Guide to Running QC

1 Receipt and Storage

- **Upon receipt of the kits ensure the product hasn't been tampered with and that all vials appear intact.**
- **Store all materials as per the recommendations stated in the IFU provided.**

Unopened *vials of a liquid stable quality control should be stored at 2°C to 8°C and will be stable until the expiry date stated on the vial. Liquid frozen controls are normally stored at -20°C and lyophilised controls at 2°C to 8°C.*

2 Safe Handling

- **Wear appropriate Personal Protective Equipment (PPE) before handling samples and ensure your working environment is clean.**
- **Quality control samples should be handled in the same manner as a patient sample.**

3 Preparation

- **Liquid Ready-to-Use - No further preparation is required.**

Proceed to step 4

Preparation

- **Liquid Frozen - Allow the sample to completely thaw at room temperature before proceeding to step 4.**

Once thawed ensure the contents are thoroughly mixed by rolling for 30 minutes.

Liquid frozen controls should not be re-frozen.

Preparation

- **Lyophilised - Bring the material to room temperature and carefully reconstitute the contents with the required volume of distilled water and leave to roll for 30 minutes (refer to the IFU for volumes) before proceeding to step 4.**

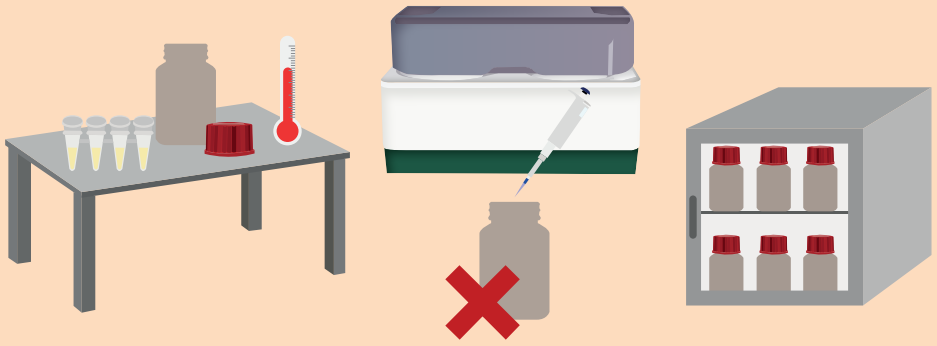
When reconstituting always use a pipette for accuracy.

It is a good idea to label the vial with the date of reconstitution to avoid the use of expired material.

To extend the stability lyophilised controls can be divided into aliquots of at least 0.3ml and stored at -20°C to -70°C (refer to the IFU for stability claims).

4 Application

- **Open the vial/aliquot carefully and run the sample as you would a patient sample on your laboratory's analyser (refer to individual analysers for application).**
- **Refrigerate any unused material at 2°C to 8°C (prior to reuse mix the contents thoroughly).**

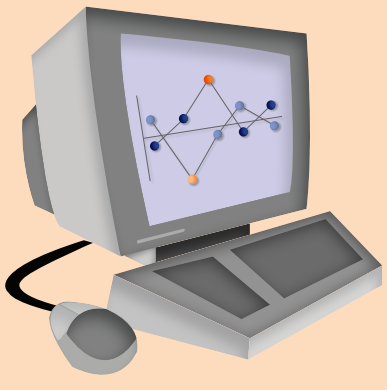


Always check the stability limitations of the control and ensure the control material is not used outside these recommendations.

The control volume used will be the same as the serum volume listed in the reagent kit insert.

5 Obtaining QC results & Data Interpretation

- **Some analysers can be programmed for data interpretation and acceptance of QC results.**
- **When interpreting QC data you should employ the target values provided on the QC kit insert for your instrument or method.**
- **Ensure the Lot Number, Expiry Date and Level (1,2 or 3) matches the kit insert you are using.**



The control values obtained should fall within the ranges provided on the kit insert. If the values do not fall within the ranges provided stop patient testing and troubleshoot to establish a root cause and implement corrective actions

An interlaboratory data management programme like **Acusera 24•7** *will help to interpret QC data.*

RANDOX QUALITY CONTROL

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