On approval of the rules and conditions for applying assisted reproductive methods and technologies

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 15, 2020 No. ҚР ДСМ-272/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 20, 2020 No. 21816.

Unofficial translation

In accordance with clause 4 of article 146 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On Public Health and Healthcare System" **I HEREBY ORDER:**

1. To approve the rules and conditions for applying assisted reproductive methods and technologies according to the appendix to this order.

2. To recognize as invalid:

1) order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 № 627 "On approval of the rules and conditions for applying assisted reproductive methods and technologies" (registered in the Register of State Registration of Regulatory Legal Acts as № 5919, published in the collection of acts of central executive and other central state bodies of the Republic of Kazakhstan № 3, 2010).

2) order of the Minister of Healthcare of the Republic of Kazakhstan dated March 30, 2011 № 162 "On amendments and additions to the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2009 № 627 "On approval of the rules and conditions for applying assisted reproductive methods and technologies" (registered in the Register of State Registration of Regulatory Legal Acts as № 6921, published on June 23, 2011 in newspaper "Yuridicheskaya Gazeta" №88 (2078).

3. Department of Maternal and Child Health Protection of the Ministry of Healthcare of the Republic of Kazakhstan in accordance with the procedure, established by law, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) placement of this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information about implementation of measures, stipulated by subclauses 1) and 2) of this clause.

4. Control over execution of this order shall be entrusted to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.

5. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *A. Tsoy*

Appendix to the order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated December 15, 2020
№ ҚР ДСМ-272/2020

Rules and conditions for applying assisted reproductive methods and technologies

Chapter 1. General provisions

1. These rules and conditions for conducting assisted reproductive methods and technologies (hereinafter - the Rules and conditions) have been developed in accordance with paragraph 4 of Article 146 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" (hereinafter - the Code) and shall determine the procedure and conditions for conducting assisted reproductive methods and technologies.

Footnote. Paragraph 1 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

2. Terms and definitions used in these Rules and conditions:

1) azoospermia – an absence of sperm in the ejaculate;

2) infertility - a disease of the reproductive system, which is expressed in the absence of clinical pregnancy after 12 months of regular sexual activity without contraception;

3) hysteroscopy – a method of minimally invasive examination of the uterine cavity using a hysteroscope, followed by diagnostic and surgical procedures;

4) the authorized body in the field of healthcare (hereinafter - the authorized body) - the central executive body exercising leadership and intersectoral coordination in the field of protecting the health of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical products, quality of *medical services (assistance);*

5) donor - a person, a human corpse, an animal from whom donor blood, its components, other donor material (including sperm, eggs, tissue of reproductive organs, gametes, embryos) are collected, as well as organs (parts of an organ) are removed and (or) tissues (parts of tissue) for tr*ansplantation to the recipient;*

6) donor function - voluntary medical examination by the donor and allogeneic donati*on of blood and its components;*

7) treatment – a complex of medical services aimed at eliminating, stopping, and (or) alleviating the course of the disease, as well as preventing its progression;

8) karyotype – a set of characteristics (number, size, shape) of a complete set of chromosomes inherent in the cells of a given biological species (species karyotype), of a given organism (individual karyotype) or line (clone) of cells

9) assisted reproductive methods and technologies (hereinafter - ART) - methods of treating infertility (artificial insemination (hereinafter - AI), artificial insemination (hereinafter - AI) and embryo implantation), in the use of which certain or all stages of conception and early development of embryos are carried out outside the maternal body (including using donor and (or) cryopreserved germ cells, tissues of reproductive organs and em*bryos, as well as surrogacy);*

10) marker chromosomes – a small fragment of a chromosome that usually cannot be identified without special genomic analysis du*e to the size of the fragment;*

11) compulsory social health insurance (hereinafter - CSHI) – a set of legal, economic and organizational measures to provide medical care to consumers of medical services at the expense of assets of the *social health insurance fund;*

12) reproductive health – human health, reflecting his ability to reproduce full-fledged offspring;

13) surrogate mother - a woman who bears a fetus after using assisted reproductive methods and technologies and gives birth to a child (children) for customers in accord*ance with a surrogacy contract;*

14) surrogate motherhood - the bearing and birth of a child (children), including cases of premature birth, under the contract between the surrogate mother and the spouses with the payment of remuneration;

15) surrogacy contract - a notarized written agreement between married persons who wish to have a child, and a woman who has given her consent to bear and give birth to a child through the use of assisted reproduc*tive methods and technologies;*

16) epididymitis - inflammation of the epididymis, characterized by an inflammatory process, hyperemia, slight swelling and swelling in the scrotum area.

Footnote. Paragraph 2 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

3. A woman and a man who are married, with informed voluntary consent, receive infertility treatment in healthcare organizations using safe and effective methods, including the use of ART, with full and comprehensive information about their effectiveness, optimal timing of use, possible complications, medical and legal consequences, and other information concerning their effects on the body.

When a woman and a man, both married and unmarried, apply together, the man's sperm shall not be frozen by their consent.

An unmarried woman receives infertility treatment in health care organizations using safe and effective methods, including the use of ART (with the exception of surrogacy) with

complete and comprehensive information about their effectiveness, optimal timing of use, possible complications, medical and legal consequences and other information regarding their effects on the body.

Footnote. Paragraph 3 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

4. Medical care in the system of CSHI provides for the ART procedure - a cycle in which stimulation of superovulation, transvaginal puncture of the ovaries, egg retrieval, insemination of the oocyte (oocytes) or injection of sperm into the cytoplasm of the oocyte (hereinafter - ICSI), embryo cultivation, embryo transfer, including the transfer of frozen embryos in cases of delayed transfer in which embryo transfer in a stimulated cycle is contraindicated (risk of ovarian hyperstimulation syndrome, the presence of factors that reduce performance - endometrial hyperplasia against the background of ovulation stimulation, endometrial hypoplasia, acute inflammatory diseases of any localization).

