



## QBC Synthetic Hematology Control Kit

STORE AT 2-25°C (36-77°F)

### Contents

**Catalog No. 424306**

Level 1: 1 vial (blue cap)  
Level 2: 1 vial (orange cap)  
Level 3: 1 vial (green cap)  
Product Insert  
Assay Sheet

**Catalog No. 424307**

Level 1: 2 vials (blue cap)  
Level 2: 2 vials (orange cap)  
Level 3: 2 vials (green cap)  
Product Insert  
Assay Sheet

### Intended Use

As a quality control material for QBC Autoread Plus hematology system.

### Summary and Principles

QBC Synthetic Hematology Control is designed as a performance monitor for the QBC Autoread Plus with AccuTube system for the measurement of Hematocrit (HCT), Hemoglobin (HGB), White Blood Cell Count (WBC), Granulocyte Count (GRAN), Lymphocyte/Monocyte Count (LY/MO), and Platelet Count (PLT). The control acts as a surrogate for whole blood in the QBC Autoread system. It contains an aqueous-oil immersion with synthetic cell components, stabilizers, and preservatives. When centrifuged in a QBC AccuTube, the synthetic components of the control separate into distinct layers that correspond to the layers that would be found in a centrifuged whole blood sample. The control can then be read on the QBC Autoread Plus and results will indicate overall performance of QBC AccuTubes, proper sample preparation, and proper processing techniques.

Controls should be assayed as set forth by your laboratory's regulatory or accreditation agency.

### Warnings

- Wear protective laboratory gloves when handling these controls.
- Avoid contact with the skin, eyes, and clothing.
- **DO NOT INGEST.**
- Consult MSDS for additional information regarding safety and disposal.

### Storage and Stability

Always store QBC Synthetic Hematology Control at 2-25°C (36-77°F) when not in use.

Do not freeze or place vials near a freezer compartment.

After sampling, the cap should be immediately replaced. Store tightly capped controls at 2-25°C (36-77°F) when not in use.

**Unopened Vial Expiration:** When continuously maintained within the recommended temperature range, unopened vials are stable until the expiration date printed on the outer package and on vial labels.

**Open Vial Expiration:** Opened vials can be used for the number of days indicated on the lot specific assay sheet included in this kit.

### Indications of Deterioration

Inability to obtain expected values may be due to instrument malfunction, incorrect preparation technique, deterioration of tube coatings, or deterioration of the control; see the **Interpreting Control Results** and **Troubleshooting** sections for more details.

### Training

Before attempting to use the QBC Synthetic Hematology Control, please completely read this product insert, the user guide, and watch a brief training video that can be found at [www.qbcdiagnostics.com/products/hema/ar/iat.asp](http://www.qbcdiagnostics.com/products/hema/ar/iat.asp) or on DVD by request.

### Preparation and Test Procedures

The following materials are provided in this kit.

- QBC Synthetic Hematology Controls - Level 1, Level 2, Level 3
- Assay sheet
- Instructions for use
- Absorbent materials

The following materials are required but not provided in this kit.

- QBC Autoread Plus with QBC centrifuge
- QBC AccuTubes
- QBC Pipetter with AccuTube spacer
- Lint-free tissues

### Mixing the Control

If more than one shift is running control, the use of one vial set per shift is recommended. Always date the vials when first opened. Always keep the vials stored in the original kit when not in use.

**NOTE:** Refer to video and user guide for additional training.

1. Remove controls from the kit carton and check that the open vial stability and lot expiration date have not been exceeded.
2. Mix one vial at a time. To mix, shake the control vial extremely hard for three to five seconds to initiate emulsion and then briskly invert the vial for 30 seconds to ensure the control is fully mixed. **For further clarification, please refer to training video.**
3. Immediately prepare the QBC AccuTube.

**Do not** mix controls on a mechanical mixer or vortex.

### Filling a QBC AccuTube with Synthetic Control

1. Prepare a QBC AccuTube with control using the QBC blood pipetter with AccuTube spacer. Consult package insert supplied with the QBC AccuTubes for detailed directions on filling and preparing tubes.
2. Immediately after preparing an AccuTube with control, replace the vial cap.

### Processing the Synthetic Control

Promptly place the control tubes in the system centrifuge and start the instrument. Centrifuge the control tube in the QBC centrifuge for 5 minutes.

If prepared tubes must sit un-spun, ensure they remain upright and are placed in centrifuge within 5 minutes of preparation.

### Analyzing in the QBC Autoread Plus

Analyze the AccuTube in the Autoread Plus within 15 minutes after centrifugation.

To read the tube press the Autoread Plus mode key until the message "CBC Mode" appears in the display.

Insert the control tube with the closure to the left, then close the platform door to start the control assay. Record or print out the results and initial and date the record for your quality control files.

### Interpreting Synthetic Control Results

Compare control results to the ranges listed on the assay sheet to determine whether or not the results are acceptable. The lot number on the assay sheet must match the lot number on the

control vials. Find the control level being tested on the assay sheet and verify results against the range shown.

### Troubleshooting

Under normal or “in-control” situations, quality control results will occasionally be outside acceptable limits. When a result exceeds QC limits, do not begin testing patient specimens. A suggested approach for responding to the out of range result(s) is described below.

#### STEP 1

If one control is out of range, wipe off the QBC tube with an alcohol pad and reread the same tube. If results are within range, QC requirements are met. Indicate in QC records that the control was reread. If the control is out of range, go to STEP 2.

#### STEP 2

Check QBC tube and control expiration date and open vial stability date. If acceptable, prepare and read a new control tube from the same vial of control. If results are within range, QC requirements are met. Indicate in the QC records that a new control tube was tested. If the control is still outside the acceptable range, go to STEP 3.

#### STEP 3

Repeat the control test using a fresh vial of control. If results are within range, QC requirements are met. Indicate in the QC records what was done. If control is outside the acceptable range, review QC failure with the Laboratory Director.

#### STEP 4

If necessary, contact QBC Technical Services for technical assistance at +1-814-692-7661 or [qbcsupport@qbcdiag.com](mailto:qbcsupport@qbcdiag.com).

### Performance Characteristics

The mean values and ranges on the assay sheet are based on data collected from replicate analyses on multiple QBC instruments. The ranges shown on the assay sheet reflect the variability of the control materials and estimated interlaboratory variation for each parameter. Interlaboratory variation is influenced by overall performance of the instrument system, disposables, sample preparation and processing techniques.

Control results should fall within the range on the assay sheet. On occasion, results may fall outside the range limit specified on the assay sheet. Refer to TROUBLESHOOTING section for a suggested approach to responding to the out of range result. If results consistently fall outside the ranges, contact QBC at +1-814-692-7661 or [qbcsupport@qbcdiag.com](mailto:qbcsupport@qbcdiag.com) for further assistance.

### Limitations and Interfering Substances

For *in vitro* diagnostic use only.

The performance of this product is assured only by proper storage and use, as indicated above. Improper mixing techniques, storage outside of temperature requirements, use beyond expiration date, or introduction of contaminants such as debris or other chemicals may result in inaccurate results.

### References

1. QBC AccuTube Product Insert. 3406-200-002, Rev. D. 06/2006.

### Ordering Information

QBC Synthetic Hematology Control:

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Level 3: 1 vial (green cap)

#### Catalog No. 424307

Level 1: 2 vials (blue cap)

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Manufacturer



Authorized Representative in the European Community



Use By



Catalog Number



In Vitro Diagnostic Medical Device



Temperature Limitation



Batch Code (Lot)



Consult Instructions for Use

