



INSTRUCTIONS FOR USE

sthemE
by Stago

Qualiris

EXTERNAL QUALITY ASSESSMENT PROFICIENCY TESTING KIT

For use with the



Suitable for testing with the QPlus® Cartridge or the QStat® Cartridge.
Intended for Evaluation Purposes Only.

MNL-0003 Rev. 00

REFKT-0048

REVISION HISTORY

Revision Number	Description of Change	Revision Date
00	Commercial Release: Universal Kit.	MAY2026



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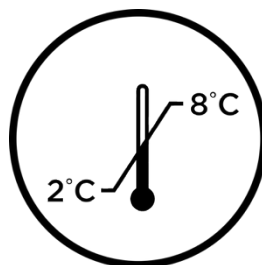
Section 1: Proficiency Kit Information

The **sthemE Qualiris External Quality Assessment (EQA) Proficiency Kit** contains materials to evaluate the performance of trained operators (users) of the Quantra Hemostasis Analyzer with either the QPlus or the QStat Cartridge assay.

The EQA Kit is compatible for use globally with Quantra instrument(s) using **Software Versions 2.3.X or greater.**

Warnings and Precautions

- EQA Kits and Cartridges are single-use. Handle all kit components as biohazardous material; Dispose of materials after testing in observance of institutional policies.
- EQA Kits are to be used only by trained professionals and should be stored refrigerated at 2-8 °C until used. Once reconstituted, reagents remain stable for 2 hours at room temperature.
- Do not use EQA Proficiency Materials or Quantra System Cartridges if they are visibly damaged, have been subject to temperature excursions outside of listed storage conditions, or are beyond expiration as labeled on the packaging.
- Quantra System Cartridges used for testing are not provided with the EQA Kit.



This kit contains testing materials for the full calendar year (Figure 1). Each user will perform **Q1** and **Q2** in the Spring; **Q3** and **Q4** in the Fall.

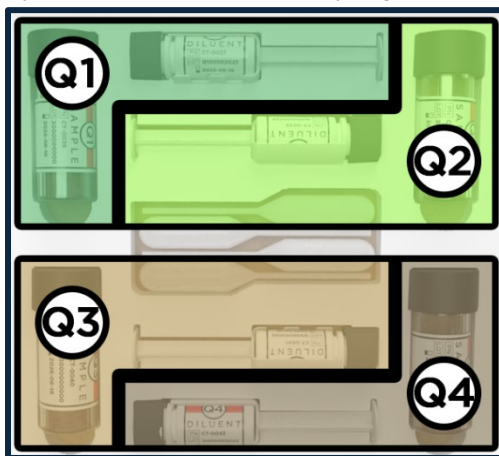


Figure 1. Overview of sthemE Qualiris EQA Proficiency Kit Contents.

- Each Kit of EQA Testing Materials contains the following:

[1] Q1 Lyophilized Sample + [1] Q1 Diluent on Extender

[1] Q2 Lyophilized Sample + [1] Q2 Diluent on Extender

[1] Q3 Lyophilized Sample + [1] Q3 Diluent on Extender

[1] Q4 Lyophilized Sample + [1] Q4 Diluent on Extender

[4] Disposable Dropper Pipettes

Testing Materials are labeled for use during designated seasonal campaigns.

PLEASE NOTE:

The sample IDs for EQA Kit materials
will change between Spring and Fall campaigns.

Q1 and Q2 Samples should both be tested during the
Spring; **Q3 and Q4** Samples
should both be tested during the **Fall**.

- The Result Submission Form will request sample IDs when you enter your results, as detailed below and in Figure 2:

SPRING:

Enter your Q1 Sample results for 'Q1'

Enter your Q2 Sample results for 'Q2'

FALL:

Enter your Q3 Sample results for 'Q3'

Enter your Q4 Sample results for 'Q4'

