

TCS BIOSCIENCES LTD, CHANGE NOTICE: CCI 140

To: Customers who have purchased Accu-Bac medium batches listed below

It is our intention to make the changes listed below. The details of the changes and the reasons for them 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: Accu-Bac medium batches as listed below		
Product code and lot number:		
Product code	Strain	Batch number
AB04	Klebsiella pneumoniae	422067-M
AB17	Enterococcus faecalis	422389-M
AB26	Klebsiella aerogenes	419451-M
AB40	Pseudomonas aeruginosa	420278-M
AB75	Escherichia coli	419450-M
AB75	Escherichia coli	420882-M
Proposed Change Date: 16 June 2025 Change Details: The expiry dates of the above batches will be increased from 18 months to 36 months from month of manufacture. Justification: TCS continues to carry out in-house real-time shelf-life studies on the range of Accu-Bac products. Shelf-life studies have recently been completed and data accrued to support an expiry date of 36 months for the above products. For the specific batches listed above, the CoAs have been amended with the updated expiry date. An explanation for the change of expiry is included on the CoA and the updated CoAs are now available on our website www.tcsbiosciences.co.uk . Conclusion: The expiry date for the Accu-Bac batches listed in this change control has been increased; this is reflected on the amended CoAs. If unopened vials of the above batches have been stored in accordance with the IFU then these can be used to the expiry date stated on the amended CoA see our website www.tcsbiosciences.co.uk		

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

Signed:

Date:

Position:

On Behalf of (Company):

Form 188 Iss 2/29.03.2021