Footnote. Paragraph 4 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

5. The selection criteria for carrying out a procedure using ART in the system of CSHI shall be the following factors:

1) satisfactory ovarian reserve, characterized by the presence of at least 2 factors from the following: anti-Mullerian hormone (hereinafter - AMH) more than 1.0 nanograms/milliliter, follicle-stimulating hormone (hereinafter - FSH) less than 12 (on days 2-5 of the cycle), the number of antral follicles at least 3 (three) (on days 2-5 of the cycle) in each ovary or 5-6 antral follicles in the case of a single ovary;

2) absence of factors reducing the effectiveness of pregnancy (anomalies in the development of internal genital organs that prevent implantation and development of pregnancy, hydro (sactosalpings), synechia of the uterine cavity of the 3-4 degree, ovarian cysts, non-obstructive azoospermia);

3) infertility caused by male factor (by definition: oligozoospermia - decrease in sperm concentration less than 15 million/milliliter; asthenozoospermia - progressively mobile (class A + B) from 5% of 1 milliliter to 32% in 1 milliliter of ejaculate; teratozoospermia - from 1% up to 4% of sperm of normal structure; combined pathology of sperm (various combinations of changes in the concentration, motility and structure of sperm, reducing the fertilizing ability of sperm); the presence of antisperm antibodies in the ejaculate (MAP test more than 50%) prevent natural fertilization in cases of normal sperm concentration;

Footnote. Paragraph 5 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

6. The procedure using ART in the system of CSHI is provided to the citizens of the Republic of Kazakhstan.

In case of delayed transfer of frozen embryos, the procedure shall be carried out at a favorable period for the patient.

If the AI program is not completed due to poor ovarian response or arrest of embryo development, cases shall be closed as incomplete, sent to the social health insurance fund (hereinafter - SHIF) and paid according to actual costs.

The criterion for the effectiveness of infertility treatment using ART in the system of CSHI is the proportion of women (% of the number of those treated) whose pregnancy was confirmed by ultrasound examination.

Indications for the surgical production of sperm cells for performing procedures using ART shall be:

non-obstructive and obstructive azoospermia;

ejaculation disorders: aspermia, retrograde ejaculation;

100% necrozoospermia in the ejaculate.

Contraindications to surgical sperm retrieval shall be acute infectious diseases of any location.

The optimal way to obtain sperm shall be carried out by a urologist.

Indications for ICSI shall be:

male factor infertility, which manifests itself in a significant decrease in ejaculate parameters;

use of surgically obtained sperm cells;

use of oocytes after freezing;

conducting preimplantation genetic testing (hereinafter - PGT) using the polymerase chain reaction method;

low fertilization rate in the previous ART program.

Procedures using AI in the system of CSHI for the obstructive form of azoospermia (agenesis of the vas deferens, chronic bilateral obstructive epididymitis) shall be carried out with satisfactory FSH and karyotype tests.

Footnote. Paragraph 6 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

6-1. Performing the AI procedure in the CSHI system in the obstructive form of azoospermia (deferens agenesis, chronic bilateral obstructive epididymitis) is allowed if FSH and karyotype tests are satisfactory.

A footnote. Chapter 1 is supplemented by paragraph 6-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten days of the date of its first official publication).

7. Health organizations at the place of attachment of the patient include persons suffering from infertility in the electronic register of dispensary patients (hereinafter referred to as the ERDP). After examining and establishing the causes of infertility within 12 months, the organization of health care at the place of attachment of the patient, on the basis of the conclusion of a specialized specialist, sends the patient's documents to the commission on high-tech medical services of local government health authorities of regions, cities of republican significance and the capital (hereinafter referred to as the HTMS Commission) for resolving the issue of conducting ART in the CSHI system.

Medical organizations providing assistance using ART in the treatment of infertility enter data on ART procedures into the medical information system, carried out in the CSHI system in a form approved by the authorized body in accordance with subclause 31) of article 7 of the Code.

8. The choice of a medical organization to receive medical care using ART shall be made by the patient. If a positive decision is made, the HTMS Commission shall register a referral for hospitalization in the portal of the Hospitalization Bureau, attaching a package of patient documents.

Chapter 2. Procedure for artificial insemination

9. AF shall be carried out without superovulation (in the natural menstrual cycle) or with stimulation of superovulation.

10. AF procedure with stimulation of superovulation consists of the following steps:

1) selection and examination of patients;

2) induction of superovulation, including monitoring of folliculogenesis and development of endometrium;

3) puncture of ovarian follicles, obtaining an oocyte (oocytes);

4) insemination of oocyte (oocytes) and (or) ICSI, in vitro cultivation of embryos (in a test tube);

5) implantation (transfer) of embryos into the uterine cavity;

6) post-transfer hormonal support;

7) early pregnancy diagnosis.

AF procedure without stimulation of superovulation (in the natural menstrual cycle) consists of the following steps:

1) selection and examination of patients;

2) monitoring of folliculogenesis and development of endometrium;

3) puncture of ovarian follicles, obtaining an oocyte (oocytes);

4) insemination of oocyte (oocytes) and (or) ICSI, in vitro cultivation of embryos (in a test tube);

5) implantation (transfer) of embryos into the uterine cavity;

6) post-transfer hormonal support;

7) early pregnancy diagnosis.

