Magnetic rack

DTmag-16S

for nucleic acid extraction
for *in vitro* diagnostics

Operation Manual

"DNA-Technology R&P", LLC
Protvino

Contents

1.General safety requirements 5
2.Purpose 6
3.Technical parameters 6
4.Delivery set 6
5.Device design and operation principle 6
6.General operation instructions 7
Premises requirements 7
Preparation to operation 7
Device installation 7
7.Working with device 7
8.Marking symbols 8
9.Device maintenance 8
10.Recommendations for disinfection during operation 9
11.Disinfection requirements before repair 9
12.Environment safety and disposal 9
13.Precious metal content 9
14.Warranties 10
15.Acceptance certificate 11
16.Packaging certificate 11
17.Warranty repair coupons 13
18. Annex A 15

READ THIS MANUAL CAREFULLY BEFORE USING THE DEVICE!

1.General safety requirements

WARNING! *Qualified personnel trained in molecular diagnostics and rules of work in clinical diagnostic laboratory are allowed to work with the device.*

If the device is used with violation of manufacturer's requirements, the device protection level may decrease.

The device must be protected from shocks, falls, and ambient temperature higher than 60°C.

WARNING! *Do not open the device yourself! There are no user-serviceable components inside the device.*

Do not place the rack near electronic and magnetic data storage devices (bank cards, flash cards), watches, mobile phones, or other electronic devices.

When using the product, it is necessary to comply with the requirements of the standards and safety regulations applicable in medical organizations in the user's country.

2.Purpose

The DTmag-16S magnetic rack for nucleic acid extraction for *in vitro* diagnostics (hereinafter referred to as the Device) is auxiliary laboratory equipment designed for the magnetic separation of high-molecular organic compounds bound to magnetic nanoparticles (hereinafter MNPs) in 1.5 mL tubes

Area of application: clinical diagnostic laboratories of medical institutions and research practice.

3.Technical parameters

1	Number of Eppendorf-type tube slots, tube bottom type — conical; Tube diameter — 10.8 ±0.1 mm; volume 1.5 mL, pcs	16
2	Magnetic field induction on the rack surface at the central collection point of magnetic nanoparticles on the inner walls of the tubes at least, T	0.35
3	Central collection point of magnetic nanoparticles on the inner walls of the tubes at the mark, mL	0.1
4	Optimal (recommended) solution volume per tube, μL.	50-600
5	Dimensions (width × depth × height), mm	179x52x52
6	Rack weight, kg	0.4

4.Delivery set

1	DTmag-16S magnetic rack	1 pc
2	Operation manual	1 pc

5.Device design and operation principle

The DTmag-16S Magnetic Rack is a single module enclosed in a plastic housing. The device material is resistant to disinfectants and ultraviolet radiation.

The set of magnets, structurally integrated into the device housing, ensures complete collection of magnetic nanoparticles and their deposition on the inner wall of the tube, facilitating convenient solution aspiration and washing steps. The magnetic nanoparticle deposition site is indicated by an arrow in Figure 1.

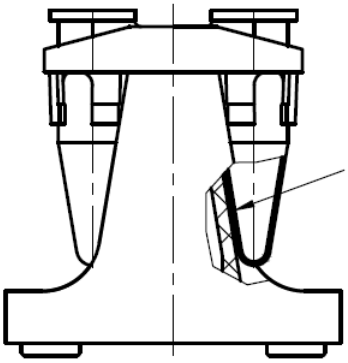

Figure 1 - **Magnetic rack.**

The contoured surface of the tube placement positions in the device ensures reliable and stable fixation of the tubes.

The streamlined design allows for quick and easy surface cleaning during maintenance.

The light-colored surface of the side walls enables the user to visually monitor the completeness of magnetic nanoparticle collection on the tube wall.

6.General operation instructions

Premises requirements

The device is intended for indoor use under the following conditions:

- temperature during operation from 10°C to 35°C,
- relative humidity for temperature 25°C must be up to 80%.

Preparation to operation

Unpack the device and examine it for external damage.

