EQA provider template for reporting performance concerns to MHRA

1. Device description / analyte

2. Reporting reason (multiple options can be ticked)

- ☐ Consistent positive bias
- ☐ Consistent negative bias
- ☐ Concentration-dependant bias
- ☐ Imprecision
- ☐ False-positive results generated
- ☐ False-negative results generated
- ☐ Other

3. Provide a summary of observations / issues

4. What action have you taken as an EQA provider to resolve this issue?

5. Provide a summary of any communications with the manufacturer, including dates and outcomes

6. Is the issue related to a clinical risk or evidence of harm to patients?

   Yes / No

   Evidence to support clinical risk / harm

7. Is the issue related to a technical issue?

   Yes / No

8. Over what timeframe has this issue been observed?

9. Do you think the issue has now been resolved and what further action should the MHRA consider?
