Technical Release Bulletin QwikCheck™ Liquefaction Kit Issue date: February 27th 2020

BACKGROUND

The QwikCheck™ Liquefaction kit manufactured by Medical Electronic Systems (MES) is used to accelerate the liquefaction of viscous or incompletely liquefied semen samples that remain viscous thirty minutes after collection. The kit contains: 20 single dose, 5 mg vials of lyophilized α-Chymotrypsin and a product insert.

OVERVIEW

Semen hyperviscosity (SHV) represents a problem for an accurate semen assessment due to uneven spread of spermatozoa throughout semen volume and difficulties for active sperm movement. WHO 5th ed. manual emphasized influence of SHV on the semen parameters and necessity of sample treatment for overcoming this effect (WHO 5th ed. manual, p.14-15). Though WHO 5th ed. manual suggests using enzyme bromelain with proteolytic activity for treatment the semen samples with delayed liquefaction or SHV (WHO 5th manual, p. 14-15), difficulties of dissolving bromelain in a buffer and diluting the semen samples with bromelain solution requiring implementation of correction factor for semen assessment makes using bromelain less popular in the labs.

In contrast, chymotrypsin is routinely used in the number of IVF labs worldwide for treatment of sperm hyperviscosity (SHV) due to simplicity and effectiveness, as its powder can be easily dissolved in semen and in 10 minutes viscosity is brought to normal. The corresponding publications can be found in the Reference section. Clinical testing of the Chymotrypsin using treated vs. non-treated semen samples did not demonstrate any significant change or negative impact on semen parameters.

CLINICAL PERFORMANCE: Semen Samples Treated with Chymotrypsin (QwikCheck Liquefaction kit):

| Parameter: | Correlation Coefficients: Semen samples Treated with Chymotrypsin vs. Non-treated semen samples | Conclusions: |
|-------------------------|---|---|
| | | Test results demonstrated high correlations for Concentration, Total Motility, Progressive Motility and Morphology between the treated with chymotrypsin (QwikCheck™ Liquefaction Kit) and non-treated semen samples when run on the SQA-V. No detrimental effect is seen when treating semen samples with QwikCheck™ Liquefaction kit containing 5 mg chymotrypsin. |
| Concentration | R = 0.98 | |
| Total Motility | R = 0.99 | |
| Progressive Motility | R = 0.99 | |
| Morphology | R = 0.95 | |

REFERENCES

- 1. WHO laboratory manual for the examination and processing of human semen, 5^{th} edition, World Health Organization 2010.
- 2. Honea KL, Houserman VL, Merryman DC, Free DA, Stringfellow SE. Effect of limited proteolysis with alpha-chymotrypsin on semen with an abnormal sperm penetration assay and possible application for in vitro fertilization or intrauterine insemination. J Assist Reprod Genet. 1993 May;10(4):255-60.
- 3. Stephanus du Plessis S, Gokul S, Agarwal A. Semen hyperviscosity: causes, consequences, and cures. Frontiers in Bioscience, Elite, 5, 224-231, January 1, 2013.
- Jeyendran RS. Sperm collection and processing methods. A practical Guide. Cambridge University Press, 2003.

Compliance Date: Effective May 27th, 2020 Authority: Marcia Deutsch, CEO Distribution: SOA-V, SOA-Vision, OwikCheck GOLD and OwikCheck™ Liquefaction users