11. If there are indications for the use of donor germ cells with the patient's written consent, the AF procedure shall be supplemented with the following steps:

1) cryopreservation of embryos;

2) cryopreservation of germ cells (oocytes, sperm);

3) intrauterine administration of a cryopreserved embryo.

12. The indications for AF are:

1) infertility insusceptible to therapy within 12 months;

2) tubal infertility associated with the absence of both fallopian tubes;

3) tubal, tubal - peritoneal infertility caused by the occlusion of the fallopian tubes (the only remaining tube), pelvic adhesions, with the futility of further conservative and surgical treatment;

4) endocrine infertility, in the absence of the effect of hormone therapy for 6-12 months;

5) infertility caused by endometriosis of the pelvic organs, with the failure of conservative methods of treatment for 6-12 months;

6) infertility of unclear origin and with the ineffectiveness of its conservative treatment;

7) absence of ovaries;

8) male infertility insusceptible to treatment within 6 months;

9) combination of the mentioned forms of infertility.

Footnote. Item 12 as amended by the Order of the Minister of Health of the Republic of Kazakhstan № KR DSM-52 dated 18.06.2021 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

13. Conducting AF and implantation (transfer) of embryos into the uterine cavity shall not be performed with the following contraindications:

1) somatic and mental illnesses that have contraindications for carrying pregnancy;

2) congenital malformations, acquired deformities of the uterine cavity (preventing the implantation (transfer) of embryos and the development of pregnancy);

3) benign ovarian tumors that require surgical treatment and (or) prevent the collection of oocyte (s);

4) hyperplastic processes of the endometrium;

5) benign tumors of the uterus requiring surgical treatment;

6) acute inflammatory diseases of any localization;

7) malignant neoplasms of any localization (with the exception of cases in which oocyte collection is indicated before chemotherapy and radiation therapy, according to the conclusion of a multidisciplinary group of specialists about the stimulation of superovulation)

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Footnote. Item 13 as amended by the Order of the Minister of Health of the Republic of Kazakhstan № KR DSM-52 dated 18.06.2021 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

14. In the absence of contraindications, AF shall be performed at the request of the patient or patients for any form of infertility.

15. If there are contraindications to implantation (transfer) of embryos into the uterine cavity, oocytes shall be taken from a woman without superovulation and (or) with stimulation of superovulation with further implantation (transfer) of the embryo (embryos) into the uterine cavity of the surrogate mother.

16. Examination of patients before AF shall be carried out in accordance with Appendix 1 to these Terms and Conditions.

17. Stimulation of superovulation shall be carried out by the attending physician using the following groups of drugs included in the Kazakhstan National Drug Formulary (hereinafter referred to as the KNDF):

selective estrogen receptor modulators;

gonadotropins (human menopausal gonadotropin, follicle stimulating hormone, recombinant follicle stimulating hormone, recombinant luteinizing hormone, chorionic gonadotropin and recombinant, follitropin delta);

gonadotropin-releasing-hormone agonists;

gonadotropin-releasing-hormone agonists;

growth hormones and antiestrogens;

enzyme inhibitors.

The choice of stimulation schemes administered medications, dose adjustments and changes in stimulation of superovulation protocol shall be carried out by the attending physician on a case-by-case basis.

For dynamic control of the development of follicles and endometrium without stimulation of superovulation and (or) with stimulation of superovulation, the attending physician shall use ultrasound monitoring and (or) hormonal monitoring.

In the process of ultrasound monitoring, the number of follicles is ascertained, their average diameter is measured (based on the sum of two measurements), and the thickness of the endometrium is determined.

With hormonal monitoring, a dynamic determination of the concentration of estradiol and progesterone in the blood is carried out.

Indicators of completeness of stimulation of superovulation are:

1) the diameter of the leading (leading) follicle (follicles) is more than 17 millimeters and the maturity of the functional layer of the endometrium;

2) the level of activity of steroidogenesis (concentration of estradiol in blood plasma).

To complete the maturation of oocytes, chorionic gonadotropin or gonadotropin-releasing hormone agonists are administered in appropriate doses, selected individually.

18. Puncture of ovarian follicles and aspiration of follicular fluid (hereinafter referred to as puncture) is performed 32-40 hours after the administration of an ovulation trigger (chorionic gonadotropin, gonadotropin-releasing hormone agonists, their analogs and synthetic

derivatives with appropriate indications) or without the use of an ovulation trigger under the control of hormonal tests indicating the presence of a peak of endogenous luteinizing hormone (LH).

Puncture is performed on an outpatient basis, in a small operating room, usually by transvaginal access under ultrasound guidance using special puncture needles with general anesthesia and / or without anesthesia (the need, possibility and type of anesthesia is decided individually).

If it is impossible to perform transvaginal puncture access, oocytes shall be obtained transabdominally.

19. Follicular fluid obtained as a result of follicular puncture is placed in a special container. The aspirate is examined under a stereomicroscope, and the resulting oocytes are transferred to a culture medium. The dish with oocytes is placed in a special incubator.

20. For AF, specially prepared sperm from a sexual partner or donor is used.

Sperm collection is carried out by means of:

masturbation;

by puncture,

percutaneous (through the skin) aspiration (collection) of sperm from the epididymis;

percutaneous aspiration of sperm from testicular tissue;

obtaining spermatozoa during an open biopsy of the epididymis followed by their extraction (sampling);

obtaining spermatozoa during open testicular biopsy followed by their extraction.

A special sterile container for collecting ejaculate is marked. Sperm and / or biopsies for delayed use are cryopreserved.

Native, cryopreserved spermatozoa are washed from seminal plasma before use. The fraction of morphologically normal and most motile spermatozoa is separated from the rest of the spermatozoa by centrifugation (flotation) or density gradient centrifugation.

