Organisation Name and Address

Company Name:	**NHS Blood and Transplant**
Company Address:	**Second Floor, Oak House, Reeds Crescent, Watford, Herts, WD24 4QN** **Tel: 0192 336 6800, Fax: 0192 336 6801**
Contact Name:	**Ian Bateman, Associate Director of Quality**
Email:	**ian.bateman@nhsbt.nhs.uk**
Telephone:	**0161423 1214**
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Product or service details

Product/Service Details:	**Blood & blood components** **NHSBT reagents**
Model/ Item Number:	**Blood & blood components** **Red cell Identification Panels** **IgG coated red cells** **Weak anti-sera – Anti-D** **Reference Services – Red Cell Immunohaematology (RCI) and Histocompatability and Immunogenetics (H&I)**

SUPPLIER AUDIT QUESTIONNAIRE

QUESTION	YES	NO
Do you currently hold any Quality Accreditation? **Please detail:** **Inspection Body: Medicines and Healthcare Products Regualtory Agency (MHRA)** **Accreditation Number/Reference:** **Blood Establishment Licence number BEA25224** **Date of last/next inspection: August 2014, next March 2015** **Inspection Body: Underwriters Laboratory Ltd (UL)** **Accreditation Number/Reference:** **EC Examination Certificate No. 309.131203 expiring 12/12/18** **Full Quality Assurance System Certificate No. 308.130328 expiring 11/12/15** **Inspection Body: Clinical Pathology Accreditation Ltd (CPA)** **Accreditation Number/Reference:** **RCI: 2817 North cluster, 2818 Midlands cluster, 2819 South cluster**	**√**	☐

QUESTION	YES	NO
H&I: 2823 North cluster, 2821 Midlands cluster, 2822 South cluster **Outcome: Successful**		
Quality Policy **Is there a quality policy in place?**	√	□
Organisation **Are all responsibilities clearly defined?**	√	□
Training **Are there systems in place for training?** **Are staff appropriately qualified and trained to carry out procedures correctly?**	√ √	□ □
Internal Quality Audits **Are there procedures in place for planned quality audits?** **Is there a review of the effectiveness of your governance systems to ensure data integrity and traceability?**	√ √	□ □
Purchasing **Is there a procedure in place for the control/assessment of suppliers, including verification of supplier's/ manufacturers bona-fides?** **Does this procedure define actions to be taken when dealing with suppliers that do not meet the requirements?**	√ √	□ □
Process Control **Are there documented procedures for the processes?** **Are there any process / quality controls?** **Is there a formal release process?** **Is there a unique batch documented for each batch?** **Are certificates of analysis available?** **Have critical steps of the processes/premises and production and any significant changes been validated?** **Are records of manufacture including distribution retained in a comprehensible and accessible form?**	√ √ √ √ □ √ √	□ □ □ □ **N/A** □ □

QUESTION	YES	NO
Process Change Control **Is there a documented procedure in place for change control to processing and materials used?**	√	☐
Are there procedures for the investigation of non-conformances and documentation of corrective actions?	√	☐
Recall **Is there a procedure for the recall of a product?**	√	☐
Is the effectiveness of the recall system regularly tested?	√	☐
Are complaints about products examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective product and to prevent reoccurrence?	√	☐
Handling, Storage and Delivery of the product **Are these stages controlled to maintain product quality?**	√	☐
Is the temperature monitored during transport? **Blood products are transported either in validated transport boxes or in temperature controlled vehicles.** **If Yes, how/when is this reviewed and how are OTC events actioned? (detail below)** **The temperature controlled vehicles are fully validated to maintain temperatures within the specified limits and are monitored with alarms. Temperature excursions are reported, reviewed and actioned through the CAPA system. Records of temperature monitoring of the vehicles are reviewed and retained.**	√	☐
Do we have your permission to share this questionnaire with the Joint TAG on the London & SE Coast RTC website? **http://www.transfusionguidelines.org.uk/**	√	☐

Additional Comments
Please provide an explanation or brief description to any answers that were marked "NO":

Questionnaire completed by:	**Fiona Harper**		
Position:	**Quality Project Specialist**	**Date:**	**27/02/15**