**easi-tab™ Reference Materials**

**Statement of Measurement**

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>RM32</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis:</td>
<td>Enumeration of Enterococcus spp.</td>
</tr>
<tr>
<td>Organism:</td>
<td><em>Enterococcus faecalis</em> NCTC 775</td>
</tr>
<tr>
<td>Lot No.:</td>
<td>321801</td>
</tr>
<tr>
<td>Storage:</td>
<td>Store at &lt; -20°C</td>
</tr>
<tr>
<td>Expiry Date:</td>
<td>12 months from despatch date</td>
</tr>
<tr>
<td>Format:</td>
<td>Tablet</td>
</tr>
<tr>
<td>Passages:</td>
<td>2</td>
</tr>
<tr>
<td>Despatch Date:</td>
<td>xx/xx/xx</td>
</tr>
</tbody>
</table>

**Quality Control:** A total of ten EASI-TABS™ are taken from each batch and tested in accordance with the method quoted below. A statistical assessment procedure based upon analysis of variance (ANOVA) on replicate results is used to assess for “sufficient homogeneity”. (M Thompson, S L R Ellison, R Wood, ‘International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories’, *Pure Appl. Chem.*, 2006, 78, 145-196).

The mean concentration for the batch is given in the Table below, along with the lower and upper 95% confidence limits based on an expanded uncertainty of $\pm 0.5 \log_{10}$ (coverage factor $k = 2$).

<table>
<thead>
<tr>
<th>Determinand</th>
<th>Concentration (cfu/RM)</th>
<th>Lower $-0.5 \log_{10}$</th>
<th>Upper $+0.5 \log_{10}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enumeration of Enterococcus spp.</td>
<td>68</td>
<td>22</td>
<td>215</td>
</tr>
</tbody>
</table>

**Test method based on:**


**Date:** 25/04/18  
**Signature:** 
Tracey Noblett  
Head of Microbiology
1. Storage

On receipt, the easi-tab™ Reference Materials should be stored in a freezer at < -20°C. An expiry date is stated on the Statement of Measurement as being 6 or 12 months from the date received. This date should be added manually by the customer on receipt of the order. The products may still be suitable for use after the expiry date if the levels of microorganism on testing are still within the minimum and maximum limits given on the Statement of Measurement.

2. Presentation

The easi-tab™ Reference Materials provide an easy-to-use product available in packs of 10. The product may be presented in one of two different formats to ensure stability during transport and storage.

- A small tablet in a 2ml plastic tube
- A pellet of lyophilised material sealed under vacuum in a 2ml glass vial

3. Statement of Measurement

A Statement of Measurement accompanies each batch of easi-tab™ Reference Materials and this states the measured level of the microorganism(s) using the method described, along with the minimum and maximum (95% confidence) limits. The level on the Statement of Measurement represents the number of microorganism(s) per tablet or pellet of lyophilised material.

4. Reconstitution

Food microbiology enumeration tests

The easi-tab™ Reference Materials can be reconstituted in Maximum Recovery Diluent (MRD) or any comparable microbiological diluent. Different volumes of diluent can be used, e.g. 1ml, 10ml, 100ml, depending on the final level of microorganism (cfu/ml) required.

- The tablet format may be added directly to the final quantity of diluent required. Ensure that the diluent and tablet have both been held at room-temperature for at least 10 minutes before mixing. Once added to diluent, leave the tablet at room-temperature for at least 15 minutes in order to allow the microorganism to fully resuscitate. Mix again fully prior to starting the analysis and use the resulting suspension in accordance with your routine method.
- The pellet lyophilised material format must be first resuscitated directly in the vial. Ensure that diluent and vial have both been held at room-temperature for at least 10 minutes before mixing. Add 1ml of diluent to the vial and leave at room-temperature for at least 15 minutes in order to allow the microorganism to fully resuscitate. The 1ml may then be used directly or transferred to other volumes of diluent in order to give the desired final level.

Food microbiology detection tests

250ml of diluent should be used in order to be consistent with routine detection methods and also to ensure that low-levels of microorganisms are present as would be expected in routine samples. Procedures for resuscitation are the same as for “Food microbiology enumeration tests”.

Water microbiology enumeration tests

100ml of diluent should be used in order to give levels of microorganism that are suitable for water testing using membrane filtration, with the exception of RM29. This product is designed for direct enumeration, and should therefore be reconstituted in a volume of diluent suitable for the target level. Procedures for resuscitation are the same as for “Food microbiology enumeration tests”.
**Note**

In every case, please remember to take all dilutions into account when calculating the expected final level. For example, if the Statement of Measurement reports a level of 1000 microorganisms per reference material:

- If diluted in 1ml of diluent, this will give 1000 cfu/ml in the final volume
- If diluted in 10ml of diluent, this will give 100 cfu/ml in the final volume
- If diluted in 100ml of diluent, this will give 10 cfu/ml in the final volume

**5. Adding directly to food samples**

*easi-tab™ Reference Materials* may be used to spike real food or *easi-tab™ Sterile Materials*. Once diluent has been added, allow a recovery period of at least 15 minutes, mix the resulting suspension thoroughly and test the sample in accordance with your routine method. If the *easi-tab™ Reference Materials* is to be added to food samples, consideration must be given to the potential inhibitory effects of the food material.

**6. Stability information**

Each microorganism used in *easi-tab™ Reference Materials* will be validated for stability at < -20°C for 12 months, 2-8°C for 1 month and 22°C for 3 days. The products are packaged and transported in such a way as to minimise the effects of environmental conditions on the viability of the microorganisms. If on receipt and testing of the *easi-tab™ Reference Materials* you find that the levels have fallen below the limits given in the Statement of Measurement, please report immediately to your local office or ptcustomerservices@lgcgroup.com

**7. Safety information**

All reference materials must be regarded as containing potentially pathogenic microorganisms and must be handled by, or under the supervision of, competent persons who have received training in microbiological techniques. The responsibility for ensuring the safe handling of reference materials after receipt rests with the recipient. LGC Ltd. cannot accept responsibility for any event resulting from the mishandling of reference material. For Safety Data information, please refer to the Material Safety Data Sheet.