# Considerations for Laboratory Point of Care Testing in Clinical Trials

Point of Care (POC) Testing is laboratory diagnostic testing performed in the vicinity of the patient, avoiding the necessity to send samples for processing at a central laboratory. A POC analyser or device can also be termed an IVD (In-Vitro Diagnostic) device. According to the EU IVD directive (98/79 EC), IVD devices can be defined as any medical device intended to be used alone, or in combination, in-vitro, for the examination of specimens (including blood and tissue donations) derived from the human body solely or principally for the purpose of providing information:

- Physiological or pathological state
- Congenital abnormality
- Determining the safety and comparability with potential recipients
- Monitoring of therapeutic measures

## Applications for POC Testing

There are several areas in a Clinical Trial that POC testing can prove useful. At each stage, POC testing, and POC testing in conjunction with centralised laboratories, has multiple benefits to relying on centralised laboratories alone. These benefits include speed, portability, convenience, connectivity, reduced workload on the centralised laboratories, and optimum sample quality.

*Suitability to Enter the Trial-*
This can be varied and in some cases highly specific when in some instances specific assays are developed to aid in the selection criteria by identifying if the participant is a 'responder' or a 'non-responder'. Although central laboratories are more usually employed, POC analysers can be capable of identifying highly complex biomarkers

*WBC HemoCue Analyser*

*Safety Testing-*
This is usually done prior to the administration of the study drug to ensure the patient is in an appropriate state of health to participate and to avoid any undue risk to them. This testing may cover a range of analytes and parameters such as:

- White blood cell count/ differential count
- Platelet count
- Glucose, Potassium, hCG, PT/APTT

*Compliance with Patient Protocols-*
This is usually when it needs to be established that other interfering factors are not present and that the patient is compliant with the criteria required by the study protocol. Factors that may be tested for using POC testing devices include: Alcohol, Drugs of Abuse, Carbon Monoxide.

*Testing Labile Analytes –*
Some analytes are highly labile or have a short half life which in most cases means that transport to a central laboratory is not possible or practical. Some examples are CK MB, Troponin I and T, Pro BNP and coagulation screening tests. In such situations POC testing provides the only realistic solution.

**Choice of Supply Company**

Once the decision has been made to employ the use of one or several POC devices in a trial it is important that these devices are obtained from an appropriate source, to ensure the smooth running of the trial, and maintain data acceptance.

*Considerations-*

- Not all devices and methodology are registered for use in every country.
- All countries have different customs regulations and some require you to know exactly what components make up the test system with particular reference to biological or genetically modified material.
- Knowledge of expiry dates of test devices, calibrants and controls are vital throughout the whole supply process. The number of batches should be minimised, known and agreed in advance.

*Manufacturer Vs Secondary Supplier-*

A manufacturer will usually deal with sales only and provide one type of equipment. The supply of a particular product to a particular country may be difficult or not even possible. Choosing to work with a secondary supplier can ease these problems and can be more appropriate and beneficial for a Clinical Trial. A secondary supplier can work with different manufacturers to find the most appropriate product for its intended use. In addition they will usually hire for short or long term and provide appropriate support, including training worldwide, throughout the length of the trial.

*Requirements of a Suitable Supply Company-*

It is important that a Clinical Trials supply company has appropriate scientific knowledge and expertise, as well as logistical capabilities. A good supply company should have appropriate Biomedical specialism to be able to advise and provide technical support and training. It should have a well equipped service department to ensure equipment is fully calibrated and maintained. It should also have experience in logistics to maintain the supply of sensitive reagents worldwide, across difficult borders in a timely manner.

**Training**

When using POC testing it is important that all necessary training is completed. Training in the use of POC devices must be given to appropriate clinical staff by appropriately trained Biomedical Scientists. Training must be documented and include:

- Background information
- Sample collection
- Storage of test devices
- Calibration of analyser
- Internal and external quality control checks
- Reporting results
- Routine maintenance of the analyser or device


*Reflotron Plus Clinical Analyser*

**In Summary**

The manufacturer or specialist supply company should be employed to advise on choice of analyser, training of staff, ongoing technical support, supply of reagents, routine maintenance and decommissioning of the system at the competition of the trial. Although POC analysers and devices can seem simple, their use in the UK is highly regulated and controlled to ensure maximum safety to the patient.

***About the authors:***

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