

Study designs

NOTE: Follow the design listed below unless otherwise noted on the Method Type tab(s)

NOTE: Detailed study designs are discussed in AOAC training courses or through AOAC technical consultants

Study	Level	Study Design
Selectivity	Full Study	Perform the full study. This includes inclusivity & exclusivity for micro. This includes analytes, cross-reactors and potential interferents for chemistry.
	Subset	Perform a subset of the full study (minimum of 10 or 50% of required amount, whichever is greater). This includes inclusivity & exclusivity for micro. This includes analytes, cross-reactors and potential interferents for chemistry. Subset must be chosen in collaboration with AOAC consultant.
Calibration Study	Level 2 or 3	Run standard or samples across the methods analytical range to establish linearity.
Matrix Study & if applicable Limit of Detection (LOD)/Limit of Quantification (LOQ)	Level 2	For methods with a claim of 1 to 5 matrixes, test 1 matrix. For methods with a claim of 6-10 matrixes, test 2 matrixes. For methods with a claim of 11-25 matrixes, test 3 matrixes. For >25 matrixes, test 4 matrixes. Must test diverse and challenging matrixes, matrixes will be chosen in collaboration with AOAC technical consultant. At least 1 matrix must be tested from each matrix group. If standards are matrix matched then additional matrixes may be required per standard based on subject matter expert input.
	Level 3	For methods with a single matrix claim, test that matrix. For methods with a claim of 2 to 5 matrixes, test 2 matrixes. For methods with a claim of 6-10 matrixes, test 4 matrixes. For methods with a claim of 11-25 matrixes, test 5 matrixes. For >25 matrixes, test 6 matrixes. Must test diverse and challenging matrixes, matrixes will be chosen in collaboration with AOAC technical consultant. At least 1 matrix must be tested for each category group (e.g. food, environmental sample or cannabis). If standards are matrix matched then additional matrixes may be required per standard based on subject matter expert input.
Independent laboratory study	Level 2 or 3	Independent lab tests 1 matrix study for every 5 tested in the matrix study above.
Product Stability	Internal Studies	Internal stability testing is expected. Changes to shelf life must be reported as a level 1 modification. Any changes to instructions or literature would follow standard editorial level 1 modification process.
	Level 2 or 3	Perform accelerated or real-time stability testing, internal study designs are acceptable. If accelerated stability is submitted, real-time must be submitted at next annual renewal.
Lot-to-lot consistency	Internal Studies	Internal lot to lot consistency data is expected. If data from the new process falls outside of the performance claims (within method sponsors quality management system tolerance), change must be reported to AOAC as a level 2 modification. If the same change is made across multiple SKUs, the method sponsor may choose to test lot to lot consistency on representative SKUs from diverse technology platforms. The remaining affected SKUs may be verified through internal verification of product quality. Any changes to instructions or literature would follow standard editorial level 1 modification process.
	Level 2 or 3	Real time stability and lot-to-lot consistency may be combined. Lot-to-lot consistency testing uses 3 lots of the new version of the method only.
Robustness	Level 2 or 3	Perform robustness testing on 1 matrix.
Instrument Variation Study	Level 2 or 3	Perform instrument variation study on 1 matrix.
Verification of product quality	Internal Studies	Internal verification of product quality is expected. If data from the new process falls outside of the performance claims (within method developers quality management system tolerance), change must be reported to AOAC as a level 2 modification. Any changes to instructions or literature would follow standard editorial level 1 modification process.