

Standard Operating Procedure

Title: Microbiology Laboratory Investigation and Retest Procedure for Atypical and Out-of-Specification Results

procedures should provide guidance on when OOL results should be more thoroughly investigated including when to raise DR.

4.1.5 For Action Level excursions (OOS) it is necessary to investigate thoroughly to determine a definitive cause and recommend corrective and preventative actions, (CAPA). If an OOS result, is deemed valid, A DR should be raised in accordance with QMS 035 and further investigation should be conducted.

4.1.6 Phase 1 and 2 should include assessment of the following details as a guideline. This list is not exhaustive and other relevant information should also be included where possible.

4.2 Phase 1

4.2.1 When completing Phase 1 of Form 690 for OOS/OOL results the following details should be evaluated.

- Sample collection, storage and preparation
- Sample and test preparation
- Test equipment (calibration)
- Technician Training records
- Expiry of consumables
- Media quality control passed
- Test method followed
- Observations made during test procedure.
- All calculations checked and verified
- All test control results, where relevant, are satisfactory
- Review of other test results for the test session, to determine a trend

4.2.2 At the conclusion of Phase 1 Investigation, an evaluation of the validity of the original OOS/OOL result should be made. If through the investigation process, it has been demonstrated that the OOS/OOL result is valid, a DR should be raised and a more detailed investigation initiated, including a root cause analysis.

4.3 Phase 2

4.3.1 Phase 2 involves a thorough systematic analysis of the incident, to determine the root cause for the OOS result. The investigation should be tailored for each incident to reflect the significance of meeting or exceeding either the ALERT or ACTION Levels.

4.3.2 The minimum requirements for most situations are listed as below, this list is by no means exhaustive and specialist assistance from departments other than Microbiology should be utilised in the investigation.

4.3.3 Where re-testing, repeat testing or confirmatory or investigational testing is required to confirm the root cause, refer to Section 5.

5. Retest Procedures

5.1 Prior to conducting any re-testing, Microbiology Manager or delegate must be consulted.

5.2 As part of Phase 2, further testing may be required to determine a root cause(s). Further testing may also be required if a possible cause has been identified.

5.3 A second technician may perform retesting where appropriate or required.

5.4 Standard Retest Protocol

5.4.1 The retest protocol generated in Phase 2 must specify which retest results will be reported