


2021年1月18日

お客様各位

 極東製薬工業株式会社
東京都中央区日本橋小舟町7-8

試験成績書変更のご案内

謹啓

時下 益々ご清栄のこととお慶び申し上げます。平素は、格別のお引き立てをいただき、厚く御礼申し上げます。さて、このたび下記製品の試験成績書を変更することとなりましたので、ご案内申し上げます。今後とも弊社製品につきまして、引き続きのご愛顧を賜りますようお願い申し上げます。

謹白

記

1. 対象製品

| 統一商品コード No. | 製品名 | 包装・内容 |
|-------------|---------------|--------|
| 551-10050-1 | プロスミック MTB- I | 5 検体用 |
| 551-10052-5 | プロスミック NTM | 10 検体用 |
| 551-10087-7 | プロスミック RGM | 5 検体用 |

2. 変更内容

- 感度・正確性試験に精度管理菌株及び管理幅の記載を追加いたします。
- 上記変更に伴い、版数に変更となります。

※試験成績書変更の詳細については、別紙1『プロスミック 試験成績書変更・見本』をご参照ください。

3. 変更理由

顧客要望を受けての変更

4. 変更時期

2021年1月20日以降包装分より

以上

③ プロスミック RGM

| 変更前 | | | 変更後 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|------------------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-------|-----|------------------------------------|-------------------------------|---------------------------------|-----------------------------------|-----|----|----|-----|----|-----|-----|----|----|----|-----|------|----|----|----|------|---|----|---|---|------|---|----|----|----|------|-------|-------|------|-----|-----|---|-------|---|---|------|----------|-----------|---|---|----|---------------|----------|----------|--------|------|------|------|-----|---|------|------|----|-----|----|-----|-----|-----|-----|---|-----|---|---|---|---|------|---|---|---|---|
| 10087-1 | 試験成績書 | | 10087-2 | 試験成績書 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 製品名 | プロスミック RGM | | 製品名 | プロスミック RGM | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lot No. | | | Lot No. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 有効期限 | | | 有効期限 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 判定日 | 極東製薬工業株式会社 | | 判定日 | 極東製薬工業株式会社 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 判定 | 合格 | | 判定 | 合格 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 茨城県高萩市上手綱朝山3333-26 | | | 茨城県高萩市上手綱朝山3333-26 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 試験項目 | 規格 | 結果/判定 | 試験項目 | 規格 | 結果/判定 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 包装 | 異常を認めない | 適合 | 包装 | 異常を認めない | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 性状 | 異常を認めない | 適合 | 性状 | 異常を認めない | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 無菌試験 | 陰性 | 適合 | 無菌試験 | 陰性 | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 感度・正確性試験 | MICが規格内であること | 適合 | 感度・正確性試験 | MICが規格内であること | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 同時再現性試験 | 感度・正確性試験を3回繰り返し、全て規格に適合する | 適合 | 同時再現性試験 | 感度・正確性試験を3回繰り返し、全て規格に適合する | 適合 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | <table border="1" style="border: 1px solid red; width: 100%;"> <thead> <tr> <th>薬剤名</th> <th><i>M. peregrinum</i> ATCC700686</th> <th><i>S. aureus</i> ATCC29213</th> <th><i>E. faecalis</i> ATCC29212</th> <th><i>P. aeruginosa</i> ATCC27853</th> </tr> </thead> <tbody> <tr> <td>AMK</td> <td>≤4</td> <td>≤4</td> <td>≥64</td> <td>≤4</td> </tr> <tr> <td>TOB</td> <td>2~8</td> <td>≤1</td> <td>≥8</td> <td>≤1</td> </tr> <tr> <td>IPM</td> <td>2~16</td> <td>≤2</td> <td>≤2</td> <td>≤4</td> </tr> <tr> <td>FRPM</td> <td>—</td> <td>≤2</td> <td>—</td> <td>—</td> </tr> <tr> <td>LVFX</td> <td>—</td> <td>≤1</td> <td>≤2</td> <td>≤4</td> </tr> <tr> <td>MPLX</td> <td>≤0.25</td> <td>≤0.25</td> <td>≤0.5</td> <td>1~8</td> </tr> <tr> <td>AZM</td> <td>—</td> <td>0.5~2</td> <td>—</td> <td>—</td> </tr> <tr> <td>CAM*</td> <td>0.06~0.5</td> <td>0.125~0.5</td> <td>—</td> <td>—</td> </tr> <tr> <td>ST</td> <td>4.8/0.25~38/2</td> <td>≤9.5/0.5</td> <td>≤9.5/0.5</td> <td>≥152/8</td> </tr> <tr> <td>DOXY</td> <td>≤0.5</td> <td>≤0.5</td> <td>2~8</td> <td>—</td> </tr> <tr> <td>MEPM</td> <td>2~16</td> <td>≤2</td> <td>2~8</td> <td>≤2</td> </tr> <tr> <td>LZD</td> <td>1~8</td> <td>1~4</td> <td>1~4</td> <td>—</td> </tr> <tr> <td>CLF</td> <td>—</td> <td>—</td> <td>—</td> <td>—</td> </tr> <tr> <td>STFX</td> <td>—</td> <td>—</td> <td>—</td> <td>—</td> </tr> </tbody> </table> | | | 薬剤名 | <i>M. peregrinum</i> ATCC700686 | <i>S. aureus</i> ATCC29213 | <i>E. faecalis</i> ATCC29212 | <i>P. aeruginosa</i> ATCC27853 | AMK | ≤4 | ≤4 | ≥64 | ≤4 | TOB | 2~8 | ≤1 | ≥8 | ≤1 | IPM | 2~16 | ≤2 | ≤2 | ≤4 | FRPM | — | ≤2 | — | — | LVFX | — | ≤1 | ≤2 | ≤4 | MPLX | ≤0.25 | ≤0.25 | ≤0.5 | 1~8 | AZM | — | 0.5~2 | — | — | CAM* | 0.06~0.5 | 0.125~0.5 | — | — | ST | 4.8/0.25~38/2 | ≤9.5/0.5 | ≤9.5/0.5 | ≥152/8 | DOXY | ≤0.5 | ≤0.5 | 2~8 | — | MEPM | 2~16 | ≤2 | 2~8 | ≤2 | LZD | 1~8 | 1~4 | 1~4 | — | CLF | — | — | — | — | STFX | — | — | — | — |
| 薬剤名 | <i>M. peregrinum</i> ATCC700686 | <i>S. aureus</i> ATCC29213 | <i>E. faecalis</i> ATCC29212 | <i>P. aeruginosa</i> ATCC27853 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| AMK | ≤4 | ≤4 | ≥64 | ≤4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TOB | 2~8 | ≤1 | ≥8 | ≤1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| IPM | 2~16 | ≤2 | ≤2 | ≤4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| FRPM | — | ≤2 | — | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| LVFX | — | ≤1 | ≤2 | ≤4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| MPLX | ≤0.25 | ≤0.25 | ≤0.5 | 1~8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| AZM | — | 0.5~2 | — | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAM* | 0.06~0.5 | 0.125~0.5 | — | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ST | 4.8/0.25~38/2 | ≤9.5/0.5 | ≤9.5/0.5 | ≥152/8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DOXY | ≤0.5 | ≤0.5 | 2~8 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| MEPM | 2~16 | ≤2 | 2~8 | ≤2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| LZD | 1~8 | 1~4 | 1~4 | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CLF | — | — | — | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| STFX | — | — | — | — | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | * : <i>M. peregrinum</i> ATCC700686 のMICレンジは14日目の判定 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |