



# Verification of New Blood Bank Analysers

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# Buckinghamshire Blood Transfusion

- Process ~30,000 group and saves at Stoke Mandeville Hospital and ~15,000 at Wycombe General Hospital yearly.
- Primarily for antenatal, pre-operative and haematology patients.
- Replacing three Blood bank analysers.
- Two at Stoke Mandeville and one at Wycombe.



# Blood Bank Analysers

- Received in June 2018.
- Performs grouping, antibody screening, phenotyping, DAT, crossmatching, titrations and full antibody panels.
- Capable of running 42 samples at a time.
- Very noisy.
- Crashed constantly.



# What is Verification?

- ISO 15189:2012 – the international standard for a quality management system states:
  - *‘confirmation, through provision of objective evidence that specified requirements have been fulfilled.’*
- Verified through thorough testing that the analyser is meeting the performance claims from the validation.
- Ensuring precision, accuracy and comparability through a range of results.
- Critically important that results are analytically valid.



# The Verification Process

Collection of Patient Results



Interface Testing



Reagent Stability



Evaluation of Process



# Collection of Results

- Initial analyser setup.
- Run all the samples received each day through both analysers.
- Collate results.
- Evaluate whether further testing is required.
- Does the analyser meet performance expectations?





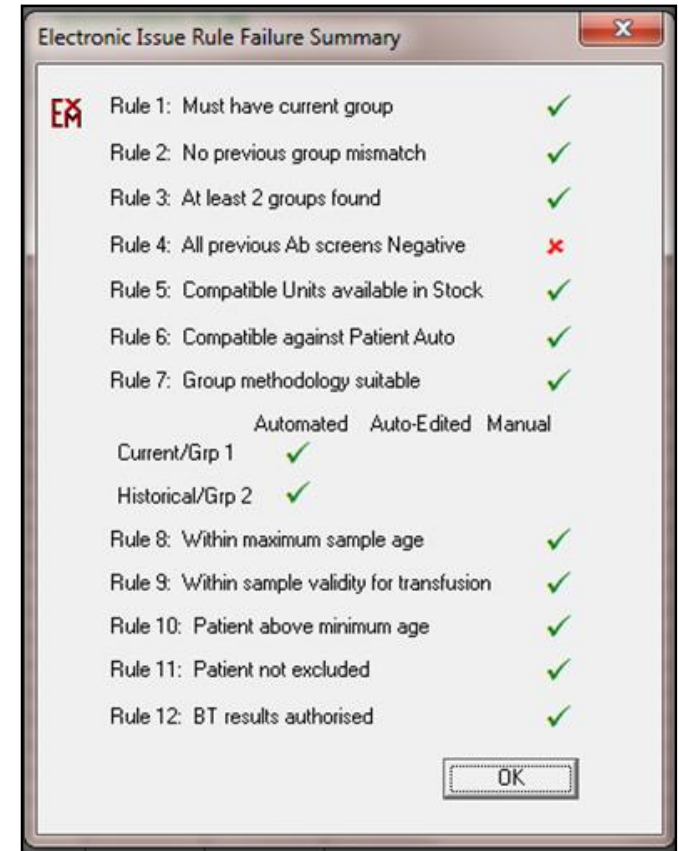
# Issues During Data Collection

- Logistically difficult to set up every day.
- Plagued with software and hardware issues.
- Limited numbers of the less common blood groups. AB- totalling 8 samples over the entire verification.
- More obscure antibodies difficult to find.
- **Under-staffing.**



# Interface Testing

- Test script produced ensuring requests and results are received and transmitted correctly for all groups.
- Do valid results transmit directly onto patient's record?
- Are all results which would affect electronic issue held back in a validation queue?
- Are patient's automatically excluded from Electronic Issue when required?





# Interface Testing Results

- All results with no errors behaved as expected.
- Group mismatches, positive antibody screens and manually amended groups were automatically excluded from electronic issue.
- **Manually amended antibody screens were not recognised and were allowed electronic issue.**
- System already in place. Addressed with an imminent WinPath upgrade.
- Interface verification successful and suitable for use.



# Reagent Stability

- Processed internal quality controls and 10 patient samples daily.

1	DATE	Lab Number	analyser	Group						Interpretation	Antibody Screen			Interpretation	Comments	Antibody specificity
				Anti-A	Anti-B	Anti-D	Control	A1	B		1	2	3			
33	16.09.19	19T008177	WinPath	4	0	4	0	0	3	A Positive	0	0	0	Negative		
34	16.09.19	19T008177	Vision	4	0	4	0	0	3	A Positive	0	0	0	Negative		
35																
36	16.09.19	19T008117	WinPath	4	0	4	0	0	4	A Positive	0	0	0	Negative		
37	16.09.19	19T008117	Vision	4	0	4	0	0	3	A Positive	0	0	0	Negative		
38																
39	16.09.19	19T008158	WinPath	4	0	4	0	0	3	A Positive	0	0	0	Negative		
40	16.09.19	19T008158	Vision	4	0	4	0	0	3	A Positive	0	0	0	Negative		
41																
42	16.09.19	19T008178	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
43	16.09.19	19T008178	Vision	0	0	4	0	4	4	O Positive	0	0	0	Negative		
44																
45	16.09.19	19T008186	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
46	16.09.19	19T008186	Vision	0	0	4	0	4	4	O Positive	0	0	0	Negative		
47																
48	16.09.19	19T008197	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
49	16.09.19	19T008197	Vision	0	0	4	0	4	4	O Positive	0	0	0	Negative		
50																
51	16.09.19	19T008168	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
52	16.09.19	19T008168	Vision	0	0	4	0	4	4	O Positive	0	0	0	Negative		
53																
54	16.09.19	19T008194	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
55	16.09.19	19T008194	Vision	0	0	4	0	4	3	O Positive	0	0	0	Negative		
56																
57	16.09.19	19T008161	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		
58	16.09.19	19T008161	Vision	0	0	4	0	3	4	O Positive	0	0	0	Negative		
59																
60	16.09.19	19T008173	WinPath	0	0	4	0	4	4	O Positive	0	0	0	Negative		

# Closing Thoughts

- Planning – Technical hitches will happen.
- Samples – Start collecting patient samples in advance. Contact NHSBT early.
- Reagents – Check stock.
- Staffing – Have someone off-bench as long as possible.
- Deadlines – It will take longer than anticipated.

