

TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 146a

To: Customers and Distributors of Selectrol®

It is our intention to change the Manufacturing Process of the products listed below. The details of the change and the reason for it are given below.

Please acknowledge receipt of this notification and confirm your acceptance of the change by completing the section below and emailing a copy of the form to qc@tcsgroup.co.uk. Acceptance of the change is assumed if a response is not received within two weeks of issue of this notification.

If you have any difficulties or concerns accepting the change, please contact us immediately.

Product: Selectrol strains as listed on pages 2 and 3.

Proposed Change Date: 01/12/2025

Change Details:

All the listed strains/products will be given a 24 month / 2 year shelf life (expiry 11.2027) from the 1st of December 2025.

Reason for Change:

From our on-going shelf life studies, we have obtained stability data to support the extension to shelf life of Selectrol® strains when stored in a fridge (+2 to +8°C) as indicated on the vial label.

Considerations:

All these strain types have been shelf life tested when stored in the fridge confirming they will still perform/grow as expected.

This change only impacts the **unopened** shelf life. The opened shelf life of all strains remains the same as stated on each Certificate of Analysis.

There are a small number of E. coli strains that will not change as further testing is required.

I understand and accept the changes proposed to the product given above.

Signed:

Date:

Position:

On Behalf of (Company):

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Form 188a customer Iss 3/10.01.2022

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Product code (-5 = 5 disc, -10 = 10 disc, -25 = 25 disc)	Strain Name
MM01-10	<i>Enterobacter cloacae</i>
MM03-10	<i>Pichia kudriavzevii</i>
MM04-10, MM04-25	<i>Klebsiella pneumoniae</i>
MM09-10, MM09-25	<i>Proteus vulgaris</i>
MM10-10, MM10-25	<i>Pseudomonas aeruginosa</i>
MM11-10, MM11-25	<i>Salmonella Typhimurium</i>
MM12-10	<i>Serratia marcescens</i>
MM13-10, MM13-25	<i>Staphylococcus aureus</i>
MM14-10, MM14-25	<i>Staphylococcus aureus</i>
MM15-10, MM15-25	<i>Staphylococcus epidermidis</i>
MM16-10	<i>Streptococcus agalactiae</i>
MM17-10, MM17-25	<i>Enterococcus faecalis</i>
MM18-10, MM18-25	<i>Enterococcus faecalis</i>
MM19-10, MM19-25	<i>Streptococcus pneumoniae</i>
MM20-10, MM20-25	<i>Streptococcus pyogenes</i>
MM21-10	<i>Bacillus cereus</i>
MM23-10	<i>Enterococcus faecium</i>
MM25-10	<i>Acinetobacter baumannii</i>
MM26-10, MM26-25	<i>Klebsiella aerogenes</i>
MM28-10, MM28-25	<i>Candida albicans</i>
MM29-10, MM29-25	<i>Bacillus subtilis subsp. spizizenii</i>
MM30-10, MM30-25	<i>Staphylococcus aureus</i>
MM35-10	<i>Enterococcus hirae</i>
MM39-10	<i>Candida parapsilosis</i>
MM40-10, MM40-25	<i>Pseudomonas paraaeruginosa</i>
MM41-10	<i>Pseudomonas aeruginosa</i>
MM42-10, MM42-25	<i>Candida albicans</i>
MM43-10	<i>Proteus mirabilis</i>
MM46-10, MM46-25	<i>Staphylococcus aureus</i>
MM47-10	<i>Listeria monocytogenes</i>
MM48-10, MM48-25	<i>Listeria monocytogenes</i>
MM49-10	<i>Candidozyma auris</i>
MM51-10	<i>Enterobacter cloacae</i>
MM52-10	<i>Enterococcus faecalis</i>
MM55-10	<i>Klebsiella pneumoniae CRE</i>
MM56-10	<i>Klebsiella pneumoniae CRE</i>
MM58-10	<i>Klebsiella pneumoniae CRE</i>
MM59-10	<i>Klebsiella pneumoniae CRE</i>
MM60-10	<i>Streptococcus dysgalactiae subsp. equisimilis</i>
MM62-10	<i>Salmonella Enteritidis</i>
MM64-10	<i>Staphylococcus aureus</i>
MM65-10	<i>Pseudomonas aeruginosa</i>

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Product code (-5 = 5 disc, -10 = 10 disc, -25 = 25 disc)	Strain Name
MM66-10	<i>Listeria ivanovii</i>
MM68-10	<i>Proteus mirabilis</i>
MM70-10	<i>Burkholderia cepacia</i>
MM73-10	<i>Saccharomyces cerevisiae</i>
MM76-10	<i>Lactobacillus brevis</i>
MM77-10	<i>Listeria monocytogenes</i>
MM79-10	<i>Candida tropicalis</i>
MM83-10	<i>Klebsiella pneumoniae</i>
MM84-10	<i>Salmonella</i> Nottingham
MM85-10	<i>Staphylococcus aureus</i>
MM86-10, MM86-25	<i>Bacillus cereus</i>
MM87-10	<i>Listeria monocytogenes</i>
MM88-10	<i>Raoultella planticola</i>
MM89-10, MM89-25	<i>Salmonella</i> Poona
MM91-10	<i>Staphylococcus aureus</i> (MRSA)
MM92-10	<i>Listeria innocua</i>
MM94-10	<i>Aspergillus brasiliensis</i>
MM95-10	<i>Streptococcus pneumoniae</i>
MM97-10	<i>Rhodococcus hoagii</i>

Those which are NOT going to have a change to shelf life are the following strains:

Product code (-5 = 5 disc, -10 = 10 disc, -25 = 25 disc)	Strain Name
MM02-10, MM02-25	<i>Escherichia coli</i>
MM24-10, MM24-25	<i>Escherichia coli</i>
MM33-10, MM33-25	<i>Escherichia coli</i>
MM34-10	<i>Escherichia coli</i> (mcr-1)
MM38-10, MM38-25	<i>Escherichia coli</i>
MM57-10	<i>Escherichia coli</i> CRE
MM63-10	<i>Escherichia coli</i>
MM75-10	<i>Escherichia coli</i>
MM93-10	<i>Escherichia coli</i> O157 (non-toxigenic)