**Record of Technical Anomaly**

**Technical Anomaly No: TA427**

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

**Raised by: Hannah Ford** **Date: 08/02/22**

**OP / Method: OP222**

**Analytical sequence(s) affected** *(where appropriate)***: 11/22**

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

R QC point(s) above/below ±2SD □ 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*

Both Actual Strength and Actual-Apparent difference were >2SD. It was noted that analyst performing this run (HF) was exhibiting a positive bias with this point and a second point notably above the chart mean (44.64 and 44.56, mean 44.47) and both points performed by analyst on the previous chart (ActS042) were also >2SD (40.69 and 40.68, mean 40.55). Every QC result by this analyst has been above respective chart means since being signed off on the method (going back to ActS040).



□ 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.

As method is so hands-on, it is highly susceptible to analyst error. Analyst bias will be investigated with a mutual observation of and by another analyst experienced in the method to identify any differences in carrying out standard procedure. If this does not reveal anything, analyst will perform trial distillations on Ethanol/UHQ mixtures (where there is no obscuration so Actual strength can be directly compared to Apparent strength results).

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

The most common source of error in this method is a loss of ethanol which would result in a low bias – a high bias is less concerning. Also all QC results are still within 3SD action limits. The three samples on the run in question are SWA legal samples, and the results obtained would not give cause for authenticity criticism.



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