Device installation

Set the device onto the working table with plane, hard, horizontal surface.

7.Working with device

The magnetic rack is used during the nucleic acid (NA) extraction step from samples for subsequent work with them.

Tubes containing the suspension with MNPs and NA are placed into the wells of the rack. The tubes must be closed with their caps.

The process of collecting (precipitating) the MNPs along the inner wall of the tube placed in the rack takes from a few seconds to several minutes.

Without removing the tube from the rack well, rotate it several times around its axis — the MNPs will collect at a local point on the tube wall (the collection site is indicated by the arrow in Figure 1).

Then proceed to the washing steps for the extracted NA.

8.Marking symbols

The trademark of the manufacturer and the product name are placed on the side surface of the device.

The holes for placing tubes in the rack are numbered from “1” to “8” from left to right on one side, and from “9” to “16” on the other side.

A label plate bearing the product number according to the manufacturer's numbering system is affixed to the base of the device.

Labels are placed on the top and side surfaces of the product packaging (Figure 2).

Figure 2 - **Plate example.**

9.Device maintenance

The following actions shall be performed by the maintenance personnel with the specified frequency:

1. Visual inspection for the absence of damage on the product surface.

   Frequency: before starting work.

2. Removal of dust and dirt from the device surface using disinfectant solutions, in accordance with the requirements mandatory for application in the user’s facility.

   Frequency: after completion of work.

10.Recommendations for disinfection during operation

WARNING!

To prevent damage to the device and its failure:

- ***Do not** autoclave the rack.*
- ***Do not** disinfect the rack by immersion or excessive wetting with disinfectant solution, to avoid liquid penetration into the device.*

The external surfaces of the device are resistant to repeated treatment with disinfectants.

For disinfection, clean the external surfaces of the rack with cloth wipes moistened with disinfectant solutions.

Use disinfectant solutions specified in Section 11 of this manual, or other solutions in accordance with the requirements of norms and regulations mandatory for application in the user's facility.

11.Disinfection requirements before repair

It is the responsibility of the user to decontaminate the instrument before maintenance or repair work is performed.

Before using the instrument for the first time and after each use thereafter, disinfect the external surfaces of the instrument by wiping them twice with a calico or gauze cloth soaked in a disinfectant solution approved for use in medical practice for plastic and metal products, observing the interval between wipes (see Annex A).

12.Environment safety and disposal

Disposal of products is carried out in accordance with the classification, rules for the collection, use, neutralization, placement, storage, transportation, accounting and disposal of waste established in the state of the user.

Disposal of products is carried out by organizations with the appropriate right, at specially equipped sites, landfills and in premises in accordance with environmental protection requirements.

After use in a healthcare facility , the product is classified as epidemiologically safe waste, similar in composition to solid municipal waste.

13.Precious metal content

The device does not contain precious metals.

14.Warranties

The manufacturer guarantees correct operation of the DTmag-16S magnetic rack in case of observance of the operation rules stated in this manual.

The warranty period for the device and accessories is 24 months from the date of sale to the customer. Warranty repair is performed only upon presentation of the operation manual for this device with a completed claim sheet.

During the warranty period the manufacturer undertakes to eliminate defects of the device free of charge by repairing it or replacing it with a similar one, provided that the defect occurred due to the manufacturer's fault.

Fulfillment of warranty obligations by the manufacturer for repair of the failed equipment entails extension of the warranty period for the time of repair of the equipment.

The warranty storage period of the device, provided that the storage conditions (Section 11) are observed, is 60 months from the date of manufacture.

In no event shall the manufacturer or seller be liable for any damages whatsoever, including loss of data, loss of profits, or other incidental, consequential, or indirect damages, resulting from improper installation, maintenance, or operation by the user, or from failure or temporary inoperability of the product.

The manufacturer is not liable for defects and malfunctions of the device, which have occurred as a result of:

- non-compliance with transportation, storage, operation rules, or incorrect installation;
- incorrect actions, use of the device not for its intended purpose, non-compliance with the requirements set forth in the operation manual;
- repair or modification of the equipment design by persons not authorized by the manufacturer, as well as in case of breach of warranty seals;
- acts of God (fire, flood, earthquake, etc.).

