

Technical Release Bulletin

QwikCheck™ Liquefaction Kit

Issue date: May 4th 2017

BACKGROUND

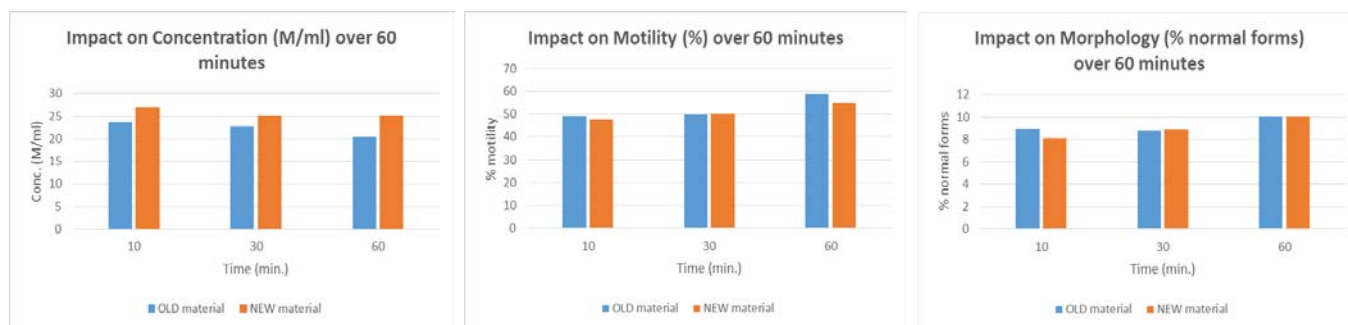
The QwikCheck™ Liquefaction kit manufactured by Medical Electronic Systems (MES) is used to accelerate the liquefaction of viscous or incompletely liquefied semen samples that remain viscous thirty minutes after collection.

The kit contains: 20 single dose, 5 mg vials of lyophilized α -Chymotrypsin and a product insert.

OVERVIEW

- Recently the Chymotrypsin used in the kit has changed in the following ways:
 - New supplier
 - Chymotrypsin is now a thin powder (previously it was irregular crystalized particles).
 - Although the 5mg powder weight is exactly the same as the irregular crystalize particles of the previous Chymotrypsin, it can be seen to occupy a smaller volume in the individual single dose vials.
- Clinical testing of the new Chymotrypsin vs. the old did not demonstrated any significant change or negatively impact semen parameters.
- The required amount of 5 mg of chymotrypsin per vial has not changed
- The product insert (instructions) has not changed.

CLINICAL PERFORMANCE: Semen Samples Treated with NEW Chymotrypsin vs. the OLD Chymotrypsin:



REFERENCES:

WHO laboratory manual for the examination and processing of human semen, 5th edition, World Health Organization 2010.

Compliance Date: Effective May 4th, 2017 **Authority:** Dr. Lev Rabinovitch, CTO
Distribution: SQA-V, SQA-Vision, QwikCheck GOLD and QwikCheck™ Liquefaction users

