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Reply to "Risks of 'Blind' Automated Identification Systems in Medical Microbiology"

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We thank Mancini et al. for their correspondence (1) in relation to both their and our recent publications (2, 3). Mancini et al. raise the concern that if clinical microbiology laboratories are unable to modify/enhance automated identification system databases, in particular matrix-assisted laser desorption ionization (MALDI)–time of flight (TOF) mass spectrometry (MS) databases, that the consequence may be failure to identify or misidentification of new and emerging taxa. The point raised is important, and while we acknowledge that closed access to databases could be inhibitory, failure to restrict access to databases could have serious consequences. In particular, the unsystematic/unregulated enrichment of databases could generate erroneous microbial identifications.

To avoid such errors, *in vitro* device (IVD) manufacturers and clinical microbiology practitioners in the United States must adhere to the regulatory requirements set forth by the Food and Drug Administration (FDA). FDA requirements stipulate that IVD systems are closed to the user and that the addition of strains/species to a regulated database requires additional submission of data prior to clearance by the FDA. To further prevent misidentifications, automated identification systems should discriminate between those taxa included and those not included in the database. Ideally, in situations when taxa not included in the database are encountered, "no identification" would be returned rather than an incorrect identification. This outcome has been demonstrated in some MALDI-TOF MS evaluations (4, 5).

Laboratories do have the option of procuring and concomitantly setting aside data in a research-use-only database. However, as suggested by Mancini et al., and endorsed by us, in those environments not subject to regulatory body restrictions, database enhancement should be the domain of larger, centralized reference laboratories, and standardized efforts to enforce this practice should be encouraged. Alternatively, and especially in those environments subject to requirements established by regulatory bodies, the responsibility for the continued development and validation of IVD databases with rare, new, and emerging strains/species for regulatory body review could be borne solely by the IVD manufacturers themselves, although perhaps the optimal approach is a collaborative one between large government-funded reference laboratories and the IVD manufacturers. In this instance, strains/species could be characterized and analyzed by the reference laboratories and the resultant data shared with the IVD manufacturers for regulatory body submission.

In summary, the points raised by Mancini et al. certainly give us pause for thought; however, as outlined above, there are factors that should, and indeed do, preclude broad-sweeping user modifications of databases associated with automated identification systems.

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