



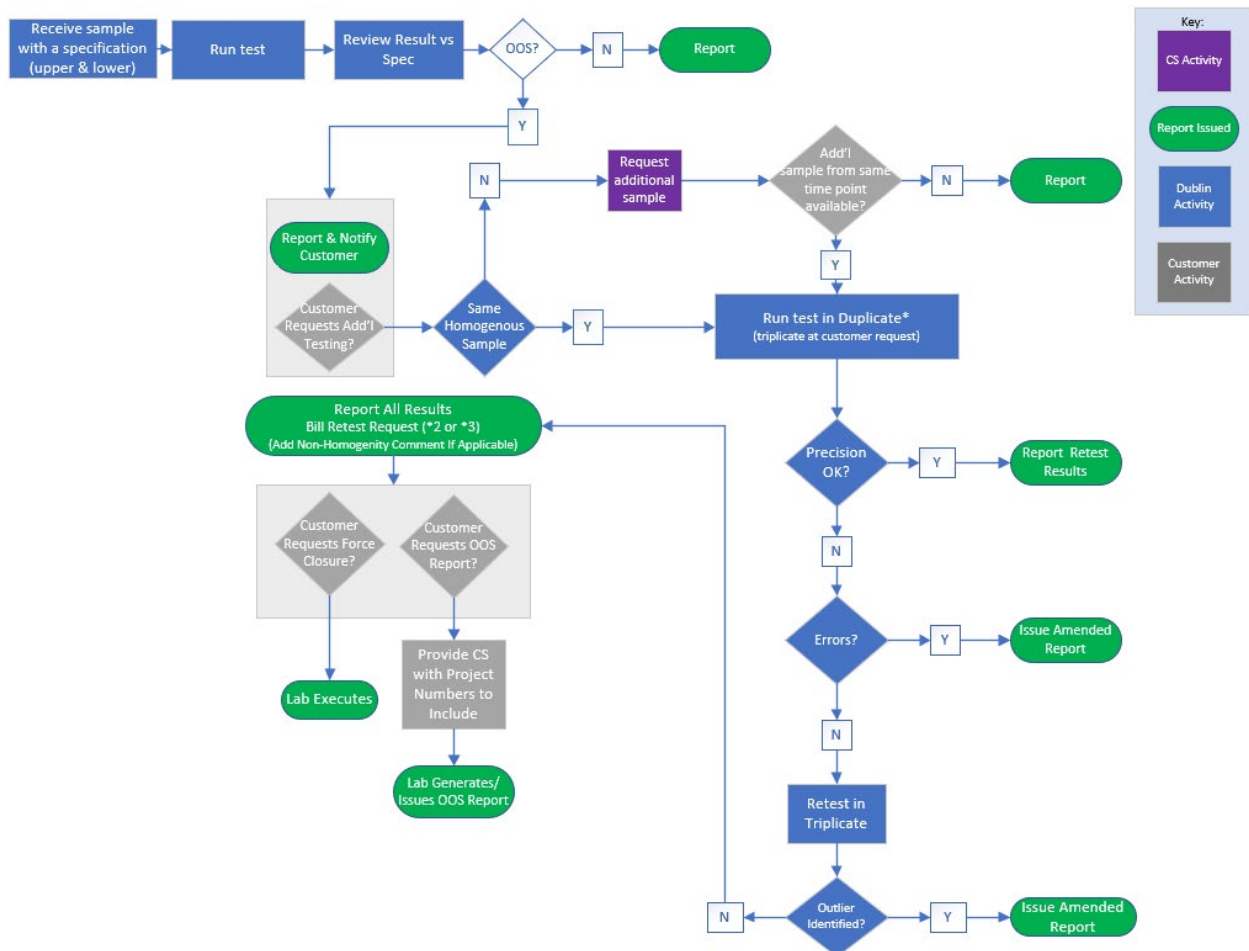
## MICRO OUT OF SPECIFICATION (OOS) PROCESS

### Why should I enroll in this OOS process?

The OOS process is designed to provide additional data for customers receiving results which do not meet their expected levels and/or specifications on specified submissions. The concept is focused on additional testing; with the goal to provide a statistical evaluation of the result and determine the possibility of outliers.

Customers can enroll in this program by contacting our Customer Service team ([nqacdublincustomerservice@us.nestle.com](mailto:nqacdublincustomerservice@us.nestle.com)) and registering your NQAC Customer ID Number for this process.

High-level process flow is outlined below:



**\*Please Note: additional charges may apply per above**

## What do I need to provide to ensure success?

1. The laboratory will need a clear minimum and/or maximum specification provided when submitting. Provide quantitative specifications in comma-separated format (ex: 10,000) per 1 g or mL. The laboratory team will test the appropriate number of dilutions to meet the specification.
2. If you do not provide clear product specifications and you are signed up for this process, our team will not follow the OOS process steps above. The submission will follow the routine testing and reporting process with no OOS emails sent.

## What should I expect to see with OOS Alerts?

1. All submissions sent under your NQAC Customer ID Number will be designated as "OOS alerts needed".
2. Our team will compare the provided minimum and/or maximum specification to the test results.
3. If the result is found as OOS per the specification, an email will be sent alerting the report recipients what test is OOS so the next steps can be confirmed.
4. Results will automatically be reported.

## What are the limitations/risks related to this process?

1. Pathogens (*Salmonella*, *Listeria*, *Cronobacter*, STEC) are excluded from this process. OOS results are issued through Presumptive Notifications (must be signed up for these notifications and do not select "Full Submission" online).
2. Customer Specific Methods (CSMs), Microbial Identification, Pathogen isolate confirmation, Serology, and Spoilage Assessments are excluded from this process.
3. Process variation has been seen to also attribute to variance in analytical results. Because of this, the process may produce inconclusive results when the following occur:
  - **Situations where the original homogenous retain sample is no longer available for testing.** it is not recommended to use only analytical reproducibility to evaluate statistical equivalence. Results may vary and be impacted by storage, shelf-life, time-point used and, if these factors are not controlled, must be accounted for when evaluating the results. When retests meet data acceptability requirements, they will be billed per our retest policy at listed price.
  - **Original container.** Another un-opened finished product container or a sub-sample which matches the original submission from the same time-point sent. Retest results have been proven to vary and may be impacted by storage, shelf-life, time-point used and, if these factors are not controlled, they must be accounted for when evaluating the results.

## How do I add this correctly to my submissions?

1. **Online submissions:** choose specification in the "limit or level" and then enter the value, including units of measure. If more space is needed the utilize the test instruction to add longer specifications or more details.
2. **Manual submissions:** choose specification from the drop down and then enter the value including units of measure. If more space is needed adjust the row height to allow for additional space.
3. **SAP submissions:** add specifications into SAP as needed and this will flag on our side automatically.
4. **All Probiotic Test Requests:** It is a requirement to provide a COA of probiotic strains and estimated levels to allow for the proper method preparations.

**Feel free to request support from our Customer Service team as we are here to assist you with setting up the process correctly and answering your questions!**