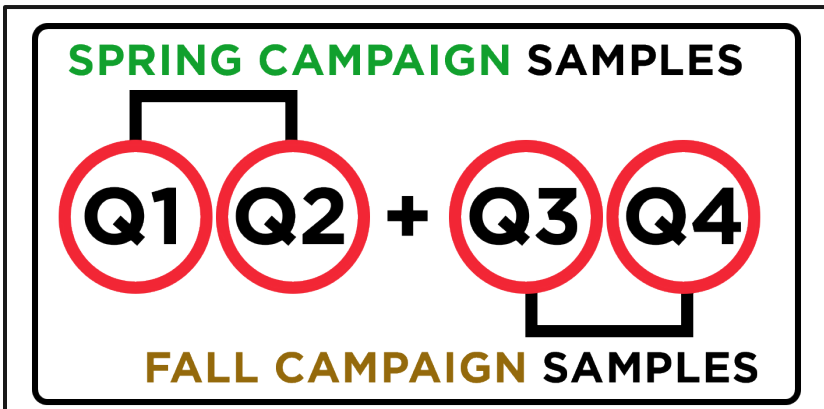


Figure 2. EQA Kit Sample ID Designation by Seasonal Campaign.

Section 2: Preparation of Proficiency Samples

The following section contains instructions for preparing EQA Quality Control Samples.
For additional information about result parameters, consult the relevant Instructions for Use.

1. Remove a **set of materials** from the kit box (Figure 1, Page 2) as relevant to the seasonal campaign you are performing testing for (**Spring: Q1 + Q2, Fall: Q3 + Q4**). Return the kit box to refrigerated storage if additional materials remain.

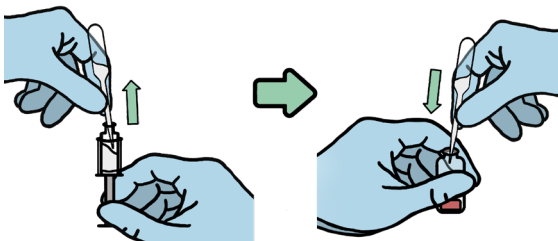


Figure 3. Performance of Step 3 Transfer.

2. Remove the screw cap and stopper from the first glass **Sample Vial** and remove the cap from its associated **Diluent Vial**.

3. Using the pipette, transfer the **entire liquid contents** of the **Diluent Vial** into the paired **Sample Vial** (Figure 3).

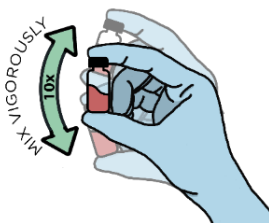


Figure 4. Vigorous Mixing as in Steps 5, 7.

4. Place the stopper and screw cap back on the glass vial. **Save the Pipette and Diluent Vial for reuse in Step 8.**

5. Grasp the Sample Vial firmly and **vigorously mix 10 times** to assist in reconstitution (Figure 4). Check that there are no solids stuck to the inside wall of the vial. **If solids or clumps are observed, continue mixing until dissolved.**

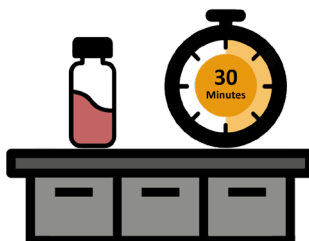


Figure 5. Step 6 Reconstitution Time.

6. Allow the mixture to sit for 30 minutes at room temperature to reconstitute (Figure 5).

7. After 30 minutes have elapsed, **vigorously mix** the Sample Vial 10 times (Figure 4).

8. Use the pipette to **transfer the entire contents** of the Sample Vial back into the Diluent Vial (Figure 6).

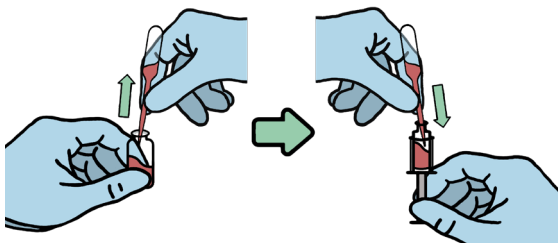


Figure 6. Performance of Step 8 Transfer.

Note: For each sample, the mixing in Section 2: Step 9 is also referenced in Section 2: Step 6. No more than [5] minutes should occur between mixing (Section 2: Step 9) and pressing 'Start' (Section 3: Step 7).

9. Replace the cap on the Diluent Vial and **vigorously mix** the Diluent Vial 10 times (Figure 7) to resuspend the solution prior to insertion into the Cartridge for testing.

