The Leeds Teaching Hospitals NHS
NHS Trust

Department of Blood Transfusion

VALIDATION OF AUTOVUE / LIS INTERFACE

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1 Introduction

1.1 Validation must be performed on all automated systems that are considered critical. In transfusion an automated system is considered critical:

> If its use is directly linked to the decision made for blood or blood product manufacturing, testing (donor/patient), labelling and release for transfusion.

And/or

> If it is used to manipulate the related information.

1.2 A validation plan is a well planned set of test cases that:-

Evaluate the performance of a system with regard to its effectiveness based on the intended purpose.

Establish documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

2 The Autovue / LIS link

2.1 The Ortho AutoVue automated blood bank system will be used for a number of critical Blood Bank tests; these are given in the table in appendix 1. Some of the tests will always be performed on the AutoVue; others may be performed manually or on the AutoVue.

2.2 The interface linking the AutoVue machines and the Laboratory information system (LIS) [TelePath] is a bi-directional link; with sample data passing from the LIS to the AutoVue and test result data passing from the AutoVue to the LIS.

2.3 It is vital that information transferred between the AutoVue and the LIS is done so reliably and accurately.

2.4 The following document gives the list of test cases required to validate that information is transferring correctly in both directions; *section 1 test cases* (pages 4 to 5) and *section 2 test cases* (pages 5 to 7)

3 Auto-Authorisation

3.1 As part of the changes introduced the LIS system will use an auto-authorisation of all results which meet the following criteria: -

3.1.1 Positive antibody screens
3.1.2 Current group does not match previous group
3.1.3 Positive Direct Antiglobulin tests

3.2 *Section 2 test cases* (see pages 5 to 7) and *Section 3 test cases* (see page 7: 7.1 to 7.3) check the auto-authorisation program

4 Samples used for validation

4.1 The samples chosen for validation are such that they give all possible ABO and RhD results and all possible combinations of antibody screen results with the batch of screen cells used for testing. On other occasions different cell and antibody combinations will need to be used to produce the desired antibody screen reaction patterns.

Cell Name	ABO & D	Screen result pattern	Antibody used
QCV1	A NEG	- - -	None
QCV2	B NEG	- - -	None
QCV3	O POS (E-)	- + -	E
QCV4	O NEG (K-)	- - +	K
QCV5	A POS (C-)	+ - -	C
QCV6	B POS (E-K-)	- + +	E+K
QCV7	AB POS	- - -	None
QCV8	AB NEG	+ + -	D
QCV9	O NEG (K-)	+ + +	D+K
QCV10	O POS (C-K-)	+ - +	C+K

5 <u>Section 1 test cases; information transfer from LIS to AutoVue</u>

5.1 Do the details for a *Full Group* request transfer from LIS to AutoVue

5.2 Do the details for a *Short Group* request transfer from LIS to AutoVue

5.3 Do the details for a *Full group and screen* request transfer from LIS to AutoVue

5.4 Do the details for a *Short Group and Screen* request transfer from LIS to AutoVue

5.5 Do the details for an *Antibody screen* request transfer from LIS to AutoVue

5.6 Do the details for a *Baby Group* request transfer from LIS to AutoVue

5.7 Do the details for a *Cord Group* request transfer from LIS to AutoVue

6 Section 2 test cases; results transfer from AutoVue to LIS

6.1 The test cases chosen in this section are done so to reflect a full range of ABD blood groups and a full range of antibody screening result patterns with the screening cells used.

6.2 Do the results for *Full Groups* transfer from LIS to AutoVue?
6.2.1 QCV1
6.2.2 QCV2
6.2.3 QCV3
6.2.4 QCV4
6.2.5 QCV5
6.2.6 QCV6
6.2.7 QCV7
6.2.8 QCV8
6.2.9 QCV9
6.2.10 QCV10

6.3 Do the results for *Short Groups* transfer from LIS to AutoVue?
6.3.1 QCV1
6.3.2 QCV2
6.3.3 QCV3
6.3.4 QCV4
6.3.5 QCV5
6.3.6 QCV6
6.3.7 QCV7
6.3.8 QCV8
6.3.9 QCV9
6.3.10 QCV10

6.4 Do the results for *Full Group and screens* transfer from LIS to AutoVue?
6.4.1 QCV1
6.4.2 QCV2
6.4.3 QCV3
6.4.4 QCV4
6.4.5 QCV5
6.4.6 QCV6
6.4.7 QCV7
6.4.8 QCV8
6.4.9 QCV9
6.4.10 QCV10

