CIAL | When does CIAL Charge for Investigations?

CIAL makes every effort to minimize **Out of Specification (OOS)** results through meticulous training and review. Despite these efforts, OOS results are possible. Each sample received will be tested, and if necessary, investigated to the extent defined below:

- If method validation (VAL.900.xxx) and a corresponding Customer Approved Method (CAM) has been established, CIAL can perform additional investigative testing at no additional cost.

- If no method validation or CAM are associated with the sample, investigative testing will come at an additional cost based on the requested scope of work.

The following process is used for the assessment of OOS investigations:

1. Initial (Phase 1) testing submitted for *Potency* testing will be tested per CIAL's Terms and Conditions - *Services*.
    a. If the Phase 1 result conforms to the defined acceptance criteria, the result will be reviewed and published to the Customer's reports website.
2. If Phase 1 recovers a result that does not conform to the defined acceptance criteria, referred to as "Out of Specification (OOS)", the sample will be assessed if investigative (Phase 2) testing is needed.
    a. CIAL will perform an internal review of the Phase 1 data, normally through a re-pour (RP) and/or re-dilute (RD) of the initial preparation, to confirm no laboratory and/or instrument error is found to be the reason for the OOS result.
3. If the sample is associated with a method validation (VAL.900.xxx) and corresponding Customer Approved Method (CAM), Phase 2 testing can be performed at no cost to the Customer.
4. Phase 2 testing may include any combination of the following: *re-pour*, *re-dilute*, and/or *re-prep* of the sample.
    a. The result(s) of Phase 2 testing will be reviewed, along with the Phase 1 result, to assess if the root cause can be identified.
        i. If the root cause of the OOS is determined to be the result of system or analyst error, the affected result(s) will be *invalidated*.
            1. An *invalid* result(s) will be assessed to determine if additional testing is required to produce a valid result.
        ii. If the root cause of the OOS is consistent between Phase 1 & 2, and no laboratory or sample error identified, the result(s) will be considered *inconclusive.*
            1. An *inconclusive* result(s) will conclude the OOS investigation and valid result(s) published.
5. If the sample is not associated with a validation (VAL.900.xxx) and does not have a corresponding Customer Approved Method (CAM), additional investigative testing can be requested (refer to Phase 2) at an additional cost to the Customer.
6. If further investigative testing (Phase 3) is requested, the Customer will be responsible for any additional costs.
    a. The cost of Phase 3 testing will be determined by the requested scope of work and assessed on a case-by-case basis.