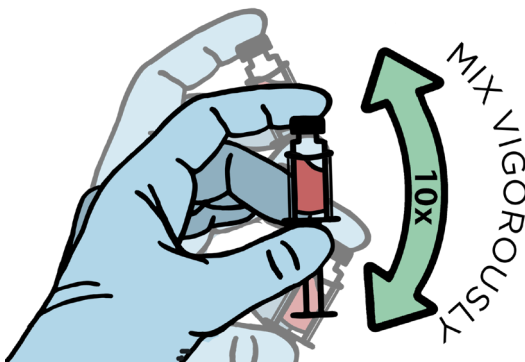


Figure 7. Performance of Step 9 Diluent Vial Mixing.

10. Repeat Steps 1 through 9 to prepare the **Second Sample** in the same manner.

After completion of Step 9, the EQA Sample is now ready to be run on the Quantra with either a QPlus Cartridge or a QStat Cartridge. Proceed to Section 3.

NOTE: Do NOT refrigerate Proficiency Materials after reconstituted.

Section 3: Testing Quantra Proficiency Samples

Note: Ensure that a Proficiency Sample is reconstituted and ready for testing before proceeding.

1. Click the **[+] Run** tab at the top left of the screen to initiate a new test (Figure 8).

2. When prompted, scan the barcode on the foil pouch reflecting your desired Quantra System Assay: (QPlus Cartridge or QStat Cartridge).

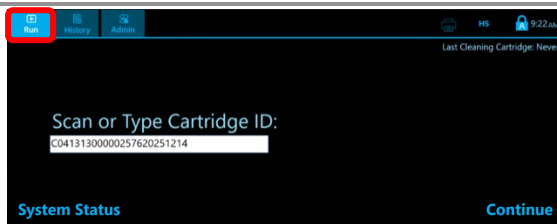


Figure 8. Step 1 Quantra Reference Screen.

3. Open the foil pouch, remove the Cartridge, and insert into the Quantra.

4. When prompted, scan the appropriate QR Code on the Proficiency Diluent Vial (blue side for QPlus, red side for QStat) as the Patient ID and **Continue** (Figure 9).

5. Verify that the **EQA ID** displayed matches the **Test Type** (QPlus/QStat) and **Q# Lot Number on your Diluent Vial**, then press **Confirm** (Figure 10).

6. As referenced in Section 2, **vigorously mix** the Diluent Vial 10 times prior to loading the sample.

7. Attach the Proficiency Sample and Press **Start** within 5 minutes of step 6 (Figure 11).

8. Following the completion of testing for the **first Sample**, repeat Steps 1-7 with the second Sample, using the same Cartridge Type per Kit.

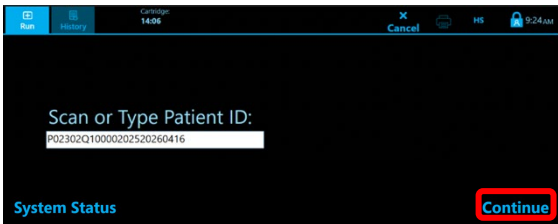


Figure 9. Step 4 Quantra Reference Screen.



Figure 10. Step 5 Quantra Reference Screen.

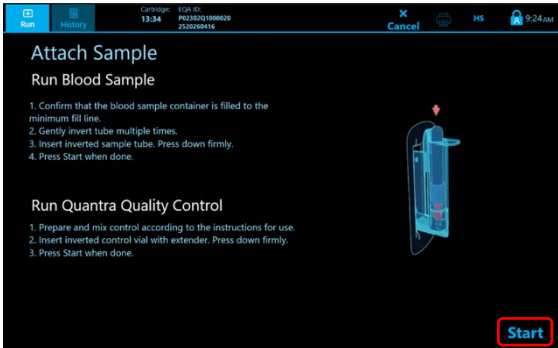


Figure 11. Step 7 Quantra Reference Screen.

Section 4: Quantra Proficiency Testing Results

Note: Accessing your Proficiency Testing Results requires Admin Access to the Quantra Analyzer.

1. Immediately following test completion, the screen will display **four fully-green dials** for each EQA Proficiency Sample that reflect the result parameters of the Cartridge Type scanned:
QPlus: CTH, CT, CS, FCS
QStat: CT, CSL, CS, FCS



Figure 12. Step 1 Quantra Reference Screen for the QStat Cartridge.

