What is the meaning of my Target Values & Ranges?

The mean provided on the IFU for the Multichem controls is a representative value giving laboratories a target to aim for while establishing their own means and ranges. For guidance with using Multichem controls please read *"Switching to Technopath Third Party Quality Controls"*.

Each laboratory is unique, operating in different environmental conditions using various reagent and calibrator lots.

As such, although there is a target value mean provided for each assay on the Multichem IFU, the expectation is that laboratories will see recovery within a range of this mean and not necessarily the exact value provided.
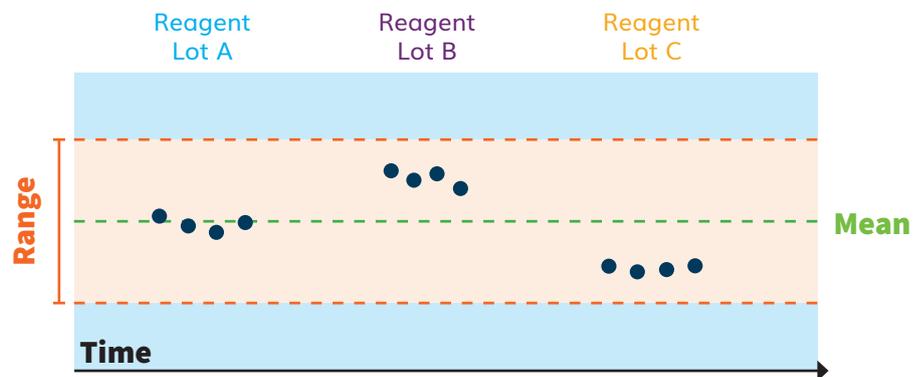

Figure 1 demonstrates how the target values and ranges provided with the Multichem controls are designed to be used across multiple reagent lots.

Quality Control Lot Verification

When transitioning to Multichem controls, the laboratory should perform their own verification / switchover study, where required follow local regulatory guidelines such as Rili-BÄK. **On review of performance of each assay...**
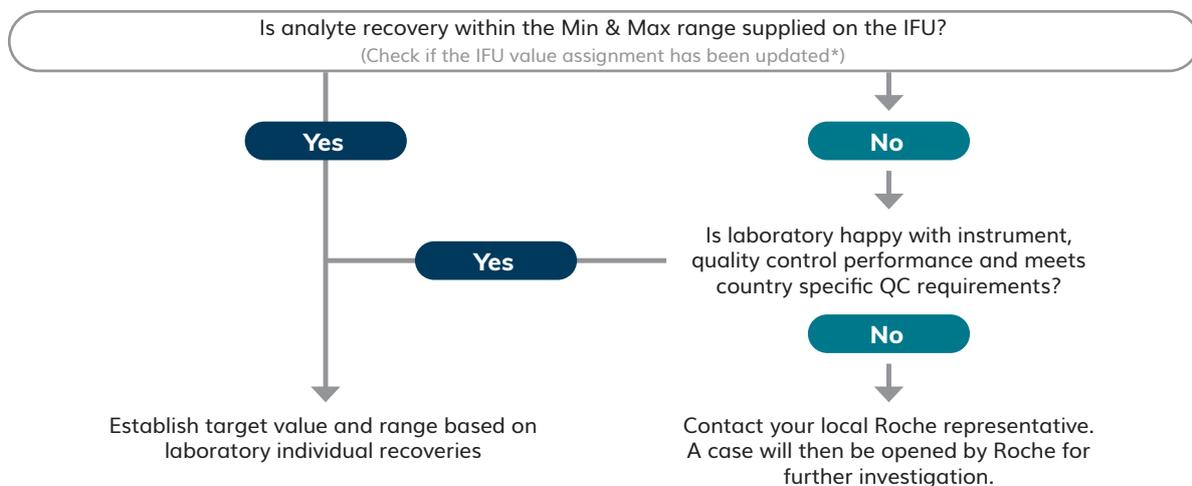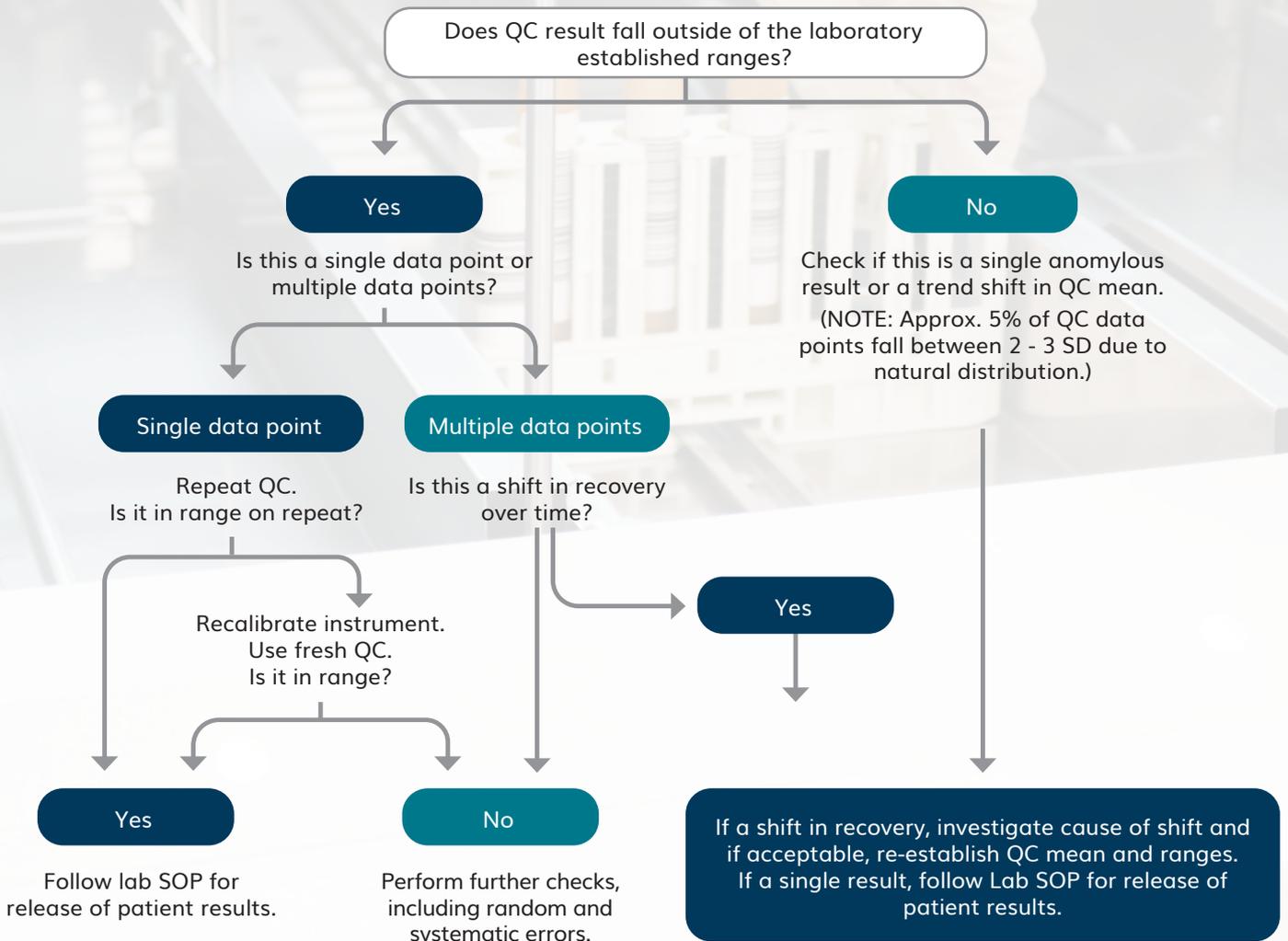