The warranty does not cover devices with external defects (obvious mechanical damage, cracks, chips on the case of the device).

15.Acceptance certificate

DTmag-16S magnetic rack
for nucleic acid extraction for *in vitro* diagnostics
manufacture number _____
produced by “DNA-Technology R&P”, LLC, has passed the acceptance tests, complies with TS 32.50.50-001-96301278-2023 and is recognized as suitable for operation.

Date of release «____» _____20__

Persons responsible for acceptance _____

Place seal

16.Packaging certificate

DTmag-16S magnetic rack
for nucleic acid extraction for *in vitro* diagnostics
manufacture number _____
produced by “DNA-Technology R&P”, LLC, is packed according to TS 32.50.50-001-96301278-2023 requirements.

Packaging date «____» _____20___

Packaged by _____(signature)

Accepted after package by _____(signature)

Place seal

Note: The form is filled out by the organization that made the packaging.

17.Warranty repair coupons

COUPON No. 1 ***filled by the manufacturer***

For warranty repair (technical maintenance) of DTmag-16S magnetic rack for nucleic acid extraction for *in vitro* diagnostics

…….manufactured……
(manufacture number) (date)

Manufacturer's technical control representative …….

(TC stamp)

Sales note _____
(organization name)

"……."…….20… organization's stamp……
(date) (signature)

Owner and his address……
…….

(personal signature)

……

COUPON No. 2 ***filled by the manufacturer***

For warranty repair (technical maintenance) of DTmag-16S magnetic rack for nucleic acid extraction for *in vitro* diagnostics

…….manufactured……
(manufacture number) (date)

Manufacturer's technical control representative …….

(TC stamp)

Sales note _____
(organization name)

"……."…….20… organization's stamp……
(date) (signature)

Owner and his address……
…….

(personal signature)

Reverse side of COUPON No. 1 ***filled out by maintenance facility***

Manufacture number of the device …….

Repair content

…….……..

……..……

……...

……

Date of repair…….
(day, month, year)

Specialist……..Owner……...
(signature, stamp) (signature)

……...

Reverse side of COUPON No. 2 ***filled out by maintenance facility***

Manufacture number of the device …….

Repair content

…….……..

……..……

Date of repair …….
(day, month, year)

Specialist……..Owner……...
(signature, stamp) (signature)

18. Annex A.

Device decontamination certificate

1	Device name	
2	Device manufacturing number	
3	Name of the organization owning the device	
4	Address of the organization owning the device	
5	Full name and signature of the person responsible for decontamination	

WARNING: Please fill in every column of the table.

1. Has the equipment been in contact with material contaminated or suspected to be contaminated with pathogenicity group I-IV microorganisms, including:	□ Yes	□ No
blood components and preparations	□ Yes	□ No
material suspected of infection with microorganisms of pathogenicity groups III-IV	□ Yes	□ No
including HBV, HCV, HIV	□ Yes	□ No
material suspected of infection with microorganisms of pathogenicity groups I-II	□ Yes	□ No
2. Has the equipment been in contact with toxic, carcinogenic or radioactive substances?	□ Yes	□ No
If so, indicate types and quantities:		
3. The following reagent kits were used (list the names of the kits with the manufacturer): _____ _____ _____		
4. The following decontamination methods were used to prepare the equipment for the manufacturer's site:		

By sending the above equipment for work, we assume full responsibility for its biological, chemical and radiological deactivation, disinfection and cleaning, as well as packaging.
We agree that in case of equipment damage during transportation due to poor quality packaging, "DNA-Technology R&P", LLC assumes obligations to carry out maintenance/repair works only after written agreement with the Customer.
Customer:

_____
Organization

_____
Head of organization full name and signature

Manufacturer:

DNA-Technology, Research & Production, LLC

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E-mail: hotline@dna-technology.ru

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http://www.dna-technology.ru/customer_support/

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