21. The selection of germ cell donors is carried out by patients voluntarily and independently on the basis of the phenotypic description.

22. The presence of oocyte fertilization is assessed after 12-24 hours, by identifying two clearly visualized pronuclei. The zygotes are transferred to a fresh culture medium, where the initial development of the embryos takes place.

23. The transfer of embryos into the uterine cavity is carried out at different stages, from the cleavage stage to the blastocyst stage, which forms in humans on the 5-7th day after fertilization. If there are difficulties in the technique of the operation, the embryo transfer is carried out under general anesthesia.

24. In cases of insurmountable impairment of the patency of the cervical canal, embryo transfer is performed through the uterine wall (transmyometrically). A needle with a mandrin is inserted into the uterine cavity transvaginally or transabdominally.

25. No more than 2 (two) embryos are transferred into the uterine cavity using special catheters that are inserted into the woman's uterine cavity through the cervical canal.

26. Before implantation (transfer) of embryos into the uterine cavity, in order to increase the frequency of implantation by facilitating the exit of the blastocyst, according to indications, the zona pellucida is dissected at the age of three to seven days.

27. Post-transfer hormonal support is provided with progesterone, estrogen and analogs included in the KNDF.

28. In the absence of the risk of ovarian hyperstimulation syndrome, post-transfer hormonal support includes the administration of chorionic gonadotropin preparations.

29. Diagnosis of pregnancy by the content of beta-chorionic gonadotropin in the blood and urine is carried out 12-14 calendar days from the moment of implantation (transfer) of embryos. Ultrasound diagnostics of pregnancy is carried out from 21 calendar days after the transfer of the embryo (embryos).

30. In order to prevent obstetric and perinatal complications associated with multiple pregnancies (two or more fetuses), with the patient's consent, an operation is performed to reduce the number of developing fetuses (fetal reduction).

31. Fetal reduction is performed with the written informed consent of the pregnant woman . The number of fetuses to be reduced is determined by the woman.

32. The choice of fetuses to be retained and to be reduced should be carried out taking into account the ultrasound data characterizing their condition in the period from nine weeks of pregnancy.

33. Access to embryos (transvaginal, transcervical, transabdominal) and the method of termination of fetal development is selected individually.

34. Contraindications for fetal reduction are the threat of termination of pregnancy and acute inflammatory diseases.

Chapter 3. The procedure for the injection of sperm into the cytoplasm of the oocyte.

35. Indications for ICSI are:

1) oligozoospermia - sperm concentration less than 15 million per milliliter;

2) asthenozoospermia - the proportion of sperm of groups A and B is less than 32% in the ejaculate;

3) teratozoospermia - less than 4% of normal forms according to morphological analysis;

4) combined sperm pathology;

5) clinically significant presence of antisperm antibodies in the ejaculate (mixed agglutination reaction) more than 50%;

6) fertilization of less than 50% of oocytes in vitro in a previous attempt of in vitro fertilization or its absence in this cycle;

7) sexual and ejaculatory disorders;

8) when using spermatozoa obtained with a puncture or open biopsy of the testicle and its epididymis;

9) use of cryopreserved oocytes;

10) all cases where the probability of fertilization by sperm injection into the oocyte cytoplasm is higher than with oocyte insemination.

36. Indications for surgical sperm retrieval are obstructive azoospermia and primary testicular insufficiency.

37. Contraindications for surgical sperm retrieval shall be acute infectious diseases.

38. The scope of examinations before the surgical intervention for obtaining spermatozoa includes determination of the blood group and Rh factor, a clinical blood test, including clotting time, a blood test for syphilis, HIV infections, hepatitis B and C, a biochemical blood test, a coagulogram, a general urine test, electrocardiogram, therapist's conclusion.

39. ICSI stages:

1) immobilization of the sperm cell by disrupting the integrity of the tail membrane;

2) violation of the integrity of the outer cytoplasmic membrane of the oocyte;

3) administration of a sperm cell into the oocyte cytoplasm using a microneedle.

40. The choice of the optimal method for obtaining spermatozoa in the forms of spermatogenesis disorders is carried out by a doctor specializing in urology and andrology (ultrasound diagnostics according to the profile of the main specialty, endoscopy according to the profile of the main specialty) (adult, pediatric) "after examination.

41. Spermatozoa for injection into the oocyte for azoospermia are obtained by open testicular biopsy followed by sperm extraction or aspiration of the contents of the epididymis, using percutaneous aspiration surgery on the epididymis or testis.

Postmortem sperm retrieval is performed by open biopsy within 24 hours after biological death is confirmed.

42. The operation is performed on the day of follicle puncture and oocyte collection from a woman. The use of cryopreserved tissue and aspirate of the testicle and (or) epididymis is carried out in the presence of a written application from the patients - in this case, the procedure for sperm collection is carried out in advance, regardless of the puncture of the spouse's ovarian follicles.

43. Before microinjection, the cells of the radiant crown of the oocyte are removed. Micromanipulation is performed on mature oocytes in the presence of the first polar body. The method of processing ejaculate and aspirate obtained from the testicle and its epididymis is selected by the embryologist individually, depending on the number and quality of spermatozoa.

44. ICSI is performed using an inverted microscope equipped with micromanipulators using special microinstruments.

Chapter 4. Surrogate maternity.

45. Indications for surrogate maternity:

1) absence of the uterus (congenital, acquired);

2) deformation of the cavity and cervix with congenital malformations or as a result of diseases that prevent implantation and pregnancy;

3) endometrial pathology: endometrial atrophy, synechiae of the uterine cavity, insusceptible to therapy;

4) somatic diseases in which carrying a pregnancy is contraindicated;

5) unsuccessful repeated attempts at ART with repeated obtaining of high-quality embryos, the transfer of which did not lead to pregnancy.

