directCHECK™ Quality Control for Hemochron™ Systems

REF DCGACT-1, DCGLR-1
REF DCGACT-2, DCGLR-2

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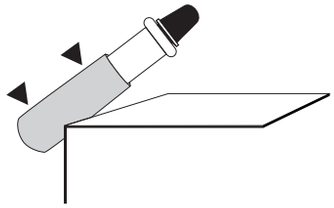
Breakage Technique

⚠ **Always use protective sleeve.**
If using the edge of a table to break, place fingers where arrows indicate.



Intended Use

The directCHECK Whole Blood Quality Controls are dried whole blood preparations which have been assayed and are intended to be used to perform quality control assays using the Hemochron test cartridges.

For *in vitro* diagnostic use. For professional use, Rx only.

Summary and Explanation

Blood coagulation instruments and assays should be quality controlled prior to and during routine use. Acceptable performance ranges are provided with each control product against which the user should compare results. A proper quality assurance program includes regular instrument maintenance, quality control assay measurements, and complete performance records.

Reagents

Level 1 and Level 2 quality control products are provided separately. These preparations consist of dried fixed bovine red blood cells, rabbit cephalin, buffered sheep and horse plasma. Assayed clotting time values are provided with each lot of material.

Each control preparation is provided in a dropper vial. Each dropper vial also contains diluent used to rehydrate the dried whole blood control. These diluent preparations consist of distilled water, sodium chloride, Tween® 20, ProClin®, and anticoagulant.

directCHECK Quality Control products are to be used with the Hemochron Systems (GEM® Hemochron™ 100 and Hemochron™ Signature Series instruments) as detailed below:

Quality Control Test Type	directCHECK Catalog Number	Test Cartridge
ACT+ Level 1	DCGACT-1	ACT+
ACT+ Level 2	DCGACT-2	ACT+
ACT-LR Level 1	DCGLR-1	ACT-LR
ACT-LR Level 2	DCGLR-2	ACT-LR

Warnings and Precautions

CAUTION: *Animal blood products are included in the directCHECK Quality Control preparation. No material in any preparation is derived from human blood. All blood products, whether of human origin or animal origin, however, should be handled with care.*

CAUTION: *All used test cartridges and quality control products are potentially infectious and must IMMEDIATELY be discarded into a container designed for sharp, medical biohazard waste and disposed per local and regional regulations. Use caution when handling and disposing of any sharp device. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.*

Handling and Storage

When refrigerated (2°C–8°C) the vials are stable until the marked expiration date. The quality control product should never be exposed to temperatures exceeding 37°C. Reconstituted vials should be used immediately. directCHECK Quality Control products may also be stored at room temperature for up to 4 weeks. (The marked expiration date must not be exceeded.) A re-dating label is provided and should be marked with 4 weeks dating if room temperature storage is selected.

Procedure

Materials Provided
directCHECK Quality Control product kits for use with the Hemochron Systems contain the following:

- 15 dropper vials of dried whole blood control (0.5 mL) in a glass ampule provided with 0.7 mL of diluent.
- 15 protective sleeves, for use in crushing ampules.

Materials Required, but Not Provided

- Test Cartridges
- GEM Hemochron 100 Instrument or Hemochron Signature Series Instrument

Graphic Symbols

Consult Instructions for Use
Caution
Do Not Reuse
REF Catalog Number
LOT Lot Number
Use-By Date
Contains Sufficient for <n> Tests
Temperature Limit
CONTROL L1 Quality Control - Level 1
CONTROL L2 Quality Control - Level 2
Device for Near-Patient Testing
Biological Risks
Professional Use, Prescription Only
IVD *In vitro* Diagnostic Medical Device
CE Conformity to European Directives
Manufacturer
EC REP Authorized Representative in the European Community

Preparation of Control Material

A. Test Cartridges

Remove the appropriate test cartridges from the refrigerator and allow them to come to room temperature (15°C–30°C) prior to testing. This could require up to 60 minutes.

B. Quality Control Product

Remove the appropriate quality control dropper vials from the refrigerator and allow them to come to room temperature. This could require up to 60 minutes. Visually inspect vial to ensure that the glass ampule is intact.

Test Procedure

Prior to running a LQC (Liquid Quality Control) test, ensure that an EQC (Electronic Quality Control) test is performed. LQC testing should be initiated directly after the instrument indicates that EQC has passed. If multiple LQC tests are run consecutively, the EQC is only needed before the first LQC test.

