

ARTICLE 25. ARTIFICIAL INSEMINATION

Rule 1. Definitions

410 IAC 25-1-1 Applicability

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 1. The definitions in this rule apply throughout this article. (*Indiana State Department of Health; 410 IAC 25-1-1; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-1-2 "Artificial insemination" defined

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 2. As used in this article, "artificial insemination" means the introduction of semen into the vagina or cervix of a woman by means other than through the act of coitus. (*Indiana State Department of Health; 410 IAC 25-1-2; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-1-3 "Confirmatory test" defined

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-12-4; IC 16-41-14

Sec. 3. As used in this article, "confirmatory test" has the meaning set forth in IC 16-8-7-1 [*IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-12-4.*]. (*Indiana State Department of Health; 410 IAC 25-1-3; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-1-4 "Donor insemination" defined

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 4. As used in this article, "donor insemination" means artificial insemination by a donor. (*Indiana State Department of Health; 410 IAC 25-1-4; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-1-5 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 5. As used in this article, "person" means an individual, corporation, business, partnership, or association. (*Indiana State Department of Health; 410 IAC 25-1-5; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-1-6 "Practitioner" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 6. As used in this article, "practitioner" means any person who performs donor insemination or receives, processes, or stores semen intended for donor insemination. (*Indiana State Department of Health; 410 IAC 25-1-6; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

Rule 2. Artificial Insemination

410 IAC 25-2-1 Artificial insemination by donor where donor is the husband of the recipient

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 1. This rule does not apply to a donor who is the husband of a recipient. (*Indiana State Department of Health; 410 IAC 25-2-1; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-2-2 Artificial insemination by donor where donor and recipient are not in a mutually monogamous relationship

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 2. When artificial insemination by a donor is to be performed and the donor and recipient are not in a mutually monogamous relationship, the practitioner must ensure that the following are done:

(1) Each semen donor must initially undergo an appropriate medical history and physical examination. The following laboratory tests must be performed before the donor provides a donation:

- (A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.
- (B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.
- (C) Serologic test for hepatitis C antibodies.
- (D) Serologic test for human T-lymphotropic virus type I antibodies.
- (E) Serologic test for cytomegalovirus antibodies.
- (F) Serologic test for syphilis.
- (G) Urethral culture for Chlamydia trachomatis.
- (H) Urethral culture for Neisseria gonorrhoeae.

The results of these procedures, combined if necessary with additional test results, must indicate the individual's semen does not contain human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, cytomegalovirus, Treponema pallidum, Chlamydia trachomatis, or Neisseria gonorrhoeae before he begins providing semen specimens for artificial insemination.

(2) Each individual semen specimen collected must be held a minimum of one hundred eighty (180) days. Then, before this specimen can be used for artificial insemination, the donor must be retested with the following tests:

- (A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.
- (B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.
- (C) Serologic test for hepatitis C antibodies.
- (D) Serologic test for human T-lymphotropic virus type I antibodies.
- (E) Serologic test for cytomegalovirus antibodies.

No semen specimen may be used for artificial insemination if the results of these tests, combined if necessary with other evidence, indicate the specimen may contain human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, or cytomegalovirus.

(3) In addition to the tests specified in subdivision (2), the following tests must continue to be performed at six (6) month intervals as long as the donor continues to provide semen for artificial insemination:

- (A) Serologic test for syphilis.
- (B) Urethral culture for Chlamydia trachomatis.
- (C) Urethral culture for Neisseria gonorrhoeae.

No semen specimen may be used for artificial insemination if the results of these tests, combined if necessary with other evidence, indicate the specimen may contain Treponema pallidum, Chlamydia trachomatis, or Neisseria gonorrhoeae.

(4) Each recipient of semen shall undergo the following tests before artificial insemination procedures are initiated. The following tests shall be repeated at least annually as long as artificial insemination procedures are continuing:

- (A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.
- (B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.
- (C) Serologic test for hepatitis C antibodies.
- (D) Serologic test for human T-lymphotropic virus type I antibodies.
- (E) Serologic test for syphilis.
- (F) Cervical cultures for Neisseria gonorrhoeae.
- (G) Cervical cultures for Chlamydia trachomatis.

The results of these procedures, combined if necessary with additional evidence, must indicate the individual is not infected with human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, Treponema pallidum, Neisseria gonorrhoeae, or Chlamydia trachomatis before artificial insemination is performed.

(5) A serologic test for rubella antibodies shall be performed on the recipient before artificial insemination procedures are initiated. If the test is negative, it is recommended that rubella vaccine be administered unless a valid medical contraindication exists. If rubella vaccine is given, artificial insemination procedures should not begin until at least three (3) months after the time of the vaccination.

(Indiana State Department of Health; 410 IAC 25-2-2; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

410 IAC 25-2-3 Artificial insemination by donor where donor and recipient are in a mutually monogamous relationship

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 3. When artificial insemination by a donor is to be performed and the recipient indicates she is in a mutually monogamous relationship with the donor, the practitioner must ensure that a serologic test for human immunodeficiency virus type 1 antibodies is performed on the donor initially and at least annually as long as artificial insemination procedures are continuing. If at any time the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed. The results of this test must indicate the donor is not infected with human immunodeficiency virus type 1 before he can provide semen for artificial insemination. *(Indiana State Department of Health; 410 IAC 25-2-3; filed Sep 15, 1992, 11:00 a.m.: 16 IR 701; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

410 IAC 25-2-4 Additional laboratory tests

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 4. The practitioner may choose to perform additional laboratory tests on the donor or recipient, or both, to rule out the

presence of infectious disease. (*Indiana State Department of Health; 410 IAC 25-2-4; filed Sep 15, 1992, 11:00 a.m.: 16 IR 701; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

410 IAC 25-2-5 Investigations and enforcement

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-9-12; IC 16-41-14

Sec. 5. The Indiana state department of health, or its designated agent, may enter upon private property to inspect and investigate possible violations of IC 16-8-7.5 [*IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-14.*] and this rule. The Indiana state department of health may commence an action under IC 16-1-9.5-10 [*IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.*] to enforce IC 16-8-7.5 [*IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-14.*] and this rule. (*Indiana State Department of Health; 410 IAC 25-2-5; filed Sep 15, 1992, 11:00 a.m.: 16 IR 702; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA*)

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