46. Examination of surrogate mothers shall be carried out to the extent according to Appendix 2 to these Rules and conditions.

47. Contraindications for AF and embryo implantation (transfer) in the "Surrogate maternity" procedure shall be:

1) somatic and mental illnesses that have contraindications for carrying pregnancy;

2) congenital malformations, acquired deformities of the uterine cavity;

3) benign tumors of the uterus requiring surgical treatment;

4) acute inflammatory diseases of any localization;

5) malignant neoplasms of any localization;

6) a multipara woman (4 or more births in past medical history);

7) burdened obstetric history (presence of a scar on the uterus after cesarean section and conservative myomectomy, uterine perforation).

48. After the conclusion of the contract, the "Surrogate maternity" procedure shall be carried out according to the following algorithm:

1) selection and examination of a surrogate mother;

2) synchronization of the menstrual cycles of a surrogate and genetic mother (in the case of transfer of cryopreserved embryos into the uterine cavity, synchronization of cycles is not performed);

3) stimulation of superovulation of the genetic mother;

4) puncture of the ovaries of the genetic mother;

5) AF procedure with implantation (transfer) of embryos into the uterine cavity of a surrogate mother;

6) support for the luteal phase of a surrogate mother.

49. During the procedure of implantation (transfer) of frozen embryos of genetic parents, the following shall be carried out:

1) selection and examination of a surrogate mother (the surrogate mother is not an egg donor at the same time);

2) preparation of the surrogate mother’s endometrium;

3) implantation (transfer) of frozen embryos into the uterine cavity of the surrogate mother (donor eggs, sperm, and embryos shall not be used simultaneously in the surrogacy program);

4) post-transfer hormonal support for the surrogate mother.

Footnote. Paragraph 49 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

Chapter 5. Artificial insemination with sperm of a sexual partner or donor.

50. AI is performed by injecting sperm into the cervical canal, uterus, and vagina.

A footnote. Item 50 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

51. The procedure is performed both without and with ovulation stimulation.

52. With AI with donor sperm, it is permissible to use only cryopreserved, quarantined sperm.

53. It is allowed to use pre-processed sperm with AI with the sperm of a sexual partner.

54. Indications for AI with donor sperm shall be:

1) on the part of the man: infertility, ejaculatory-sexual disorders and poor medical and genetic prognosis;

2) on the part of the woman: lack of a sexual partner.

55. Indications for AI with the sperm of a sexual partner shall be:

1) on the part of a man: subfertile sperm and ejaculatory-sexual disorders;

2) on the part of women: cervical factor infertility, unspecified female infertility, lack of ovulation and vaginismus.

56. AI on the part of a woman is not performed with the following contraindications:

1) somatic and mental diseases that have contraindications for pregnancy;

2) congenital malformations, acquired deformities of the uterine cavity that prevent implantation (transfer) of embryos and pregnancy development;

3) benign ovarian tumors that require surgical treatment and (or) prevent oocyte (s) collection;

4) endometrial hyperplastic processes;

5) benign uterine tumors that require surgical treatment and (or) prevent embryo implantation (transfer) and pregnancy development;

6) acute inflammatory diseases of any localization;

7) malignant neoplasms of any localization (with the exception of cases in which oocyte collection is indicated before chemo and radiation therapy, according to the conclusion of a multidisciplinary team of specialists about during superovulation stimulation).

A footnote. Item 56 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

57. Examinations before AI with the sperm of a sexual partner shall be carried out in accordance with Appendix 3 to these Rules and conditions.

58. Sperm donor examinations before AI shall be carried out in accordance with Appendix 4 to these Rules and conditions.

59. The decision to use donor sperm shall be made by patients independently.

60. The insertion of sperm into the uterine cavity shall be carried out during the periovulatory period.

61. The number of AI attempts shall be determined by the doctor.

Chapter 6. Preimplantation genetic testing.

A footnote. The title of Chapter 6 is as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

62. Preimplantation genetic testing (hereinafter referred to as PGT) of cryopreserved embryos is performed at the request of patients or according to indications:

1) with habitual miscarriage pregnancy, with two or more undeveloped pregnancies, spontaneous abortions;

2) the older age group (the woman's age is 37 years and older);

3) after two or more unsuccessful ARM attempts;

4) with severe forms of male infertility;

5) with a high risk of inheriting gender-related diseases;

6) with monogenic diseases. diseases that are carriers of monogenic diseases, provided that their molecular and genetic diagnosis is available;

7) if the parents (or one of them) already have a child with pathologies;

8) couples with a violation of karyotypes (one of the spouses), with mosaic variants of chromosomal syndromes, carriers of all types of balanced structural rearrangements, marker chromosomes;

9) with Rhesus conflict in parents to determine the embryo with a suitable Rh factor with the expectant mother.

A footnote. Item 62 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

63. PGT is performed to determine genomic, chromosomal and monogenic defects in embryos. Preimplantation genetic testing of aneuploidy (PGT-A) determines genomic and quantitative changes in chromosomes (polyploidies, aneuploidies). Preimplantation genetic testing of structural rearrangements (PGT-SP) determines the structure of chromosomes (

deletions, duplications, translocations, inversions). Preimplantation genetic testing of monogenic diseases (PGT-M) detects mutations associated with monogenic diseases (autosomal dominant, autosomal recessive, sex-linked).

A footnote. Item 63 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

64. Genetic studies are performed on polar oocyte bodies, embryo blastomere nuclei, and blastocyst trophectoderm cells. When performing PGT, patients are informed about the sex of embryos when there is a risk of chromosomal abnormalities associated with sex chromosomes .

