Appendix: KIDScore™ D3

Table of contents

1 Introduction

This appendix provides information on the KIDScore D3 model. The appendix should be used in conjunction with the user manual for the KIDScore decision support tool.

KIDScore D3 is defined by Vitrolife based on the knowledge and experience extracted from our available KID data (see the user manual for the EmbryoViewer software for a definition of KID data).

The model focuses on which embryos to avoid rather than which embryos to select. It is thus a model that is based on avoidance criteria rather than selection criteria. The model will apply the avoidance criteria to the embryos and assign a low score to the embryos with the statistically lowest probability of implanting and a higher score to the embryos with a statistically higher probability of implanting.

1.1 Important restrictions and warnings

All users of the tool must agree to read and understand this user manual, observe the restrictions regarding use and read the following warnings.

Users should contact Vitrolife immediately to report any incident and/or injury to a patient, operator or maintenance employee that occurred as a direct or indirect result of operating the tool and associated hardware. Any serious incident that has occurred in relation to the tool should be reported to the competent authority of the Member State in which the user is established.

RESTRICTIONS ON USE
• All rights in the KIDScore models belong to Vitrolife. Your installation and use of a model are subject to the terms of the end-user licence agreement. • You may not copy, modify, decompile, reverse engineer, disassemble or convert a KIDScore model or assign, transfer, sell, rent or lease a model to any third party.

WARNING
• KIDScore models may only be used by clinic personnel who have been properly trained in their function and applicability by Vitrolife. Users must be qualified to operate the tool and qualified to perform procedures associated with tool use in accordance with local qualification standards.

WARNING
• The KIDScore model assigns a score to each embryo. The embryos with the lowest scores have the statistically poorest chance of implanting, and the embryos with the highest scores have the statistically best chance of implanting. However, this does not necessarily imply that the embryo with the highest score is the one most suitable for transfer. The decision about which embryo(s) to transfer must always be made by the user after an assessment of the quality of all relevant embryos.

WARNING
• KIDScore models may not be used for any other purpose than intended and specified by Vitrolife as such usage may result in incorrect decisions being made by the embryologist.

1.2 General cyber security recommendations

Users are advised and expected to take the following measures to reduce cyber security risk in order to ensure that the device will work as designed in the intended user environment:

- Ensure that personnel are properly trained in cyber security awareness

- Prevent physical access to the equipment by unauthorised users

- Use strong passwords (at least eight characters including both uppercase and lowercase letters, numbers and at least one special character).

Users must inform Vitrolife A/S without any undue delay upon becoming aware of a cyber security vulnerability incident or any suspected security events.

1.3 Intended users

Embryologists, other laboratory personnel and clinic staff at IVF clinics trained by Vitrolife A/S-certified instructors.

1.4 Clinical benefit

As an accessory to a medical device, KIDScore D3 provides the indirect clinical benefit of improving the decision-making process by providing support for selection of embryos incubated in the incubator(s) connected to the system.

2 What KIDScore D3 is suitable for

KIDScore D3 is defined for use in standard incubation conditions and is suitable only for:

- Treatments with day 3 transfer

- ICSI and IVF treatments

- Incubation conditions:

    o 4% reduced oxygen – 20% ambient oxygen

    o Temperature level between 36.5°C and 37.5°C (97.7°F to 99.5°F).

2.1 What KIDScore D3 is NOT suitable for

KIDScore D3 is NOT suitable for:

- Treatments where the status of the embryo is evaluated by performing a biopsy or any other disruptive embryo procedure during the culture period.

3 Mandatory annotation variables

As a minimum, the following variables that are used by KIDScore D3 must always be annotated when the model is used:

- **Pronuclei** (number of pronuclei):
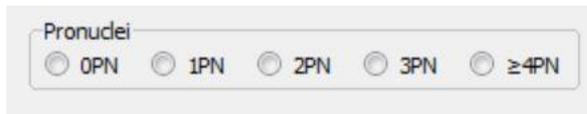
- **tPNf** (time from insemination until pronuclei have faded)
- **t2** (time from insemination to complete division to two cells)
- **t3** (time from insemination to complete division to three cells)
- **t4** (time from insemination to complete division to four cells)
- **t5** (time from insemination to complete division to five cells)
- **t8** (time from insemination to complete division to eight cells)

  For the model to function as intended, it is important to annotate t8 if the embryo cleaves to 8 cells within 66 hours. If t8 has not been annotated, the model will instead use the number of cells at 66 hours.

If one or more of these annotations are missing for an embryo, the model cannot assign a score to that specific embryo. In such cases, the software will display the score **NA** for the embryo.

4 Definition of the possible scores

The model assigns the scores by comparing the embryos to the model criteria one criterion at a time until the process stops, either because the embryo did not pass one of the criteria in the sequence or because the last criterion in the model was reached.

Below is a specification of the scores that KIDScore D3 may assign to the embryos:

Score	Description
0	• The embryo is not 2PN.
1	• The initial development was too fast or the embryo displayed a direct cleavage from one to three cells.
2	• The embryo was very slow to develop.
3	• Embryo development was irregular, and the development pace increased from day 2 to day 3.
4	• Embryo development was irregular, and the development pace slowed down from day 2 to day 3 and/or • The number of cells annotated at 66 hours was not as expected.
5	• The embryo passed all of the avoidance criteria included in the model.

Table 1: Scores assigned by the KIDScore D3 model

CAUTION

- Embryos that have been assigned the same scores by the model are not necessarily directly comparable. The model applies only morphokinetic criteria to the embryos. Additional criteria such as morphology may also be indicative of embryo quality, which means that two equally scored embryos may still be different in some aspects.

NOTE

- If embryos are incubated for less than 66 hours after fertilisation in your clinic, only the embryos for which it is possible to annotate t8 earlier than 66 hours can be assigned the score 5. A shorter incubation time will therefore reduce the number of embryos with the highest score.

5 Symbols and labels

Label	Description	Note
C E	Declaration by the manufacturer that the device meets all of the applicable requirements in the Medical Device Regulation (EU) 2017/745	-
MD	Medical device	-
▟▚	Manufacturer name and address	See section 7.

6 Disposal of waste

In order to minimise the waste of electrical and electronic equipment, waste must be disposed in accordance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) as amended by Directive (EU) 2018/849. This includes: PCBs (lead-free HASL), switches, PC batteries, printed circuit boards and external electrical cables. All components are in accordance with the RoHS 2 Directive 2011/65/EU, which states that new electrical and electronic components do not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers.

7 Contact information

Urgently need help? Call our service hotline for support:

+45 7023 0500

(available 24 hours a day, 7 days a week)

E-mail support: support.embryoscope@vitrolife.com

(response within two working days)

Vitrolife A/S
Jens Juuls Vej 20
DK-8260 Viby J
Denmark

Telephone: +45 7221 7900
Website: www.vitrolife.com

Vitrolife

VITROLIFE A/S, DENMARK