**Record of Technical Anomaly**

**Technical Anomaly No: 316**

**PART 1: Issue, impact assessment and signing open**

**Raised by: Hannah Ford** **Date: 16/12/21**

**OP / Method: 224**

**Analytical sequence(s) affected** *(where appropriate)***: EC0787 rerun**

**Details** *(please tick relevant box(es) and provide supplementary information where required)***:**

□ QC point(s) above/below ±2SD R Bracketing standard(s) outside limits

□ QC point(s) above/below ±3SD □ QC Recovery outside limits

□ QC point(s) outside expanded uncertainty R Other *(add details below)*

Signal to noise below acceptable limit of 10 for both 2.5 and 5 standard but residuals acceptable for all calibration levels. All levels included in calibration curve, reporting limit adjusted to 5ppb and LOD adjusted to 2ppb. This acceptable as, although S/N failed for 5, chromatography of 5ppb peak is visually acceptable and QCB unspiked is quantified close to historic average, which is between 5 and 10ppb calibration levels.

4th bracketing standard of 6 also failed (injection 95), due to presence of no peaks either for EC or IS. Injection was repeated (injection 113) with same result. Vial was visually inspected and found to be almost empty, which could be due to either hairline crack in vial causing leak, or incorrect preparation of vial. Either way the issue was not instrumental and no samples were affected by same issue.

□ No apparent reason for this anomaly

**Recommended Action:**

□ No action required out with the usual close monitoring of the Quality Control data in subsequent runs.

**Explanation why the issue does not impact data quality & why it isn’t a departure:**

Chromatography of 5ppb peak is visually acceptable and QCB unspiked is quantified close to historic average, which is between 5 and 10ppb calibration levels.

Bracketing standard issue was not instrumental and no samples were affected by same issue.

**Management Review:**

***I agree to open this Technical Anomaly and confirm that this would not prevent results from being reported.***

**Authorised by:**

**(Technical/Services/Quality Manager)**

**Date:**

**PART 2: Follow-up actions and close-out**

**Follow-up actions conducted:**

□ No follow up required

**Signed off & closed by Quality Manager:**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