A footnote. Item 64 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

65. Diagnostics are performed using in sita fluorescent hybridization (FISH), comparative genomic hybridization (CGH), polymerase chain reaction (PCR), and new generation sequencing (NGS) methods.

A footnote. Item 65 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 (shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

66. PGT is not an alternative to invasive prenatal diagnostics and it is allowed to be performed in the future to clarify the genetic diagnosis of the intrauterine fetus.

A footnote. Item 66 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 18.06.2021 № KR DSM-52 shall be enforced upon the expiry of ten calendar days after the date of its first official publication).

Appendix 1
to the terms and conditions
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Scope of examination of patients before artificial insemination

Footnote. Appendix 1 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication

1. Scope of examination for a woman:

1) gynecological (transvaginal) ultrasound (before each procedure);

2) determination of blood group and Rh factor (once);

3) a general blood test on an analyzer with differentiation of 5 classes of cells and measurement of ESR in the blood using the Westergren method (before each procedure);

4) study of general urine analysis (physico-chemical properties with counting the number of cellular elements of urinary sediment) (before each procedure);

5) determination of antibodies to HBsAg of the hepatitis B virus in blood serum using the ELISA method (validity period - 3 months);

6) determination of total antibodies to the hepatitis C virus in blood serum using the ELISA method (validity period - 3 months);

"7) serological examination for syphilis (blood sampling for the Wasserman reaction), validity period - 3 months;

8) determination of total antibodies to HIV infection -1, 2 and p24 antigen in blood serum using the ELISA method (validity period - 10 days);

9) determination of the degree of purity of a gynecological smear (validity period – 10 days);

10 cytological examination of a smear from the cervix (validity period - 12 months);

11) consultation with a therapist about the state of health and the admissibility of in vitro fertilization and pregnancy with the provision of a paper report (validity period -1 month);

12) determination of Ig M to the pathogen Chlamydia trachomatis (chlamydia trachomatis) in biological material (validity period - 6 months);

13) determination of Ig G, M to the rubella pathogen in blood serum using the ELISA method (once in the absence of confirmatory data on vaccination or previous illness) (validity period - 6 months);

14) determination of TSH in blood serum using the ELISA test (validity period - 6 months);

15) determination of prolactin in blood serum using the ELISA test (validity period -12 months);

16) determination of anti-Müllerian hormone in blood serum using the ELISA method (validity period - 6 months);

17) determination of FSH and LH in blood serum using the ELISA method (validity period - 6 months);

18) biochemical blood test: determination of ALaT and ACaT; total bilirubin; glucose; total protein; creatinine and urea in blood serum (validity period – 10 days);

19) determination of coagulogram: PT with subsequent calculation of PTI and INR; APTT and fibrinogen in blood plasma (validity period – 10 days);

20) Ultrasound of the mammary glands, ultrasound of the abdominal cavity and ultrasound of the kidneys (validity period - 12 months);

21) electrocardiographic study (in 12 leads) with interpretation (validity period - 3 months);

22) diagnostic fluorography (1 projection) (validity period – 12 months);

23) mammography in patients over 40 years old (once every 2 years).

2. According to indications (for women):

1) hysterosalpingography, laparoscopy, hysteroscopy with histological examination of the endometrium (according to indications) (validity period - 12-24 months);

2) determination of estradiol; progesterone; cortisol; free triiodothyronine (T3); thyroxine (T4); testosterone; DHEA and LH in blood serum by ELISA method (validity period – 12 months);

3) cytogenetic study of peripheral blood cells (karyotype) (once);

4) determination of homocysteine in blood serum using an analyzer, determination of Ig G and M to cardiolipin in blood serum by ELISA method, determination of Ig G and M to b2-Glycoprotein I in blood serum by ELISA method, determination of lupus anticoagulant (LA1/ LA2) in blood plasma (validity period – 12 months);

5) determination of vitamin D in blood serum (according to indications); (validity period – 12 months);

6) bacteriological examination of discharge from the urethra and cervical canal (isolation of a pure culture) (validity period - 12 months);

7) determination of antisperm antibodies (SpermAntibodi) (sperm antibody) in blood serum using the ELISA method and determination of total antiphospholipid antibodies using the ELISA method (validity period - 12 months);

8) infectious examination: detection of Toxoplasma gondii (Toxoplasma gondii); cytomegalovirus (HSV-V); herpes simplex virus types 1 and 2; Trichomonas vaginalis (Trichomonas vaginalis); Neisseria gonorrhoeae (Neisseria gonococcus) in biological material by PCR method, qualitative (validity period - 6 months);

9) Ultrasound of the thyroid gland (validity period -12 months);

10) examination of specialists, according to indications, with the provision of a conclusion ;

11) determination of tumor markers CA15-3 - for breast cancer and CA 125, HE-4 - for ovarian cancer and the ROMA index (validity period - 6 months);

12) in the presence of somatic diseases, before the AI procedure, the conclusion of a medical consultation commission is required in form № 026/u, approved by order of the acting Minister of Healthcare of the Republic of Kazakhstan dated October 30, 2020 № KR HCM-175/2020 “On approval of forms of accounting documentation in the field of healthcare , as well as instructions for filling them out" (registered in the Register of state registration of regulatory legal acts under № 21579).

