HEMOCHRON® Whole Blood Liquid Quality Control Tips and Frequently Asked Questions

***direct*CHECK® Whole Blood Liquid Quality Control for HEMOCHRON® Jr. Cuvettes**

How often does the liquid QC have to be performed?

Each ***lot*** of HEMOCHRON Jr. cuvettes should be validated for performance at two liquid control levels:

- When a new shipment is received, AND
- Once per 30 calendar days thereafter

Following successful performance validation as above, the cuvettes will not require any further liquid quality control unless a shift in clinical results is suspected.

What control product do I need to QC my Jr. cuvettes?

- The following *direct*CHECK products are available for quality control testing of the Jr. cuvettes:

Jr. Cuvette	Level 1 Control product (catalog number)	Level 2 Control Product (catalog number)
ACT+	DCJACT-N	DCJACT-A
ACT-LR	DCJLR-N	DCJLR-A
APTT	DCJAPTT-N	DCJAPTT-A
PT	DCJPT-N	DCJPT-A
Citrate APTT	DCJCPT-N	DCJCAPTT-A
Citrate PT	DCJCPT-N	DCJCPT-A

If you have multiple types of *direct*CHECK QC vials in the same department, ensure those personnel performing the tests know the correct vial to use for the cuvettes in use for patient testing.

The QC result was outside of the published range. What should I do?

While explained in the product instructions for use, this can happen due to any of the following reasons:

- Delay in sample application. The plastic vial label should be removed **prior** to crushing the inner glass ampule. If the control material is mixed and ready to be dispensed, removing the label at this time could result in delays and results outside the published range.

- Premature sample activation. Do not crush the ampule until "Add Sample" and "Press Start" messages are displayed**.** Crushing the ampule prior to this could result in premature clotting and a clotting time outside the published range.

- Delay in sample application. Mixing of the whole blood control material should be accomplished quickly and without delay in any step. Once the control material has been mixed, it should be **used immediately**, as clotting will occur.

- Incomplete sample mixing. The inner glass ampule should be completely crushed. Prior to crushing, ensure the ampule is at the bottom of the vial by tapping it on a flat surface, prior to insertion into the protective sleeve. Flicking the vial prior to crushing may also help. The ampule must be crushed at least 2 to 3 times to ensure the dried blood is released completely for mixing with the diluent.

- Incomplete sample mixing. The control material should be mixed thoroughly. Once the inner glass ampule is completely crushed, thoroughly mix the dried blood with the diluent by **inverting the vial <u>from end to end</u> 10 times**. Use moderate speed and force while inverting the vial, but do not shake up and down vigorously. Shaking could induce the formation of bubbles, which can enter cuvette channel and cause an error message.

- Incomplete sample mixing. The vial cap should be removed only when ready to add the mixed control material to the cuvette. If the cap is removed too soon, the diluent could leak out of the vial, resulting in too little diluent and a test result outside the published range.

An error message was displayed on the instrument: "Sample not seen".

- The control material may not have been completely mixed (see sample mixing tips above). When ready to dispense control material to the cuvette, hold the dropper tip down and use a downward snapping motion of the wrist to ensure the control material flows to the dropper tip. Squeeze the vial to discard the **first drop** of the control material **into the vial cap**. **If the material comes out clear it has been incompletely mixed. Close the cap and remix until the material has a uniform (red) consistency –** then add to the cuvette**.**

An error message was displayed on the instrument: "Sample too small".

- An insufficient amount of control material was added to the Jr. cuvette well. To avoid this error when adding the control sample, it may be easier to overfill the cuvette well and push the excess over into the outer ring – this automatically leaves sufficient sample for performing the test.

An error message was displayed on the instrument: "Sample too large".

- Too much control material was added to the Jr. cuvette well, resulting in a large dome over the top of the well. When adding the control sample, it may be easier to overfill the cuvette well and push the excess over into the outer ring – this automatically leaves sufficient sample for performing the test.

An error message was displayed on the cuvette instrument: "Bubbles Repeat".

- The vial may have been shaken rapidly instead of inverted, resulting in bubbles. Repeat the test, using inversion with moderate force and speed instead of shaking up and down. If bubbles are seen when dispensing the first drop into the vial cap, discard additional drops into the cap until no bubbles are seen.

8 Olsen Avenue • Edison, NJ 08820 USA
tel: 732.548.5700 • fax: 732.632.9299
ITC Europe • Strada Rivoltana • 20090 Rodano (MI) ITALY
tel: +39.02.9532.0196 • fax: +39.02.9532.0276
www.itcmed.com
a subsidiary of Thoratec Corporation