

Our Ref: 085/2019
February 2019

Re: Your request made under the Freedom of Information Act 2000

- 1) Do you have a full User Requirement Specification (URS) within your Laboratory Information Management System (LIMS) service?

No

- 2) Do you have a full (requirements) traceability matrix (RTM) to drive validation for LIMS

Partial

- 3) Do you have full validation evidence ready for review and fully referenced on your local QMS for LIMS?

Yes

- 4) Which LIMS is in use?

Integrated Software Solutions (Omnicient)

- 5) When was it last upgraded?

2017

- 6) When was the URS last reviewed?

Not reviewed

- 7) When did the MHRA last inspect the lab?

2006

- 8) How much notice did MHRA provide before this inspection?

Unknown

- 9) Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?

Yes