

## **Laboratory Equipment in Clinical Trials**

One of the earliest known Clinical Trials was conducted in the 1700's by James Lind, where through the use of experimentation and control groups he was able to find a cure for scurvy in British sailors. All scurvy patients were divided into groups and given the same general diet. Each group was given an additional supplement to their diet. For one group this was oranges and lemons. After six days the only patients that had recovered were those eating oranges and lemons.

Nowadays, Clinical Trial subjects are monitored both for their well being and for the direct effect of the study drug, by assessing a variety of physical and laboratory parameters dependent on the type of drug being employed. It is usual for blood to be drawn according to protocol and to be analysed at a Central Laboratory. Different anticoagulants will be used according to the analytes being measured.

### **The First Stages**

Centrifugation is the first part in the laboratory process and is a critical stage in the analysis, which if done incorrectly can invalidate the sample. A centrifuge is the basic laboratory tool and specialist advice from Biomedical Scientists should be sought for the appropriate model to be employed. The 'force' of the centrifuge can be represented in terms of Relative Centrifugal Force (RCF) or in 'g' force. This is dependent on the speed of the centrifuge, Revolutions Per Minute (RPM), and the distance from the bottom of the blood tube when spinning, to the centre of the centrifuge (RCF). This same force (RCF) can then be quoted for any centrifuge, which can further be specified as refrigerated (usually 4°C) or ambient (room) temperature, and either fixed angle or horizontal. Centrifuges that spin the sample horizontally are preferable to fixed angle versions when gel type tubes are employed to give a tighter horizontal separation line

Sample analysis then usually takes place at a Central Laboratory. Central Laboratories however cannot provide the complete solution when the purpose of testing is for safety prior to the administration of the study drug or if the analyte in question is too labile to survive transportation. These problems can be overcome by the laboratory facility being close to the patient as is the case with some Trial units, or through the use of Point of Care (POC) equipment which provide for immediate results

### **Equipment Variations**

The range of analytes that can be measured at the Point of Care are increasing and the choice of analysers or devices are many and varied. If the analyte being measured is for use in the evaluation of the study drug, it is essential that a validated means of data capture and transmission of results is available according to protocol.

The laboratory equipment can be simple devices such as those for pregnancy testing or complex for haematology, biochemistry, immunology and virology type tests. The following list consists of the type of equipment on the market and the analytes they test for...(This list is not exhaustive and many new analysers are becoming available for tumour markers, endocrine, fertility and thyroid testing).

- **Hand held blood analysers** - Creatinine, Urea Nitrogen (BUN) Glucose, Chloride, Sodium, Potassium, Ionised Calcium, Haematocrit, Haemoglobin, pH, PCO<sub>2</sub>, PO<sub>2</sub>, TCO<sub>2</sub>, HCO<sub>3</sub>, BE<sub>ecf</sub>, sO<sub>2</sub>, Lactate, Anion Gap, ACT, PT/INR, cTnI
- **Alcohol meters** - Breath or saliva for alcohol assessment
- **Cardiovascular screening devices** - Glucose, Cholesterol, Triglycerides, Lactate
- **Hand held glucometers** - Glucose
- **Drugs of abuse panel tests\*** - Amphetamine, Methamphetamine, Barbiturates, Benzodiazepines, Cannabinoids, Cocaine, Opiates, PCP, Tricyclic antidepressants, Methadone, Propoxyphene, Acetaminophen
- **Cardiac marker panel test cassettes\*** - Myoglobin, Troponin I & T, CK-MB, Pro BNP
- **Haematology analysers** – full or partial haematology profile with full or partial differential
- **Pregnancy tests** - Human Chorionic Gonadotropin (hCG)
- **Basic urinalysis\*** - Albumin, Bilirubin, Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Specific Gravity, Urobilinogen, Albumin-to-Creatinine Ratio
- **Coagulometers** - Prothrombin Time (PT), Activated Partial Thromboplastin (APTT), INR
- **Cholesterol and lipid profiles** - Alkaline phosphate, Amylase, Bilirubin, Cholesterol, CK, Creatinine, GGT, Glucose, GOT, GPT (ALT), HDL Cholesterol, Haemoglobin, Potassium, Pancreatic Amylase, Triglycerides, Urea, Uric acid,
- **Haemoglobin analysers** - Haemoglobin Levels in Blood, Plasma, Serum & Aqueous Solutions
- **White blood cell analysers** - White Cell Count, white cell differentials
- **Albumin Testing Analysers** – Micro Albumin

\*automated readers available

When choosing a supply company for laboratory equipment it is important to choose a supplier that has expertise in a number of areas. Biomedical scientists with a high level of knowledge and experience are required to provide global training and technical support. It is important to have a well-equipped service department with qualified engineers to ensure equipment is fully calibrated and maintained. Experience in logistics is also essential to maintain the supply of sensitive reagents worldwide. Reagents need to be kept at correct stable temperatures throughout the shipping process, so it is vital to work with the correct logistics companies who can move equipment and reagents across borders and through difficult countries, whilst ensuring the cold chain is maintained and documented.

Compliance with these key features will maintain data acceptance and ensure that the study runs smoothly over the shortest possible time.

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