TestGene®

NEW GENERATION OF GENETICS

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WWW.TESTGEN.RU

Catalog

- Kits for noninvasive prenatal testing
- Kits for identification of the mutations associated with targeted therapy response or resistance
- Kits for cancer testing
- Kits for Nucleic acids isolation
- Design reagent kits for detection of all known genes, polymorphisms and mutations
- Services in the field of biology and genetic engineering
- Consumables and reagents supply for molecular genetic researches

Projects

ULNANOTECH

Ulyanovsk Technology Transfer Center

Table of contents

Company profile	2
Achievements	3
Kits for noninvasive prenatal testing	5
Kits for identification of the mutations associated with targeted therapy response or resistance	9
Kits for cancer testing	13
Kits for Nucleic acids isolation	17
Designing reagent kits for detection of any known gene, polymorphisms and mutations	21
Services in the field of biology and genetic engineering	23
Consumables and reagents supply for molecular genetic researches	23

Company profile

«TestGene» develops and manufactures kits for molecular genetics.
Products are intended for use in research, practical medicine, and in the fields of molecular biology.

The focus area – non-invasive genetic testing in obstetrics and oncology. The company has its own production laboratory with the necessary equipment for manufacturing and quality assurance of kits based on «real time PCR».

The company team of internationally recognized researchers constantly improves the products according to the latest scientific achievements.

BUREAU VERITAS
Certification

ООО «ТестГен»

ISO 9001:2008

Certificate ISO 9001:2008 issued by Bureau Veritas Certification Holding SAS (UK Branch) confirms that the Management System of TestGene has been audited and found to be in accordance with the requirements of that management system standard.

Achievements

Gold Prize at the Seoul International Innovations Fair 2011. TestGene is the best of 663 inventions from 31 countries

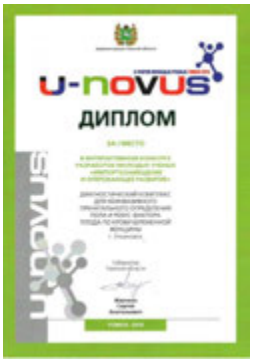
Taiwan Invention Association recognized "Test-RHD" as outstanding invention

Eurasian patent for a «kit of oligonucleotide primers and probes, and a method for fetus RhD- status detection using ccfDNA from Rh-negative pregnant women blood»

OPORA Russia: the first place of "Business success 2012" in "The best innovative project" category

The winner of the Russian Youth Prize in Nanoindustry

Quality Assurance of the Molecular-Pathological Detection of KRAS Mutations in Colorectal Carcinomas



The first place in the Interactive Competition "Import substitution and Rapid development"

Semifinal "Zworykin Award 2012": the best of 1500 inventions

Quality Assurance of the Molecular-Pathological Detection of RAS Mutations (KRAS, NRAS) in metastatic Colorectal Carcinomas

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Kits for noninvasive testing using pregnant woman blood

Detection of cell-free fetal DNA in maternal plasma since 10th week of pregnancy:

- Simply
- Easy for use
- Minimal invasive
- Sensitivity 99%
- Specificity 99%

Test-RHD – kit for noninvasive fetal RHD gene detection since 10th (embryological) week of pregnancy.

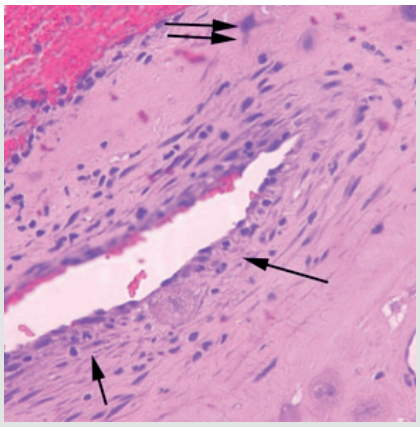
Benefit:

- timely and reasonable measures to prevent RhD conflict
- save 35% of government budget
- economy for pregnant woman

Awareness of fetal RhD status allows obstetrician-gynecologist to provide Rhesus-negative pregnant woman with necessary treatment.

Test-RHD is the safest way to detect fetal RHD-status, because it is based on pregnant woman blood testing.

Test-SRY is a kit for noninvasive fetal gender testing since 10th (embryological) week of pregnancy using maternal blood. The testing has a particular importance for families with the sex-linked diseases risk.



In 1997, Lo et al. discovered that cell-free fetal DNA is present in the plasma and serum of pregnant women (Lo YMD, Corbetta N, Chamberlain PF, Rai V, Sargent IL, Redman CWG, Wainscoat JS. Presence of fetal DNA in maternal plasma and serum. Lancet1997;350:485-48.).

The kits for noninvasive testing produced by TestGene are based on real-time PCR technique. The novel approach improves the sensitivity and allows to detect even single DNA copies in maternal blood. To achieve it, ultra-short probes, unique primers and high processive hot-start polymerases are used.

In «plus» kits we use a buffer with polymerase that makes workflow more comfortable and reliable. For analysis preparation it is necessary to add 4 mcl of PCR buffer + 4 mcl of primer mix and 12 mcl of DNA. When «classic» kits are using, it is necessary to add 0.2 mcl of polymerase per each tube.

Cat. No	Description	Tests quantity
RHD50	Kit for fetal RHD gene identification in maternal blood "Test-RHD" for 50 tests	50
RHD100	Kit for fetal RHD gene identification in maternal blood "Test-RHD" for 100 tests	100
RHD50+	Kit for fetal RHD gene identification in maternal blood "Test-RHD plus" for 50 tests	50
RHD100+	Kit for fetal RHD gene identification in maternal blood "Test-RHD plus" for 100 tests	100
SRY50	Kit for fetal SRY gene identification in maternal blood "Test-SRY" for 50 tests	50
SRY100	Kit for fetal SRY gene identification in maternal blood "Test-SRY" for 100 tests	100
SRY50+	Kit for fetal SRY gene identification in maternal blood "Test-SRY plus" for 50 tests	50
SRY100+	Kit for fetal SRY gene identification in maternal blood "Test-SRY plus" for 100 tests	100

THE KITS CHARACTERISTICS

Characteristic	Test-RHD	Test-SRY	Comments
The earliest gestational age for testing	10th week	7th week	It is recommended to use both kits since 10th week of pregnancy in order to avoid wrong results
The analytical sensitivity	50 copies per 1 ml of test material (plasma) or 5 copies per 1 reaction (tube)		While using the recommended method of DNA isolation
Number of exons	3	1 (repeat 3 times)	It is necessary in individual case when the level of fetal DNA concentration is too low
Control for circulating DNA extraction	Available, GAPDH gene (it is always present in human plasma)		Absence of the control creates risk of false-negative results (there is no guarantee that the amount of DNA isolated is sufficient for testing)
The kit format	The mixture is not dispensed		It allows to create a comfortable position of the tubes in the device; allows to use both rotary and flatbed types of thermocyclers
The performance format	Monoplex		Improved sensitivity of the kits
The testing equipment	Any real-time PCR thermocyclers		
Shelf life	12 months		
Storage conditions	Below -20 °C		
Amount of tests in the kit	For 50 or 100 patients (plus 20% as reserve)		There are 50 or 100 tests even in case of single performances
Amount of reactions in the kit	240 (kit for 100 patients) or 120 (kit for 50 patients)		If a few of patients are tested at a time, additional saving of reagents is achieved
Time of analysis	Less than 2 hours		

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Kits for identification of the mutations associated with targeted therapy response or resistance

TestGene's kits for mutation in EGFR&KRAS genes detection serve 50% of all such tests implemented in Russia. Those kits have successfully passed prequalification in European Molecular Genetics Quality Network (EGFR) and Pathologisches Institut (KRAS). Quality control was carried out on the basis of molecular diagnostic laboratory "Republican Clinical Oncology Center" of the Ministry of Health Care of the Republic of Tatarstan.