3. Scope of examination for a man:

1) determination of antibodies to HBsAg of the hepatitis B virus in blood serum using the ELISA method (validity period - 3 months);

2) determination of total antibodies to the hepatitis C virus in blood serum using the ELISA method (validity period - 3 months);

3) staging the Wasserman reaction in blood serum (validity period – 3 months);

4) determination of total antibodies to HIV infection-1,2 and p24 antigen in blood serum using the ELISA method (validity period - 10 days);

5) general clinical examination of seminal fluid (sperm examination + MAP test) (sperm examination) (validity period – 6 months);

6) determination of blood group and Rh factor (once);

7) determination of Ig M to the pathogen Chlamydia trachomatis (chlamydia trachomatis) in biological material (validity period - 6 months);

8) general clinical examination of a urogenital smear (validity period - 3 months);

9) consultation: uroandrologist (validity period – 12 months);

10) diagnostic fluorography (1 projection) (validity period – 12 months).

4. According to indications (for men):

1) Ultrasound of the scrotal organs (according to indications) (validity period – 12 months);

2) determination of TSH in blood serum using the ELISA method (validity period -12 months);

3) determination of prolactin in blood serum using the ELISA method (validity period - 12 months);

4) determination of FSH in blood serum using the ELISA method (validity period - 12 months);

5) determination of LH in blood serum using the ELISA method (validity period – 12 months);

6) determination of testosterone in blood serum using the ELISA method (validity period - 12 months);

7) cytogenetic study of peripheral blood cells (karyotype), determination of AZF factor Y chromosome in DNA by molecular genetic method, biological indication of mutagenic effects (chromosomal aberrations) (once);

8) determination of antisperm antibodies (SpermAntibodi) (sperm antibody) in blood serum using the ELISA method and determination of total antiphospholipid antibodies using the ELISA method (validity period - 12 months);

9) general clinical examination of prostate secretions (validity period – 3 months);

10) bacteriological examination of sperm (isolation of a pure culture) (validity period – 12 months);

11) blood test for prostate specific antigen (validity period - 12 months);

12) infectious examination: detection of Toxoplasma gondii (Toxoplasma gondii); cytomegalovirus (HSV-V); herpes simplex virus types 1 and 2; Trichomonas vaginalis (Trichomonas vaginalis); Neisseria gonorrhoeae (Neisseria gonococcus) in biological material by PCR method, qualitative (validity period - 6 months);

13) determination of vitamin D in blood serum (validity - 12 months).

Note:

Decoding abbreviations

Ultrasound – ultrasound examination

ESR - erythrocyte sedimentation rate
ELISA – Enzyme Linked Immuno Sorbent Assay
TSH – thyroid stimulating hormone
FSH – follicle stimulating hormone
LH – luteinizing hormone
ALaT – alanine aminotransferase
ASAT – aspartate aminotransferase
PT – prothrombin time
PTI – prothrombin index
INR – international normalized ratio
APTT – activated partial thromboplastin time
DHEA – dehydroepiandrosterone
PCR – polymerase chain reaction.

Appendix 2
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Scope of examination of surrogate mothers

Footnote. Appendix 2 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

1. Scope of examination of surrogate mothers:

1) gynecological (transvaginal) ultrasound examination (before each procedure);

2) determination of blood group and Rh factor (once);

3) a general blood test on an analyzer with differentiation of 5 classes of cells and measurement of ESR in the blood using the Westergren method (before each procedure);

4) general clinical urine test (general urinalysis) (before each procedure);

5) determination of antibodies to HBsAg of the hepatitis B virus in blood serum using the ELISA method (validity period - 3 months);

6) determination of total antibodies to the hepatitis C virus in blood serum using the ELISA method (validity period - 3 months);

7) serological examination for syphilis (blood sampling for the Wasserman reaction), (validity period - 3 months);

8) determination of total antibodies to HIV infection -1, 2 and p24 antigen in blood serum using the ELISA method (validity period - 10 days);

9) determination of the degree of purity of a gynecological smear (validity period – 10 days);

10) cytological examination of a smear from the cervix (validity period - 12 months);

11) consultation with a therapist about the state of health and the admissibility of in vitro fertilization and pregnancy with the provision of a conclusion (validity period - 6 months);

12) determination of Ig M to the pathogen Chlamydia trachomatis (chlamydia trachomatis) in biological material (validity period - 3 months); infectious disease examination: detection of Toxoplasma gondii (Toxoplasma gondii); cytomegalovirus (HSV-V); herpes simplex virus types 1 and 2; Trichomonas vaginalis (Trichomonas vaginalis); Neisseria gonorrhoeae (Neisseria gonococci) in biological material using qualitative PCR method (validity period – 3 months);

13) determination of Ig G, M to the rubella pathogen in blood serum using the ELISA method (once in the absence of confirmatory data on vaccination or previous illness) (validity period - 3 months);

14) determination of TSH in blood serum using the ELISA method (validity period - 6 months);

15) determination of prolactin in blood serum using the ELISA method (validity period - 6 months);

16) determination of testosterone in blood serum using the ELISA method (validity period - 6 months);

17) biochemical blood test: determination of ALaT and ACaT; total bilirubin; glucose; total protein; creatinine and urea in blood serum (validity period – 10 days);

18) determination of coagulogram: PT with subsequent calculation of PTI and INR; APTT and fibrinogen in blood plasma (validity period – 10 days);

19) Ultrasound of the mammary glands (validity period - 12 months);

20) Ultrasound of the abdominal cavity and ultrasound of the kidneys (validity period -12 months);

21) electrocardiographic study (in 12 leads) with interpretation (validity period - 3 months);

22) diagnostic fluorography (1 projection) (validity period – 12 months);

23) a conclusion from a psychiatrist and narcologist (validity period – 12 months);

24) mammography in patients over 40 years old (once every 2 years).

