

Target Value Update Process for Multichem Controls



Why do Technopath update target values?

The target values and ranges provided in the Multichem[®] Control IFUs are produced from multiple replicates and are specific for a particular lot of control. These values are provided as guidelines, with the recommendation that each laboratory establishes its own target values and ranges.

Changes that can occur in laboratories test systems such as calibrator lot, reagent lot, and analyser condition may impact the target value that has been assigned to the Multichem Controls.

Therefore, Technopath operates an ongoing **peer performance monitoring** and **customer feedback procedure**. This is to monitor potential movement of the target value for each analyte in each control and adjusting as required.

When do Technopath update target values?

There are two approaches by which Technopath may perform target value updates;

Peer Performance Monitoring

At regular intervals (approximately every 2 months), the Technopath Technical Services team review peer data for active lots of Multichem controls. The aim of this review is to pro-actively assess the target values and ranges contained in the IFU and whether they align with the recovery seen globally on **cobas**[®] platforms.

Customer feedback

All feedback on product performance and target values should be communicated to your local Roche representative;



If a laboratory obtains recovery values that fall outside the ranges provided on the Multichem IFUs, refer to "Educational guide for Target Values and Ranges".

Following review of the educational guide, if appropriate contact your local Roche representative to open an investigation. Roche Case Handling Unit will liaise with Technopath to review data and determine if this is a global QC trend or specific to the individual laboratory.





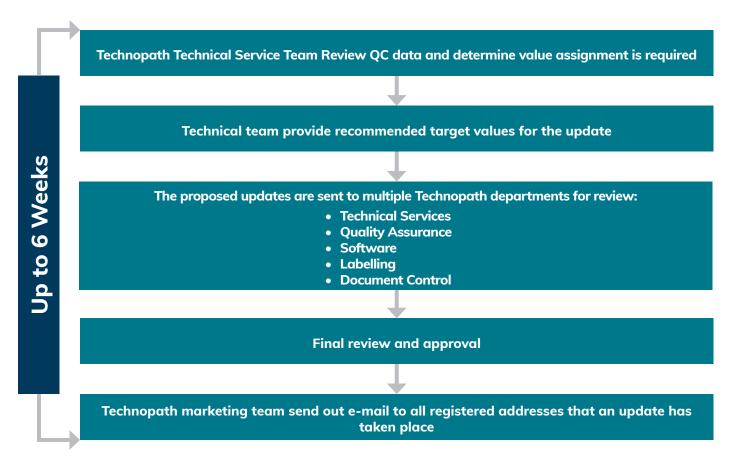




Target Value Update Process

Upon investigation by Roche and Technopath...

- If feedback is specific to the individual laboratory, no target value update will be made and further troubleshooting will be initiated.
- If after review of peer data and customer feedback it is determined that a target value update is required, the following procedure will be initiated;



What can you do in the meantime?

Whilst the value assignment process is taking place, customers can use peer data to compare their recovery means and if appropriate can re-establish their own means and ranges using this data until the value re-assignment has been released.

Notifications of target value updates

By **registering here**^{*}, you can receive notification by email of changes to target values and ranges. The updates can be accessed through the Technopath eIFU site (https://eifu.technopathcd.com/).

*https://www.technopathclinicaldiagnostics.com/landing-pages/sign-up-for-notification-of-changes-to-ifus/



Laboratories can utilize IAMQC® Peer for interlaboratory quality control comparison



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