

**TECHNICAL BULLETIN: DNA INTEGRITY ASSAY ON THE SQA-VISION, For All
SQA-VISION Systems
Wednesday, March 20, 2019**

GOAL:

The goal of this document is to introduce the DNA fragmentation test on the SQA-Vision. This new feature of the SQA-Vision can be easily implemented by using commercially available kits.

BACKGROUND:

Genetic integrity of the sperm is necessary for successful fertilization and normal embryo development. Sperm DNA fragmentation along with other semen parameters provides important information and may help in selecting the appropriate treatment method. The DNA fragmentation assay by SCD (Sperm Chromatin Dispersion) technique is visual observation of the sperm cells and differentiating cells with halo and cells without halo. The principle is that sperm with fragmented DNA does not produce the halo which is typically seen in dispersed DNA loops of cells with not fragmented DNA. A special mode mode was developed for the SQA-Vision allowing visualizing the prepared sample and counting cells based on HALO / NO HALO principle.

CLINICAL PERFORMANCE:

Two commercially available kits were tested at MES laboratory to validate the test performance on the SQA-Vision:

- **Halosperm®** by HALOTECH (FDA cleared)
Purchase at: <https://www.halotechdna.com/productos/halosperm/>
- **Sperm DNA Fragmentation Assay Kit** by BASO® diagnostics.
Purchase at: <http://basobiotech.com/en/product.php?cid=145&pid=44>

NOTE: Other kits were not tested and therefore their performance on the SQA-Vision is unknown.

TESTING DNA FRAGMENTATION ON THE SQA-VISION:

To perform DNA fragmentation test on the SQA-Vision, one of the kits above should be purchased.

- Follow the kits instructions to prepare the sample for the test.
- On the device the DNA fragmentation test can be performed in two paths:
 - As part of a complete test following the automated test by selecting the option “DNA FRAG.” Below the test results.
 - As an offline test by selecting “VISUALIZATION” from the main menu and then selecting “DNA FRAG.”

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Distribution: All SQA-VISION Users**



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