

Ref: FOI/GS/ID 5387

Please reply to:
FOI Administrator
Trust Management
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10 April 2019

Freedom of Information Act 2000

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to LIMS (Laboratory Information Management System).

You asked:

- 1. Do you have a full User Requirement Specification (URS) within your LIMS service?*
- 2. Do you have a full (requirements) traceability matrix (RTM) to drive validation for LIMS?*
- 3. Do you have full validation evidence ready for review and fully referenced on your local QMS for LIMS?*
- 4. Which LIMS is in use?*
- 5. When was it last upgraded?*
- 6. When was the URS last reviewed?*
- 7. When did the MHRA last inspect the lab?*
- 8. How much notice did MHRA provide before this inspection?*
- 9. Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?*

Trust response:

1. We did not understand what information was required.
2. Yes
3. Yes
4. iLab TP (Telepath)
5. Software update planned for Tuesday 9 April 2019
6. See Answer 1
7. November 2018
8. One week.
9. No