It is extremely important to detect mutation status of EGFR and KRAS while selecting a medication to be sure that patients are treated in accordance with the molecular features of the disease. The kits are completely free of other approaches' disadvantages, such as: the need for quantitative calibration of the DNA sample, the presence of non-specific signal in the absence of mutation, subjectivity analysis of results, false positive results in cases of excess of the recommended amounts of test material.

The type of Taqman technology used in the kits (based on destructible oligonucleotide probes with chemical modifications of locked nucleic acids) has a high sensitivity and specificity. Depending on the total amount of DNA in the sample, there is up to 1% of mutant against a background of wild DNA determined with an accuracy of at least 99,9%.

The features of the kits allow to detect reproducibly mutations presented even in low concentration and to minimize the probability of false-negative results.

The kits are compatible with all common real-time PCR thermocyclers: ABI7300/7500/StepOne, Bio-Rad iQ5/CFX, Rotor-Gene 3000/6000, DT-prime and etc.

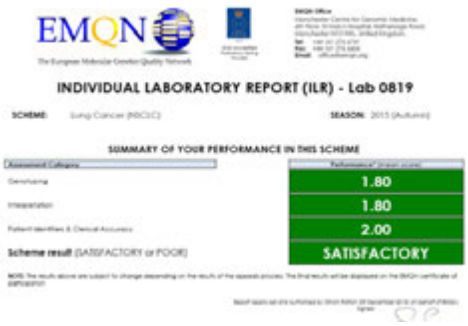
THE KITS CHARACTERISTICS

Compliant instruments	**ABI7300/7500/StepOne, Bio-Rad iQ5/CFX, Rotor-Gene 3000/6000, DT-prime and etc**
Analytical sensitivity	50 copies of mutant DNA
Amount of test in the kit per mutation	50 or 100
Number of patients at single PCR-performing	12 or 24
Possible number of patients at one PCR-performing	47 or 93
Necessity for duplicate performing	No necessity
Necessity for samples dilution before analysis	No necessity
False-positive reaction in case of high concentration DNA	No
Reaction time performance	Approximately 90 hours
Tutorial	Mandatory condition. It is carried out on the base of reference laboratory placed in Volga region; specialist's visit for on-site training is also possible
Support at all stages	Available

Major features:

- A wide range of working concentrations of DNA (from 0,5 ng to 300-400 ng per reaction)
- Analysis is implemented at single-performing of PCR
- Reaction is performed in a single tube (for each mutation)
- Presence of internal control for reaction
- High analytical sensitivity
- A simple results interpretation

The kits allow to implement detection directly from tumor tissue of biopsied material.


EMQN

INDIVIDUAL LABORATORY REPORT (ILR) - Lab 0819

SUMMARY OF YOUR PERFORMANCE IN THIS SCHEME

	1.80
	1.80
	2.00
Scheme result (SATISFACTORY or POOR)	SATISFACTORY

Version of kits for circulating tumor DNA detection allows to perform testing of patient's plasma or serum.

International double-blind clinical trials have shown a high concordance of patient's results derived from tissue and plasma using TestGene's reagents.

THE KITS CHARACTERISTICS

EGFR-Plasma-12	Reagent kit for mutations and deletions detection in EGFR gene based on real-time PCR	12
EGFR-Plasma-24	Reagent kit for mutations and deletions detection in EGFR gene based on real-time PCR	24

THE KITS FOR TUMOR TISSUE

EGFR-12	Kit for mutations and deletion detection in EGFR gene based on real-time PCR	12
EGFR-24	Kit for mutations and deletion detection in EGFR gene based on real-time PCR	24
KRAS-12	Kit for mutations and deletion detection in KRAS gene based on real-time PCR	12
KRAS-24	Kit for mutations and deletion detection in KRAS gene based on real-time PCR	24
BRAF-12	Kit for mutations and deletion detection in BRAF gene based on real-time PCR	12
BRAF-24	Kit for mutations and deletion detection in BRAF gene based on real-time PCR	24

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Kits for cancer testing

"Prosta-test" is designed for noninvasive prostate cancer diagnostics by determinants of PCA3 gene expression level by reverse transcription followed by quantitative polymerase chain reaction (PCR).

