

UK Cell Salvage Action Group Guidance Document

Minimum Standards for Quality Assurance and Control

This document sets out the minimum recommended standards for quality control (QC) checks of the end product in intra-operative cell salvage (ICS). It is acknowledged that some hospitals will employ a meticulous QC process that includes laboratory style validation processes. While this may be viewed as the 'gold standard' for QC in ICS, it is acknowledged that others will have difficulties in achieving testing of the end product. The following fundamental elements are intended to support hospitals who wish to implement a QC process for ICS.

Key Aspects of Quality Assurance and Control in ICS

- Maintenance contracts and regular servicing of machines
- Frequency of sampling from machines
- Sampling methods and equipment
- Sample labelling
- Investigations and associated actions
- Personnel involved

Maintenance and Servicing

The ICS machine will have been through a series of quality checks by the manufacturer before it is released to the purchaser. It is essential that the machine is maintained and serviced to the manufacturer's schedule to ensure reliable function. Adherence to the maintenance schedule minimises risks to the patient and operator. Therefore, as a minimum we recommend:

- **All ICS machines are maintained and serviced as recommended by the manufacturer or preferably through a service contract with the manufacturer**

Frequency of sampling from machines

There is some variability in frequency of use for ICS machines with some being used for multiple procedures during one day, while others may be used far less. Agree a suitable schedule with the laboratory for all machines. As a minimum we recommend:

- **One sample from each machine should be tested monthly using a standard, documented procedure**
- **Following servicing or changes to the machine perform a quality check during the next case or with a test sample**

Sampling Methods and Equipment

Samples should be collected from the red cell reinfusion bag prior to reinfusion. Sample tubes will be determined by the investigations you wish to conduct. Results may be adversely affected if a part bowl was processed or by poor sampling technique such as using a needle and vacuum tube:

- **Invert the filled reinfusion bag several times to ensure adequate mixing**
- **Run the salvaged red blood cells through a blood administration set with a 3-way tap at the patient end**

- **Take the sample before the end of the procedure and before connection to the patient**
- **To avoid haemolysis gently withdraw 10ml of blood from the reinfusion line via the 3-way tap**
- **Remove the rubber stopper from the sample tube and gently transfer the blood into the tube**
- **If a leucodepletion filter is used do not use a syringe; open the 3-way tap and allow the blood to run into the unstoppered tube by gravity**

Sample labelling

Establish an unambiguous method of sample labelling so that quality samples are not confused with patient samples.

- **With the laboratory agree a method for sample labelling with clear identifiers that are linked to each machine, and the patient when the sample is taken during an actual procedure**
- **Record in the patient record when the sample is taken during an actual procedure**
- **Clearly identify that the sample is for QC purposes and should not be acted on for patient care**

Investigations and associated actions

Samples of the end product may go through a range of investigations, some of which are intended to test the wash efficacy. These include free haemoglobin, albumin and/or heparin. Results should be within the parameters set by the machine manufacturer and to locally agreed acceptance criteria.

The minimum requirement is:

- **Haemoglobin level of component: to establish the quality of the component being reinfused**
- **Haematocrit level of component: to establish the quality of the component being reinfused**
- **Include in local policy the action to be taken if the machine fails the QC check, e.g. remove from service**

Personnel

All staff operating ICS machines should be trained and competent to do so. Persons collecting QC samples should be authorised locally, and appropriately trained and assessed in the required techniques.

- **Retain a log of locally authorised personnel that includes a record of training and assessment**
- **All staff should work to a standard, documented method when taking QC samples**

*The information contained in this Guidance Document has been sourced from members of the UK Cell Salvage Action Group (UKCSAG) and is generally agreed to be good practice.
The UKCSAG does not accept any legal responsibility for errors or omission.*