1. On the Home screen of the instrument, select **QC** (Quality Control).
2. Insert cartridge (room temperature) into the cartridge slot on the side of instrument.
3. Scan or manually enter QC lot information from the Acceptable Performance Range label published on the back of this package insert.
4. The instrument will signal when it is ready, the display will indicate "**Add Sample**" and then "**Press Start**".
5. Reconstitute the (room temperature) dropper vial contents as follows:

   NOTE: *Reconstitution and mixing of the whole blood control material should be accomplished quickly and without delay in any step. Once the dried control material has been reconstituted, the sample should be used immediately, as clotting will occur. The entire process should take no longer than 18 seconds. Failure to follow this procedure may affect results.*

   - Remove the label from the vial. **Ensure vial is in protective sleeve.** Holding vial upright, tap the vial on a table top to settle glass ampule to the bottom of the vial.
   - Crush the inner glass ampule by bending the vial over the edge of a table top.
   - Immediately repeat the crushing action 1–2 additional times to ensure complete breakage of the glass ampule.
   - Quickly invert the dropper vial end to end 10 times. While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to dropper tip.
6. Remove and retain the vial cap. Squeeze the vial to discard the first drop of the control material into vial cap.
7. Immediately fill the cartridge sample well flush to the top with the control material. Should a large dome extend above the center of the sample well, push the excess control material into the overflow area.
8. Press **START**.
9. The test result is displayed and archived automatically.
10. Dispose of the directCHECK vial (in its protective sleeve), vial cap, and test cartridge in a biohazardous waste and sharps container in accordance with institutional guidelines.

NOTE: *Refer to the "Troubleshooting" section should any fault message appear on the display during this procedure.*

Limitations

Technique variation can significantly alter performance characteristics. While the Hemochron Systems have a limited number of operator variables that can affect performance, improper handling of the quality control product can significantly affect results. Care must be taken to establish and adhere to the recommended test procedure found in this package insert and the associated test cartridge package insert. Variations in ambient temperature should be minimized for consistency of test performance. Avoid vigorous shaking which may cause bubbles or foaming. In cases where results fall outside of the assigned range, patient results should be considered suspect and performance of quality control tests should be repeated.

Published performance ranges reflect results found in most clinical settings. Each institution should establish its own expected range of results and provide a data tracking record to identify instruments, test cartridges, reagents, or operators whose performance is outside of the institution's expected range.

In cases where results are outside of the expected/published range, the cause will likely fall into one of the following possible categories:

1. Operator Technique
2. Quality Control Product / Test Cartridge
3. Instrumentation
4. Environmental Factors

Performance Characteristics

Expected Values

Acceptable performance ranges for each quality control product are published on the back of this package insert. These values have been established at the manufacturer's facility and are lot-specific. The range represents the acceptable performance ranges for all Hemochron instruments. The user should be able to obtain a value within the published range included with each product.

The manufacturer recommends that each institution establish its own expected range of response based on the mean ±2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range.

Troubleshooting

Please refer to the *"Troubleshooting"* section of the appropriate Hemochron instrument Operator Manual for instrument software fault messages, definitions, and actions.

PROBLEM	CAUSE	ACTION
Control value is below published range	Reconstituted control material was not thoroughly mixed.	Repeat test, ensuring that inner glass ampule is crushed at least 2 times and reconstituted control material is thoroughly mixed by inverting the vial end to end 10 times.
	Time period between control material mixing and addition to test cartridge is too long.	Repeat test. Ensure vial label is removed prior to crushing vial. After proper mixing of control material and diluent, IMMEDIATELY discard first drop into vial cap and then dispense reconstituted control material into test cartridge sample well.
Control value is above published range	Inner glass ampule was not adequately crushed.	Repeat test, ensuring that inner glass ampule is crushed at least 2 times prior to inverting the vial end to end 10 times.
	Reconstituted control material was not thoroughly mixed.	Repeat test, ensuring that reconstituted control material is thoroughly mixed by inverting the vial end to end 10 times.
	Vial cap is removed prior to inverting, allowing diluent to leak from vial.	Repeat test, ensuring that vial cap is not removed prior to inverting. Remove vial cap when control material is to be dispensed into test cartridge sample well.
Fault message obtained (see appropriate Operator Manual)	Reconstituted control material was not thoroughly mixed.	Repeat test, ensuring that reconstituted control material is thoroughly mixed by inverting the vial end to end 10 times.
		Repeat test, ensuring that inner glass ampule is crushed at least 2 times prior to inverting end to end 10 times.
	Bubbles are present in control material when added to test cartridge sample well.	Repeat test, avoiding excessively vigorous shaking that may cause bubbles or foaming.
		Repeat test, ensuring that reconstituted control material is thoroughly mixed by inverting the vial end to end 10 times.
		Repeat test, ensuring that reconstituted control material flows to dropper tip by using a downward snapping motion of the wrist prior to dispensing into test cartridge sample well.

IF "OUT-OF-RANGE" RESULTS OR FAULT MESSAGES PERSIST, CONTACT TECHNICAL SUPPORT.