Material for PCR – human RNA samples derived from fresh or fixed in the medium in order to stabilize and preserve urine RNA obtained after digital rectal examination (DRE) of the prostate, thus achieving noninvasiveness.

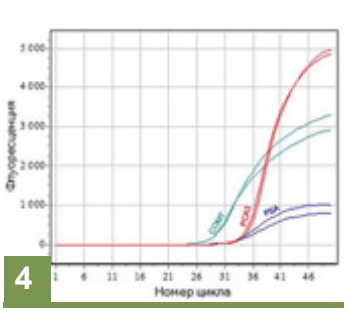
Prostate cancer takes 3-4 place in the world's structure of malignant neoplasms (more than 600 thousand cases in a year).
In the USA it takes the 1st place of morbidity – more than 200 thousand patients per a year. In Europe it takes 1-2 places (more than 200 thousands of patients per a year).

PROSTA-TEST PERFORMING INCLUDES THE FOLLOWING STEPS

Taking an urine sample after DRE

Sample preparation and RNA extraction

Reverse transcriptase PCR amplification



Interpretation of the results and calculation of PCA3 expression level

The result of "Prosta-test" expressed quantitatively indicates the risk of prostate cancer presence and may serve as an additional criterion for the first or subsequent biopsy appointment along with the measurement of the PSA level in the blood, ultrasonography (TRUS), MRI, CT and digital rectal examination (DRE).

ANALYTICAL FEATURES

Analytical specificity	100 %
Analytical sensitivity	100 RNA copies
Range of total RNA quantity required for test performance	Min 0,5 mcg, max 5 mcg
Value of PCA3 level considered as normal	< 35

THE KITS FOR TUMOR TISSUE

PCA3-12	Kit for detection of PCA3-gene expression in urine "Prosta-test"	12
PCA3-24	Kit for detection of PCA3-gene expression in urine "Prosta-test"	24

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Kits for Nucleic acids isolation

The sample preparation is crucial for obtaining correct results of PCR analysis.

That is why it is very important to use proven and reliable reagents for nucleic acid extraction. Only optimal concentration and high quality of nucleic acids allow to unlock 100% of any PCR methods potential.

TestGene LLC produces kits for DNA isolation based on two methods:

- silica-based columns
- magnetic method based on magnetic microbeads

The kits reduce time of DNA isolation – it is convenient for professionals and patients.

The kits do not require purchase of additional equipment – it is convenient for organization.

DNA-PLASMA

The kit for circulating DNA isolation from plasma. It is intended for use in prenatal noninvasive testing and in oncology.

DNA-plasma – DNA isolation from 1 ml ("DNA-plasma-1") and from 2 ml ("DNA-plasma-2") of blood plasma.

DNA-tissue – DNA isolation from formalin-fixed and paraffin-embedded tissues.

DNA-blood – kit for total DNA isolation and purification from whole blood, serum, leukocytes, lymphocytes, buccal epithelium, cell cultures, smears.

The DNA isolated is suitable for HLA-typing, detecting of polymorphisms and mutations in the genome by PCR, sequencing, mass spectrometry.

DNA plasma-M – kit for circulating DNA isolation from plasma. Absence of necessity for centrifugation allows to implement DNA isolation within 30 minutes.

