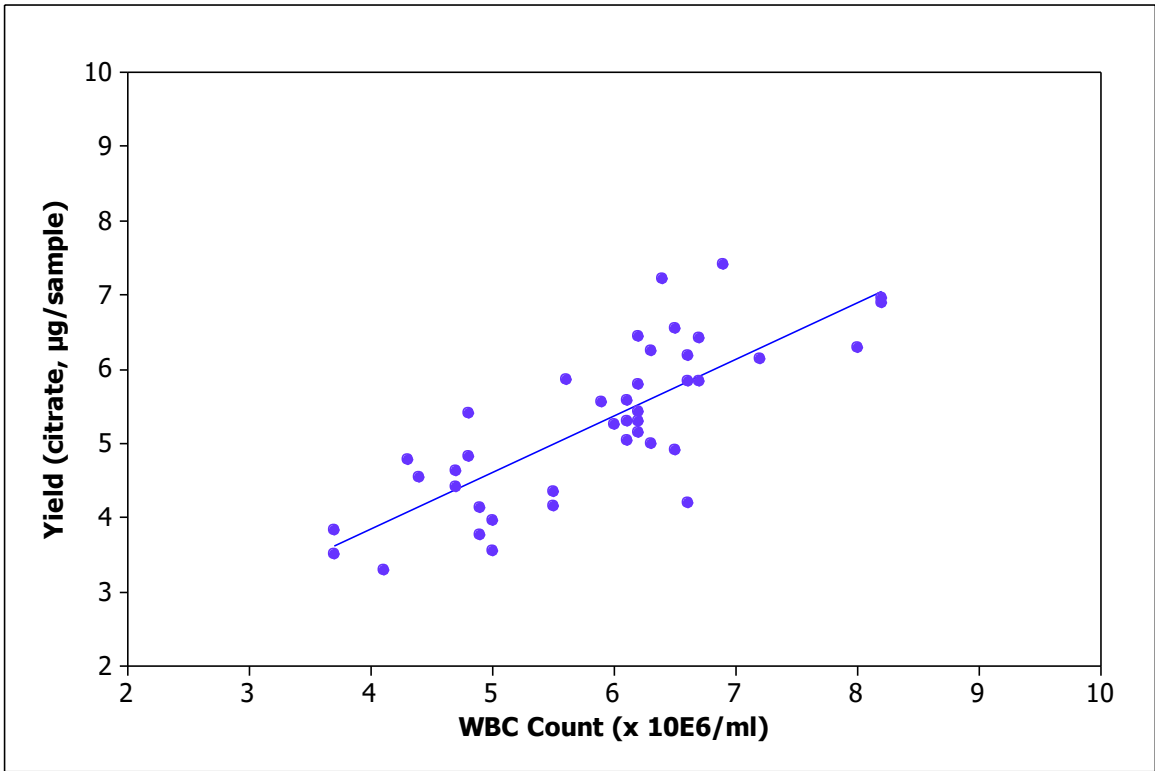

Figure 2. The DNA yield (citrate tubes, 41 specimens) from 200 µL sample volume. White blood cell counts of healthy donors were determined and were in the range 2.9 - 8.2 x 10e6 cells/mL.

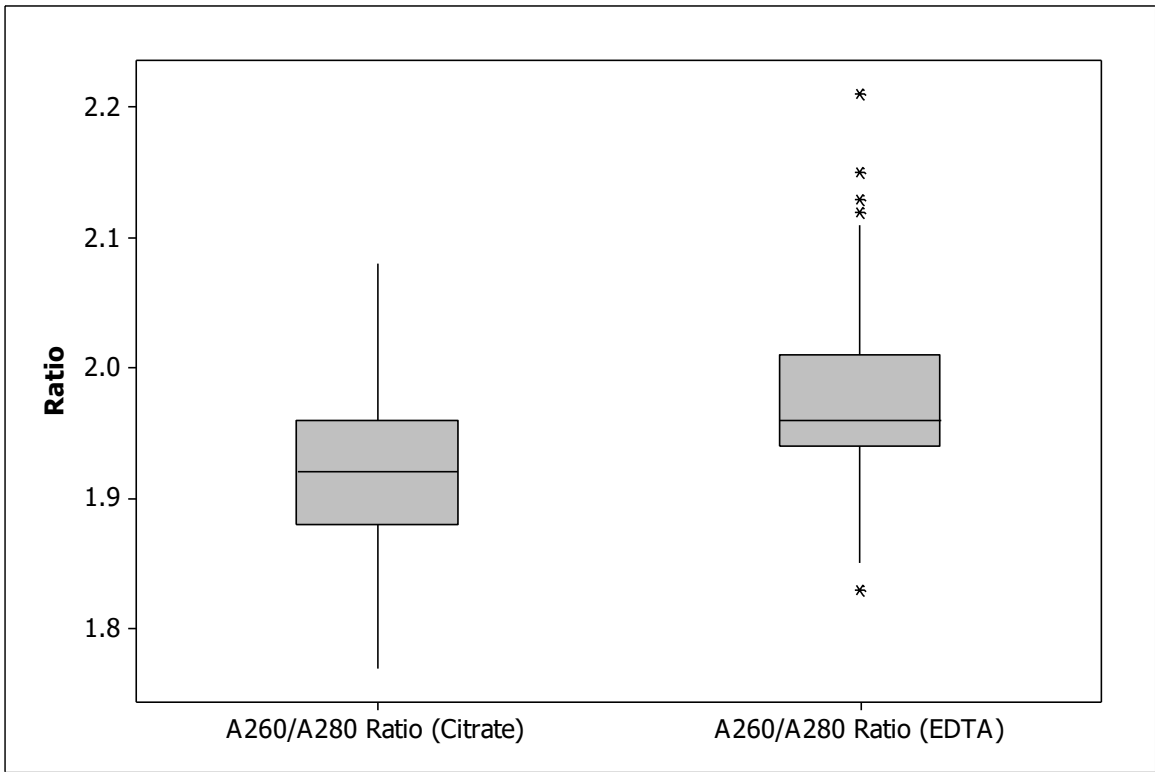

Figure 3. The purity of the extracted DNA (Absorbance ratio A260/A280) of 41 Citrate specimens (123 replicates) and 41 EDTA specimens (122 replicates).

WARRANTY

Any change or modification of the procedure not recommended by the manufacturer may affect the results, in which event Wallac Oy and its affiliates disclaim all warranties expressed, implied or statutory including the implied warranty of merchantability and fitness for use.

Wallac Oy, its affiliates and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

No content changes between the current and previous version. Company name and logo updated.

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