Note: Unless a cartridge fill error occurs, the Proficiency Material will always display a **Passing** result on-screen; This alone is not indicative of acceptable user proficiency. Each set of individual results will be analyzed against the collective outcomes of program participants to determine performance.

2. Log in to the Quantra and click on the **Admin** tab (Figure 13).

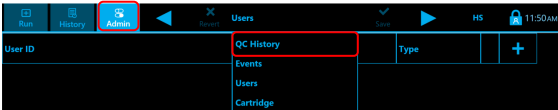


Figure 13. Steps 2, 3 Quantra Reference Screen.

3. Select **QC History** from the Drop-Down Menu.

4. Select **Proficiency** from the **Cartridge Class:** Drop-Down Menu (Figure 14).

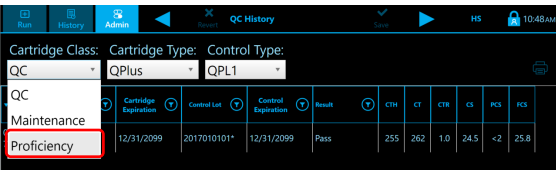


Figure 14. Step 4 Quantra Reference Screen.

5. Select **QPlus** or **QStat** from the **Cartridge Type:** Drop-Down Menu (Figure 15).

Note: **QStat** will not display as an option in this menu until at least [1] **QStat** **EQA Sample** has been tested.

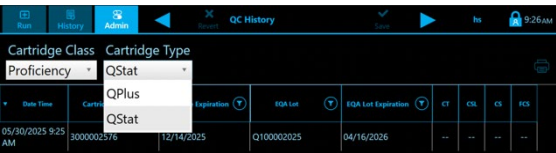


Figure 15. Step 5 Quantra Reference Screen.

6. All Preferred Proficiency Testing Results will appear.

7. Use the **Date/Time** and **EQA Lot** Columns to distinguish your results (Figure 16).

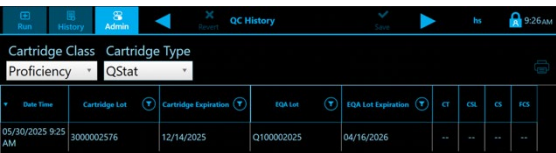


Figure 16. Steps 6, 7 Quantra Reference Screen.

Note: For Spring: Q1 Sample Lot Numbers begin with 'Q1'; Q2 Lot Numbers begin with 'Q2'.
For Fall: Q3 Lot Numbers begin with 'Q3'; Q4 Lot Numbers begin with 'Q4'.

Once results have been obtained for both Proficiency Samples, proceed to Section 5 for result entry.

Section 5: sthemE Qualiris EQA Result Entry

The **sthemE Qualiris** application portal is Stago's platform for entry of proficiency results. The sthemE program is also responsible for performance assessment report generation following the completion of the study. Adobe Acrobat Reader software (not included) is required for report access and printing. For additional information and FAQs, please reference the **sthemE Qualiris User's Guide** provided by Stago at the time of registration with the Qualiris program.

You will receive instructions via email regarding user account creation and configuration. If you have any questions or encounter issues with account registration or result entry, please contact the **sthemE Qualiris Administrator** by email: adminqualiris@stago.com.



THIS ATTESTATION FORM IS APPLICABLE TO CUSTOMERS IN THE U.S. ONLY.

sthemE QUALIRIS EQA PROFICIENCY TESTING FOR THE QUANTRA HEMOSTASIS SYSTEM

ATTESTATION

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods (US Federal Register, H 493-801 [b] [1]).

The laboratory director or designee and the testing personnel must sign this form. Please sign and retain this attestation page for your records and inspection purposes. Attach a printed copy of your result report once available. Copy this form if more signature space is needed.

We, the undersigned, have performed the analyses on these proficiency materials in a manner as closely practical to that of regular specimens. We confirm that results were not shared, and that and proficiency specimens were not tested outside of the jurisdiction of our CLIA identification number's licensure.

TESTING PERSONNEL
(Sign + Date Below)

TESTING PERSONNEL
(Sign + Date Below)

DATE: _____

DATE: _____

DIRECTOR OR DESIGNEE
(Sign + Date Below)

DIRECTOR OR DESIGNEE
(Sign + Date Below)

DATE: _____

DATE: _____

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