COMPARATIVE CHARACTERISTICS OF TESTGENE'S KITS FOR DNA ISOLATION

Characteristic	DNA-plasma-1	DNA-plasma-2	DNA-plasma-M new
Method of operation	Spin columns	Spin columns	Magnetic beads
Volume of plasma required for reliable testing of fetal gender and RhD-status since 10th week of pregnancy	1 ml of plasma (use only after 20th week of pregnancy)	2 ml of plasma	1 ml of plasma
The earliest gestational age for obtaining significant amount of fetal DNA	20 week of pregnancy	10 week of pregnancy	7 week of pregnancy
Testing time	50 minutes	50 minutes	40 minutes
Amount of isolated DNA	1-3 ng/mcl	1-3 ng/mcl	3-5 ng/mcl
Purity of isolated DNA (ratio 260/280 nm)	1,7-1,8	1,7-1,8	1,7-1,9
Necessary equipment	High-speed centrifuge	High-speed centrifuge	Magnet for tubes
The ability of integration into a robotics station	No	No	Yes
The ability to increase the started amount of biomaterial	No	No	Yes (up to 50 ml of plasma)
Contamination risk	Medium	Medium	Low

ORDER LIST

DNA-P2-50	Kit for DNA isolation from 2 ml of blood plasma DNA-plasma-2	50
DNA-P2-100	Kit for DNA isolation from 2 ml of blood plasma DNA-plasma-2	100
DNA-P1-50	Kit for DNA isolation from 2 ml of blood plasma DNA-plasma-1	50
DNA-P1-100	Kit for DNA isolation from 2 ml of blood plasma DNA-plasma-1	100
DNA-T-50	Kit for DNA isolation from fixed tissues DNA-tissue	50
DNA-T-100	Kit for DNA isolation from fixed tissues DNA-tissue	100
DNA-B-50	Kit for DNA isolation from blood DNA-blood	50
DNA-B-100	Kit for DNA isolation from blood DNA-blood	100
DNA-PM-50	Magnetic kit for DNA isolation from 1 ml of blood plasma DNA-plasma-M1	50

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ИНСТРУКЦИЯ по применению набора реагентов для генотипирования полиморфных маркеров

Designing reagent kits for detection of any known gene, polymorphisms and mutations

TestGene LLC develops kits for molecular genetic researches in the field of monogenic and multifactorial genetic disorders, oncology and prenatal testing based on the common reliable techniques: PCR "real-time" PCR and sequencing

TestGene LLC has developed analogs for such internationally well-known kits as TaqMan SNP Genotyping Assays produced by Applied Biosystems (Endpoint Fluorescence Detection) and its own test systems (electrophoretic detection and method of fluorescence detection during allele-specific amplification) for real time cyclers, such as the ABI 7300, ABI 7500, Bio-Rad iCycler, RotorGene 3000/6000 and / or agarose / polyacrylamide gels.

Every kit is intended for 600 PCR reactions (analysis of 400 DNA samples taking into account the negative controls and PCR performing checkup.

Technique: There is fluorescent detection method based on decomposable oligonucleotide probes with use of synthetic oligonucleotide analogues, used for polymorphic markers detection.

PCR is performing with use of able for freezing ready-made mixture containing dNTPs, Mg2 + and reaction buffer with the primers and probes. DNA polymerase is using for Hot Start PCR.

Genomic human DNA extracted from saliva, blood or other biological material, is used for testing.

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Services in the field of biology and genetic engineering

- Genotyping of patient's samples (SNP testing)
- Mutation detection
- Measurement of heteroplasmy level
- Gene expression measurement
- DNA sequencing services
- Identification of translocations, deletions, insertions and duplications
- Determination of the promoter region methylation status
- Designing and validation of test-systems for mutations detection
- Other services in the field of molecular biology

Consumables and reagents supply for molecular genetic researches

For molecular biology:

- Primers
- Probes
- Enzymes (polymerases, etc.)