6.5 Do the results for *Short Group and screens* transfer from LIS to AutoVue?
6.5.1 QCV1
6.5.2 QCV2
6.5.3 QCV3
6.5.4 QCV4
6.5.5 QCV5
6.5.6 QCV6
6.5.7 QCV7
6.5.8 QCV8
6.5.9 QCV9
6.5.10 QCV10

6.6 Do the results for *Antibody screens* transfer from LIS to AutoVue?
6.6.1 QCV1
6.6.2 QCV2
6.6.3 QCV3
6.6.4 QCV4
6.6.5 QCV5
6.6.6 QCV6
6.6.7 QCV7
6.6.8 QCV8
6.6.9 QCV9
6.6.10 QCV10

6.7 Do the results for *Baby Groups* transfer from LIS to AutoVue?
6.7.1 QCV1
6.7.2 QCV2
6.7.3 QCV3
6.7.4 QCV4
6.7.5 QCV5
6.7.6 QCV6
6.7.7 QCV7
6.7.8 QCV8
6.7.9 QCV9
6.7.10 QCV10

6.8 Do the results for *Cord Groups* transfer from LIS to AutoVue?
6.8.1 QCV1
6.8.2 QCV2
6.8.3 QCV3
6.8.4 QCV4
6.8.5 QCV5
6.8.6 QCV6
6.8.7 QCV7
6.8.8 QCV8
6.8.9 QCV9
6.8.10 QCV10

7 Section 3 test cases; does the REVQU program for non auto-authorisation work on the LIS system?

7.1 Have all the positive antibody screens been held?
7.1.1 Checked on each case 6.4, 6.5 and 6.6

7.2 Do non-matched groups get held?
7.2.1 O Pos
7.2.2 A Pos
7.2.3 B Pos
7.2.4 AB Pos
7.2.5 O Neg
7.2.6 A Neg
7.2.7 B Neg
7.2.8 AB Neg

7.3 Do pos DATs get held on CGV and BGV sets?

Appendix 1

		Set contents										
Set code	**Test name**	**aA**	**aB**	**aAB**	**aD**	**CTL**	**Ac**	**Bc**	**DAT**	**IAT1**	**IAT2**	**IAT3**
FGV	Full Group	✓	✓		✓	✓	✓	✓				
SGV	Short Group	✓	✓		✓							
FGSV	Full G&S	✓	✓		✓	✓	✓	✓		✓	✓	✓
SGSV	Short G&S	✓	✓		✓					✓	✓	✓
ASV	Antibody Screen									✓	✓	✓
BGV	Baby Group	✓	✓	✓	✓	✓			✓			
CGV	Cord Group	✓	✓	✓	✓	✓			✓			

Appendix 2 – Method for preparing QCV samples

1. Collect 10 empty EDTA blood bank sample tubes (6ml)
2. Label tubes appropriately (QCV1 to QCV10)
3. Select appropriate NBS donation(s) for each QCV sample

QCV1	A NEG
QCV2	B NEG
QCV3	O POS (E-)
QCV4	O NEG (K-)
QCV5	A POS (C-)
QCV6	B POS (E-K-)
QCV7	AB POS
QCV8	AB NEG
QCV9	O NEG (K-)
QCV10	O POS (C-K-)

4. From each donation aliquot approximately 2 ml of red cells from the appropriate donation into each tube
5. Wash each cell twice using saline (PBS) and leave packed.
6. To all the group A tubes (QCV1 and QCV5) add 0.5ml of monoclonal anti-B reagent
7. To all the group B tubes (QCV2 and QCV6) add 0.5ml of monoclonal anti-A reagent
8. to all the group O tubes (QCV3, QCV4, QCV9 and QCV10) add .5ml of monoclonal anti-A reagent and 0.5ml of monoclonal anti-B reagent
9. To QCV3 add 150µl of anti-E (monoclonal reagent)
10. To QCV4 add 150µl of anti-K (monoclonal reagent)
11. To QCV5 add 150µl of anti-C (monoclonal reagent)
12. To QCV6 add 150µl of anti-E (monoclonal reagent) and 150µl of anti-K (monoclonal reagent)
13. To QCV8 add 150µl of anti-D (monoclonal reagent)
14. To QCV9 add 150µl of anti-D (monoclonal reagent) and 150µl of anti-K (monoclonal reagent)
15. To QCV10 add 150µl of anti-C (monoclonal reagent) and 150µl of anti-K (monoclonal reagent)
16. For each sample top up using an inert (serologically) diluent e.g. DiaMed CellStab, Ortho Red Cell Diluent, Alsevers or PBS (saline)