INTRODUCTION AND INTENDED USE

The QwikCheck™ Liquefaction Kit can be used to accelerate the liquefaction of viscous semen samples that remain viscous thirty minutes after collection. High viscosity can impact the accurate measurement of motility and concentration. Use QwikCheck™ Liquefaction to prepare viscous semen samples for automated or manual semen analysis. For in-vitro use only.

KIT CONTENTS

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

STABILITY AND STORAGE CONDITIONS

- The product has a one year shelf life. Note the expiration date on the box and vials.
- Vials can be stored @ 15-30°C (60-86°F).
- The product is stable and shows no loss of expected performance characteristics after transport/storage over a period of 72 hours at the temperature range of -20°C to +37°C (-4°F to +99°F).

INSTRUCTIONS FOR USE

1. Select one vial of α-Chymotrypsin.
2. Tap the vial to move the contents to the bottom of the vial prior to opening.
3. Add the entire contents of one vial to a viscous semen sample.
4. Gently mix the sample to dissolve the powder.
5. Once the sample has liquefied (5-10 minutes), immediately perform automated testing or neutralize the enzymatic activity (optional) by adding of Human Serum Albumin (HSA) (not provided in this kit).
6. If sample volume is > 5 ml and it does not liquefy after adding one vial, add another vial of α-Chymotrypsin following steps 1 through 5.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Correlation Coefficients: Semen samples Treated with Chymotrypsin vs. Non-treated semen samples</th>
<th>Conclusions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>R = 0.98</td>
<td>• 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.</td>
</tr>
<tr>
<td>Total Motility</td>
<td>R = 0.99</td>
<td>• No detrimental effect is seen when treating semen samples with QwikCheck™ Liquefaction kit containing 5 mg chymotrypsin.</td>
</tr>
<tr>
<td>Progressive Motility</td>
<td>R = 0.99</td>
<td></td>
</tr>
<tr>
<td>Morphology</td>
<td>R = 0.95</td>
<td></td>
</tr>
</tbody>
</table>

PRECAUTIONS AND WARNINGS

Each vial contains α-Chymotrypsin, a protease. This protease can cause irritation to eyes, respiratory system or skin. In case of contact with eyes, rinse immediately with water and seek medical attention. Observe the following precautions when handling the product:

- Standard laboratory precautions (glove, gown, etc.)

REFERENCES: