Research & Development Use of the Beckman ALLEGRA-X12 Centrifuge

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Signature:	Signed copy held by R&D Unit
	Date:	11th March 2019
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	Signature:	Signed copy held by R&D Unit
	Date:	11th March 2019

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	8th April 2019	

Contents

1 Introduction, Background and Purpose

Many tests are performed at central and local laboratories using serum, plasma and cell free urine - requiring samples to be centrifuged prior to testing. Centrifugation of whole blood and urine samples at a suitable speed and for an appropriate duration can yield plasma or serum and from primary tubes containing or devoid of added anti-coagulants respectively.

The Research Laboratory often facilitates the processing of such blood samples in Pathology.

At the sponsors' request, it may be necessary to also control the temperature at which samples are centrifuged. All samples should be processed in accordance to the study protocol.

Used improperly, centrifuges can pose a risk to the operator and this SOP describes their basic use, including balancing, routine cleaning and fault reporting. The procedure for dealing with broken samples in centrifuges and disinfection is also described.

The centrifuge described in this SOP can be identified by its serial number and model: **Allegra-X12 R Centrifuge - SN: ALX15H11**

2 Who Should Use This SOP

This SOP applies to all research staff using the Beckman Allegra-X12R Centrifuge in Pathology. These procedures can be carried out by staff whose competence from Appendix A has been established and recorded in their training files.

3 When this SOP Should be Used

This SOP should be followed to facilitate the processing needs of the laboratory research team and individual clinical trials based on the direction of protocols and laboratory manuals.

4 Procedure(s)

4.1 Responsibilities

All staff using the Beckman Allegra X12R should receive training before using this equipment and complete Appendix A and file in their training file.
It is the responsibility of the member of staff using the equipment to ensure they have read and understood this SOP.

Responsibility for checking and maintenance of the equipment lies with the nominated member of R&D Laboratory Team who has overall accountability for laboratory equipment.

Service and calibration should be carried out annually.

4.2 Safety Precautions

All centrifuges must be operated in accordance with manufacturer's instructions. The operator manual for the Beckman Allegra X12 R Centrifuge can be located in the R&D Laboratory Filing Cabinet.

Use only the rotors and accessories designed for the centrifuge and always use bucket lids if available.

Never attempt to override the lid lock system unless you are certain the rotor is stationary.

Centrifuge buckets and contents must be properly balanced. If a centrifuge shows an imbalance, switch off immediately and investigate the cause.

4.3 General Procedure for Operation of Centrifuges

Ensure that the same numbers of specimen tubes are loaded into opposite-facing buckets. A balance tube containing an appropriate volume of water or saline must be used if there are an odd number of specimens to be centrifuged.

Ensure that the samples are loaded equally and diametrically across the individual bucket. This has the effect of ensuring that the bucket swings horizontally and not at an angle, which can cause stress on the trunnions.

Once the buckets are loaded then safety lids must be fitted and the centrifuge lid properly closed.

Check the centrifuge settings for speed, duration and temperature and adjust as outlined in the Operating Manual.

When the centrifuge stops it is safe to open the lid. Carefully remove the bucket lids and take out the samples keeping them upright.

If you suspect a specimen has broken inside the centrifuge do not open the lid - see next section.

4.4 Dealing With Broken Sample Tubes & Disinfection Procedure

Prior to disinfecting contaminated centrifuges, switch off power. Leave unopened for 30 minutes to contain potential aerosols. Contact a member of staff in Microbiology for further advice if required.

Tristel Jet (trigger spray) is suitable for cleaning external surfaces – apply onto a wipe or directly onto the contaminated surface. Wipe the surface ensuring it is completely covered and leave to dry for 30 seconds.

Use a working solution of Tristel Fuse to soak contaminated buckets and inserts if required.

Carefully remove the bucket lid and any unbroken tubes using a gloved hand and forceps where necessary.

Fully immerse the buckets containing any broken tubes, glass, etc. and lids in the disinfectant solution and leave for 30 minutes. Afterwards, rinse (in water) and dry the buckets and lids thoroughly.

Any broken tubes should be disposed of into a Sharps container taking great care.

Record the Sample ID of any samples that are unsuitable for analysis and report the incident to the Research Team and Sponsor. Document the incident in the Specimen Deviation Log in the Laboratory Investigator Site File. The incident may also need to be recorded on a DATIX form.

Unbroken tubes that are not heavily soiled may be suitable for processing – refer to the Duty Biochemist if unsure and seek further approval from central laboratory and/or Sponsors if necessary.

4.5 Maintenance & Cleaning

Centrifuges are cleaned monthly and following any known contamination. Cleaning and decontamination is recorded electronically using R&D/F85 – Centrifuge Maintenance Log.

Use Tristel Gel to clean metal buckets using tissue to wipe round buckets and dry.

Plastic inserts and unit exterior are wiped with Sani Cloth 70 (Isopropyl alcohol wipes) on a monthly basis or when visual contamination is evident.

It is necessary to monthly lubricate the trunnions to reduce wear and tear and minimise equipment noise – refer to instruction manual for further details.

The floor underneath should be swept monthly, in addition to hoovering/wiping of exterior air inlets & outlets.

The Associate Practitioner that has completed the above tasks is required to initial his/her name against the maintenance for the specific month.

Annual preventative maintenance and repairs must be carried out by authorised service engineers. Records of such maintenance is stored on the X-Drive>01.Trials Info> Equipment.

4.6 Fault Reporting

Any faults should be reported immediately to an Associate Practitioner in Research & Development, who can assist in the arrangement for the service engineers to be called if necessary and in accordance with the current service contract.

Any adverse incidents should be recorded on a DATIX form.

5 Related SOPs and Documents

- X12 Instruction manual: Electronic copy stored against in Q-Pulse.

- R&D/F85 – Centrifuge Maintenance Log

6 Risk Assessment

COSHH Risk Assessment
All human blood samples must be treated as potentially BIO-HAZARDOUS.

Take care when handling broken glass sample tubes – avoid touching wherever possible and/or use forceps etc.

Approved Personal Protective Equipment (PPE) including lab coats and gloves must be worn when handling open blood and urine samples or derivatives thereof.

Exposure to Bio-Hazardous Material
In the event of accidental blood splashes to eyes or mouth:

If skin has been punctured encourage bleeding by gently squeezing. Wash with soap and running warm water then dry and dress the wound.

Splashes to the eyes: irrigate eyes thoroughly with eye wash / saline

Splashes to the mouth: gargle with drinking water (avoid swallowing)

Contact the Occupational Health Department / Emergency Department for guidance and report all adverse incidents to your line manager / complete a DATIX form

Name	Classification & Specific Instructions
Tristel Jet (Gel trigger spray)	**Description:** Sporicidal disinfectant gel (mild oxidising solution) – chlorine dioxide generator **Preparation:** Ready to use two-component spray. See side of refill pack for assembly instructions. **Storage:** Store at room temperature **Supplier:** Tristel Solutions Ltd. Lynx Business Park, Fordham Road, Snailwell, Cambridgeshire. Tel 01638 721500. Can be obtained from 2nd Floor Store. Risk Statement & Control Measures This product is unlikely to cause harmful effects under normal conditions of use. Hazard Identification & First Aid Measures Working Solution: NO IDENTIFIED HAZARDS **Inhalation:** Non toxic **Eye contact**: rinse with water **Skin Contact:** wash with water **Ingestion:** Do not induce vomiting. Give water to drink & seek medical attention where necessary Liquid Waste Disposal Unused disinfectant may be disposed of via the laboratory sink. Flush large quantities away with fresh cold water.

Name	Classification & Specific Instructions
Sani Cloth 70 (Isopropyl alcohol wipes)	**Description:** Isopropyl alcohol wipes **Preparation:** Supplied ready for use **Storage:** Store at room temperature away from sources of heat **Supplier:** PDI Europe, Aber Park, Aber Road, Flint CH6 5EXTel. 01352 736716 Risk Statement & Control Measures This product is unlikely to cause harmful effects under normal conditions of use. Highly flammable – avoid exposure to sources of heat and naked flames. Hazard Identification & First Aid Measures  IRRITANT  HIGHLY FLAMMABLE **Eye contact:** Wash **Skin contact:** Wear gloves during extended periods of use. Wash hands after use. **Inhalation:** Move to fresh air **Ingestion:** Wash out mouth with water. Seek medical attention if any adverse symptoms Waste Disposal Small quantities may be disposed of via clinical waste bags. Avoid contact with heat sources or naked flames.

7 Appendix A – Beckman Allegra X-12 R Centrifuge

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note; all sample handling should comply with local laboratory procedure and if instruction is unclear please seek advice from the R&D Laboratory team, Biomedical Scientist or the study Sponsor.

Trainee Print Name: ……..

Sign: ……. Date: ……

Authorised By Print Name: ……..

Sign: ……. Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	C		Can identify the samples to be centrifuged.		
DD/MM/YY	C		Knows to leave the blood to clot prior to centrifugation.		
DD/MM/YY	B		Can safely operate the centrifuge; lids on buckets & balance the samples in the centrifuge.		
DD/MM/YY	B		Can change the settings and use the correct program; centrifuge.		
DD/MM/YY	C		Knows the procedure if a sample has broken (or is suspected to be broken) in the centrifuge.		
DD/MM/YY	B		Knows the maintenance procedure of the centrifuge.		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills