Correlation of Drug-Testing Results — Immunoassay versus Gas Chromatography-Mass Spectrometry

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ABSTRACT: The need for and prevalence of workplace drug-testing programs mandate the development of an effective and efficient two-step test strategy. Successful implementation of the two-step test strategy relies on the establishment of a reasonable correlation between the preliminary and the confirmatory test data and the selection of an appropriate cutoff for each test step. Correlations of test data derived form these two test steps were most commonly studied *qualitatively* by comparing the positive/negative test result concluded by these two test steps; however, when instrument-based immunoassays (IA) are used in the preliminary test step, the resulting "semiquantitative" and "apparent" concentration of the targeted analyte can be *quantitatively* correlated to the analyte concentration as determined by gas chromatography-mass spectrometry (GC-MS). Specimens selected for quantitative correlation studies should be clinical specimens with the distributions of metabolites similar to that present in test specimens; if the resulting correlation data are to be used for selecting appropriate/corresponding cutoffs for these two test steps, the concentrations of the targeted analyte in these specimens should also be within a narrow range centering on the proposed GC-MS cutoff concentration. Among the very significant number of reports correlating IA and GC-MS test data, *cannabis* and urine are the most common drug category and test specimen studied. The degree of correlation between IA and the GC-MS test data varies with the IA reagent manufacturers, and even with manufacture dates/lots of those supplied by the same manufacturer. The most important factors underlying the observed degree of correlation are undoubtedly the cross-reacting characteristics of the antibody and the metabolite distribution pattern of the drug of concern. Over time, specificities of IA reagents have been optimized so that the two-step test strategy can be most effectively and efficiently applied using the cutoffs mandated by workplace drug-testing programs. The nature of correlation and the selection of appropriate/corresponding cutoffs between IA and GC-MS test data derived from alternate biological matrices are yet to be fully understood and established.

KEY WORDS: Alternative specimen, drug of abuse, GC-MS, immunoassay, urine.