*Technopath operates an ongoing target values assignment process. Please review the e-IFU website[1] for any value assignment updates. Register for IFU alerts: Sign up for updates[2].

1. https://eifu.technopathcd.com/
2. https://www.technopathclinicaldiagnostics.com/landing-pages/sign-up-for-notification-of-changes-to-ifus/

Routine Use (After Verification)

The below flowchart can be utilized for means and ranges after laboratory quality control verification...
(Follow local regulatory guidelines as required)

Does QC result fall outside of the laboratory established ranges?

Yes

Is this a single data point or multiple data points?

No

Check if this is a single anomylous result or a trend shift in QC mean.
(NOTE: Approx. 5% of QC data points fall between 2 - 3 SD due to natural distribution.)

Single data point

Repeat QC.
Is it in range on repeat?

Multiple data points

Is this a shift in recovery over time?

Yes

Recalibrate instrument.
Use fresh QC.
Is it in range?

Yes

Follow lab SOP for release of patient results.

No

Perform further checks, including random and systematic errors.

If a shift in recovery, investigate cause of shift and if acceptable, re-establish QC mean and ranges. If a single result, follow Lab SOP for release of patient results.

Laboratories can utilize IAMQC® Peer for interlaboratory quality control comparison

Common causes for systematic errors

- Calibration
- Reagent integrity (new lot or newly prepared)
- Lack of or inconsistent instrument maintenance
- Failure to follow manufacturers instructions
- A levey-jennings chart that is improperly set
- Target value or standard deviation not properly calculated
- Instrument malfunction

Common causes for random errors

- Operator issue - follow manufacturers instructions
- Reagent preperation (error in or inconsistent preporation of reagent)
- Temperature fluctuation
- Quality control material (Preparation of control, failure to consistently follow manufacturers instructions)
- Possible contamination
- Software malfunction

Following review of this 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.

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