Performance and Utility of Whole Blood and Oral Fluid Point-of-Care Cotinine Testing When Compared to LC/MS-MS

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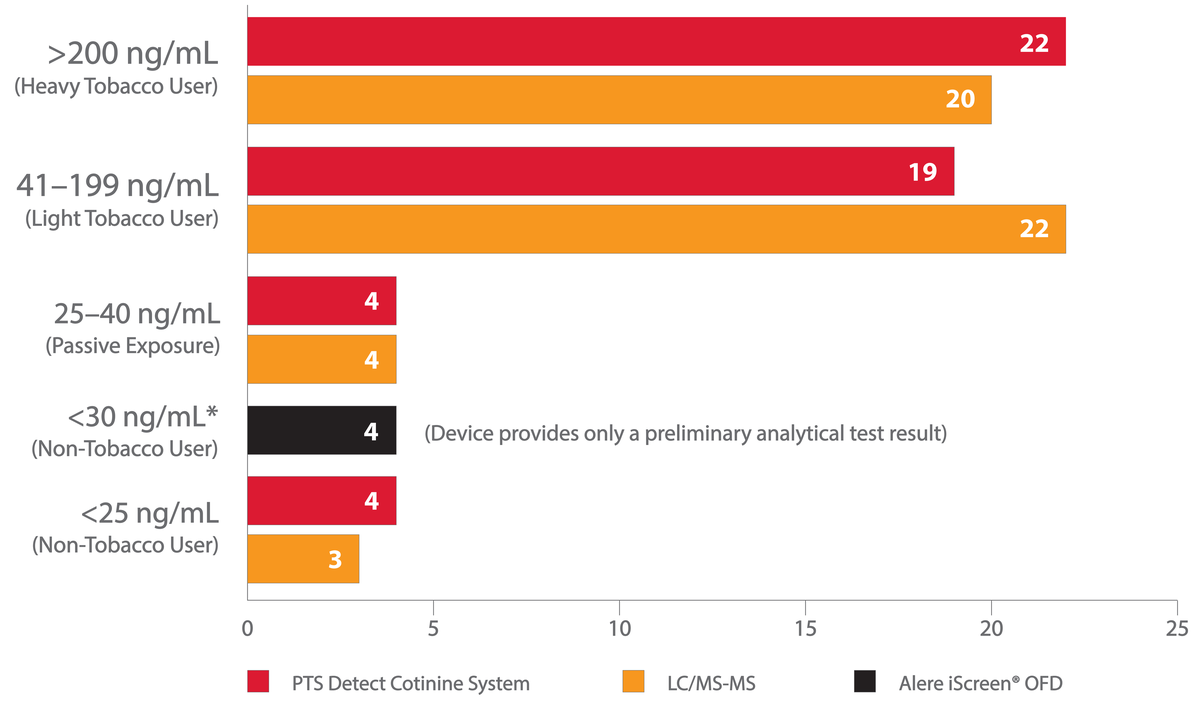
Point-of-care testing (POCT) for tobacco use detection via cotinine levels is widely utilized to stratify potential health risks in settings such as employee wellness events, insurance screenings and the new hire process. Two POCT methods were used to screen a population of non-tobacco and tobacco users (n=49) to determine tobacco use status. The first method (PTS Detect™ cotinine system) utilized whole blood to obtain a quantitative cotinine value, with a cut point of <25 ng/mL indicating a non-tobacco user. The second method (Alere iScreen) utilized oral fluid to obtain a qualitative value with a cut point of <30 ng/mL also indicating a non-tobacco user. Both were considered equivalent sources despite the higher oral fluid cut point of <30 ng/mL due to saliva cotinine levels being 1.3x higher than plasma levels. Both POCT methods exhibited a sensitivity of 97.8% and specificity of 100% compared to the LC/MS-MS methods. The main differentiator between the two POCT methods was the ability of the whole blood quantitative device to determine categorical tobacco use as effectively as the LC/MS-MS method based upon four categories of placement. The placement categories used were <25 ng/mL indicating a non-tobacco user (category 1), 25-40 ng/mL indicating passive exposure (category 2), 41-199 ng/mL indicating light use (category 3), and >200 ng/mL indicating heavy use (category 4). The LC/MS-MS and whole blood POCT method respectively placed individuals in category 1: 3 and 4, category 2: 4 and 4, category 3: 22 and 19, and category 4: 20 and 22. The performance of the PTS Detect cotinine device in classifying individual tobacco use showed significant correlation compared to LC/MS-MS. Additionally, while the sensitivity and specificity of the whole blood and oral methods were the same, the quantitative POCT method demonstrated greater utility for the applications examined by providing a definitive value for cotinine. This allowed an accurate categorical determination of tobacco use at the point-of-care within 5 minutes, thereby reducing the need for confirmation testing that may be required when using a qualitative method, such as the oral fluid method examined.

Nicotine Use Placement



*Alere iScreen OFD Cotinine Test Device, Package Insert for the COT Test for Oral Fluids. Limitations. 11-19-2013.

pts Diagnostics

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