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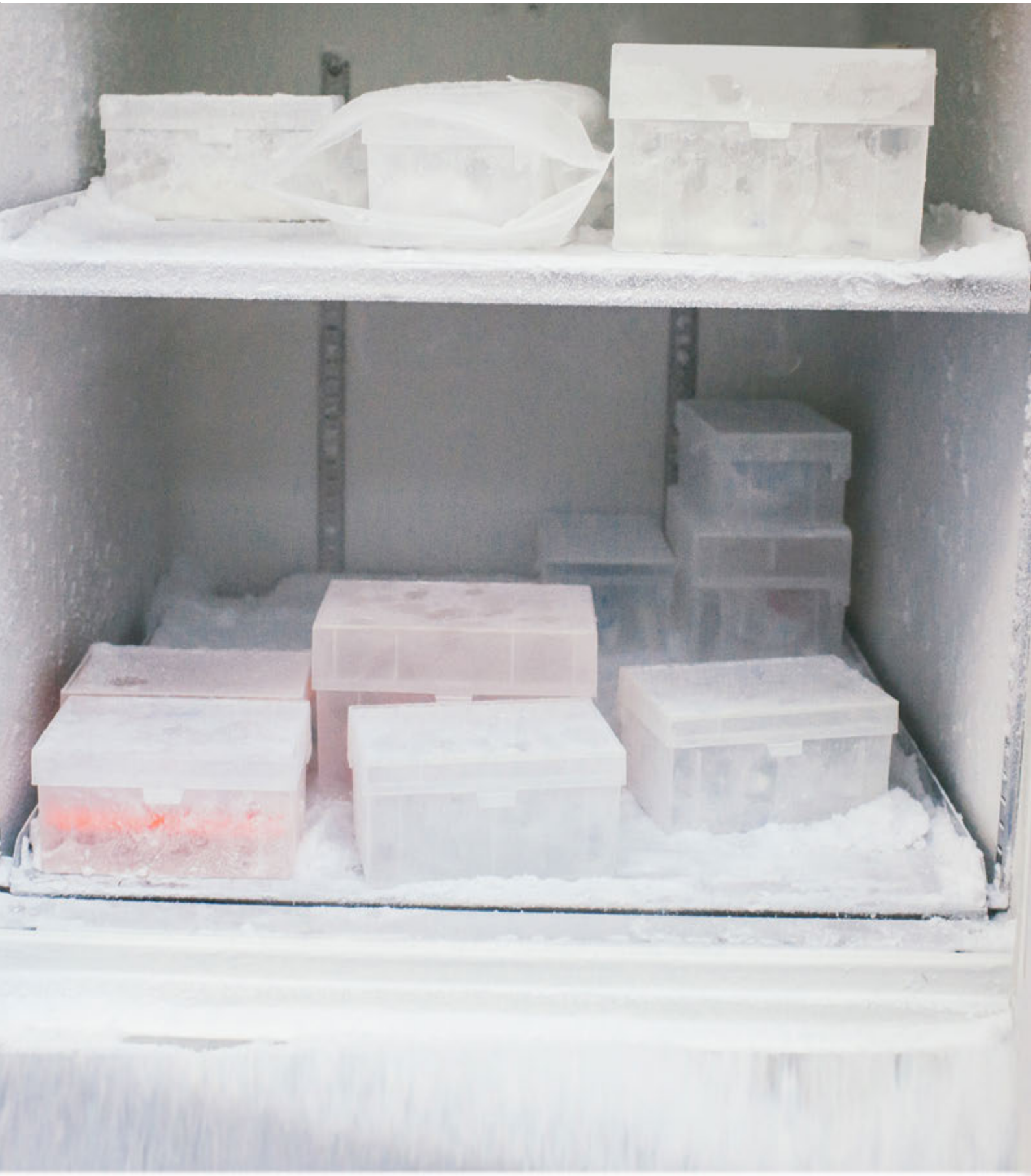

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