2. According to indications (for surrogate mothers):

1) hysterosalpingography, laparoscopy, hysteroscopy with histological examination of the endometrium (according to indications) (validity period - 12 months);

2) determination of estradiol in blood serum using the ELISA method, determination of cortisol in blood serum using the ELISA method,

determination of free triiodothyronine (T3) in blood serum by ELISA method,

determination of total thyroxine (T4) in blood serum using the ELISA method,

determination of testosterone in blood serum by ELISA method,

determination of DHEA in blood serum by ELISA method,

determination of LH in blood serum using the ELISA method (validity period - 6 months);

3) determination of homocysteine in blood serum, determination of Ig G and M to cardiolipin in blood serum by ELISA method, determination of Ig G and M to b2-glycoprotein I in blood serum by ELISA method, determination of lupus anticoagulant (LA1/ LA2) in blood plasma (validity period – 12 months);

4) bacteriological examination from the urethra and cervical canal (isolation of a pure culture) (validity period - 3 months);

5) determination of total antiphospholipid antibodies using the ELISA method (validity period - 6 months);

6) determination of prolactin in blood serum using the ELISA method (validity period - 12 months);

7) examination of specialists, according to indications, with the provision of a conclusion;

8) determination of tumor markers CA15-3 - for breast cancer and CA 125 - for ovarian cancer (validity period - 6 months).

Note:

Decoding abbreviations

Ultrasound – ultrasound examination

ESR - erythrocyte sedimentation rate

ELISA – Enzyme Linked Immuno Sorbent Assay

TSH – thyroid stimulating hormone

FSH – follicle stimulating hormone

LH – luteinizing hormone

ALaT – alanine aminotransferase

ASAT – aspartate aminotransferase

PT – prothrombin time

PTI – prothrombin index

INR – international normalized ratio

APTT – activated partial thromboplastin time

DHEA – dehydroepiandrosterone

PCR – polymerase chain reaction

Appendix 3
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Scope of examination before artificial insemination with the sperm of a sexual partner

Footnote. Appendix 3 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

1. Scope of examination for a woman:

1) Ultrasound of the pelvis (before each procedure);

2) a general blood test on an analyzer with differentiation of 5 classes of cells and measurement of ESR in the blood using the Westergren method (validity period - 1 month);

3) determination of antibodies to HBsAg of the hepatitis B virus in blood serum using the ELISA method (validity period - 3 months);

4) determination of total antibodies to the hepatitis C virus in blood serum using the ELISA method (validity period - 3 months);

5) serological examination for syphilis (blood sampling for the Wasserman reaction), (validity period - 3 months);

6) determination of total antibodies to HIV infection -1, 2 and p24 antigen in blood serum using the ELISA method (validity period - 10 days);

7) determination of the degree of purity of a gynecological smear (validity period – 1 month);

8) cytological examination of a smear from the cervix Pap test (validity period - 12 months);

9) diagnostic fluorography (1 projection) (validity period – 12 months);

10) qualitative detection of Chlamydia trachomatis (chlamydia trachomatis) in biological material by PCR method (validity period – 12 months);

11) Ultrasound of the mammary glands (validiy period -12 months);

12) consultation with a therapist (validity period -12 months).

2. Scope of examination for a man:

1) general clinical examination of seminal fluid (sperm examination + MAP test) (validity period – 6 months);

2) determination of antibodies to HBsAg of the hepatitis B virus in blood serum using the ELISA method (validity period - 3 months);

3) determination of total antibodies to the hepatitis C virus in blood serum using the ELISA method (validity period - 3 months);

4) serological examination for syphilis (blood sampling for the Wasserman reaction), (validity period - 3 months);

5) determination of total antibodies to HIV infection -1, 2 and p24 antigen in blood serum using the ELISA method (validity period - 10 days);

6) general clinical examination of a urogenital smear (before each procedure).

Note:

Decoding abbreviations

Ultrasound – ultrasound examination

ESR - erythrocyte sedimentation rate

ELISA – Enzyme Linked Immuno Sorbent Assay

PCR – polymerase chain reaction

Appendix 4
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Scope of examination of sperm donors before artificial insemination

Footnote. Appendix 4 is in the wording of the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 15.02.2023 № 23 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

1. Scope of donors examination:

1) determination of blood group and Rh factor (once);

2) consultation: therapist (validity period – 12 months);

3) consultation: uroandrologist (validity period – 6 months);

4) consultation: psychiatrist and narcologist (validity period – 12 months);

5) consultation: genetics, medical genetics (clinical and genealogical research), cytogenetic study of peripheral blood cells (karyotype) (once);

6) molecular genetic analysis for carriage of mutations in the genes of the most common hereditary diseases (determination of PAH gene mutations in phenylketonuria in DNA by a molecular genetic method, determination of mutations of the cystic fibrosis gene in DNA by a molecular genetic method) - according to indications;

7) determination of antibodies to HBsAg of the hepatitis B virus, total antibodies to the hepatitis C virus in blood serum using the ELISA method, serological examination for syphilis (blood sampling for the Wasserman reaction), determination of total antibodies to HIV infection-1,2 and p24 antigen in serum blood using the ELISA method (before freezing and 3 and 6 months after freezing);

8) determination of Ig M to the pathogen Chlamydia trachomatis (chlamydia trachomatis) in biological material (validity period - 3 months); infectious disease examination: detection of Toxoplasma gondii (Toxoplasma gondii); cytomegalovirus (HSV-V); herpes simplex virus types 1 and 2; Trichomonas vaginalis (Trichomonas vaginalis); Neisseria gonorrhoeae (Neisseria gonococci) in biological material using qualitative PCR method (validity period – 3 months);

9) general clinical examination of a urogenital smear (before each procedure).

Note:

Decoding abbreviations

ELISA – Enzyme Linked Immuno Sorbent Assay

PCR – polymerase chain reaction.