A Comparative Evaluation of Wondfo SAFElife™ Multi-Drug Rapid Hair Test with Neogen® ELISA in Human Hair: Comparison with Gas Chromatography or Liquid Chromatography-Mass Spectrometry

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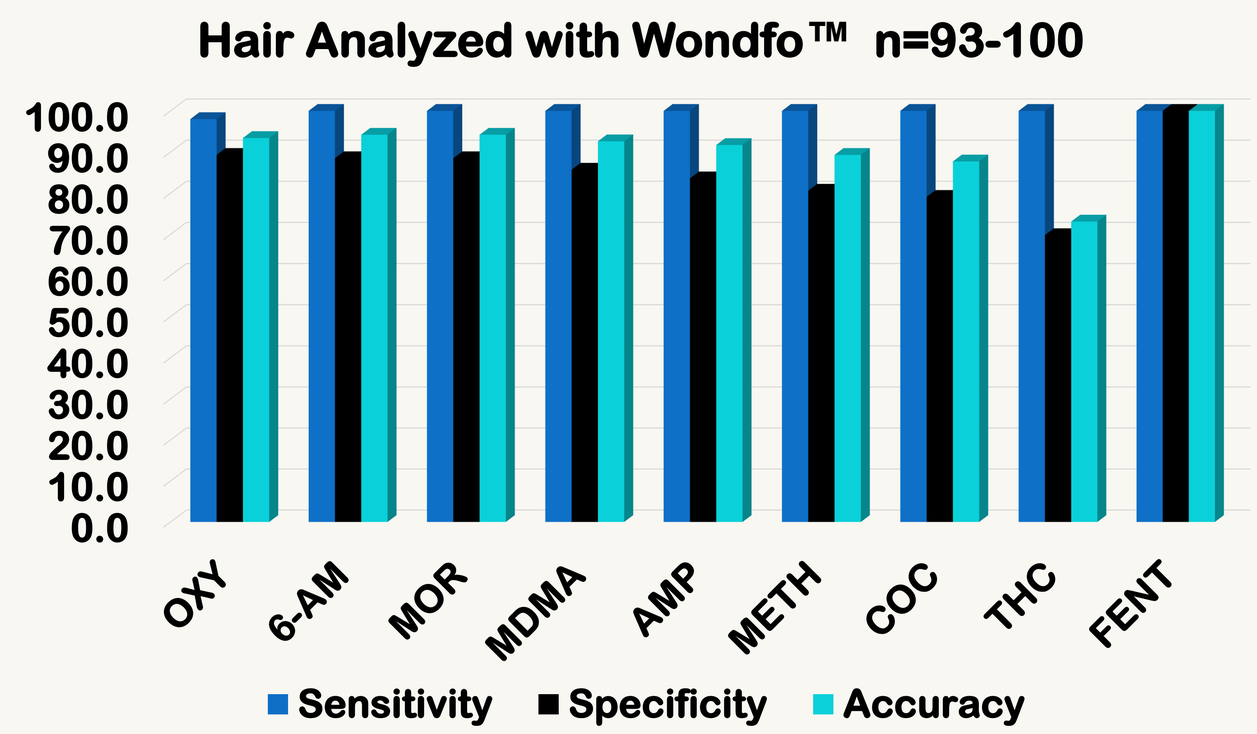
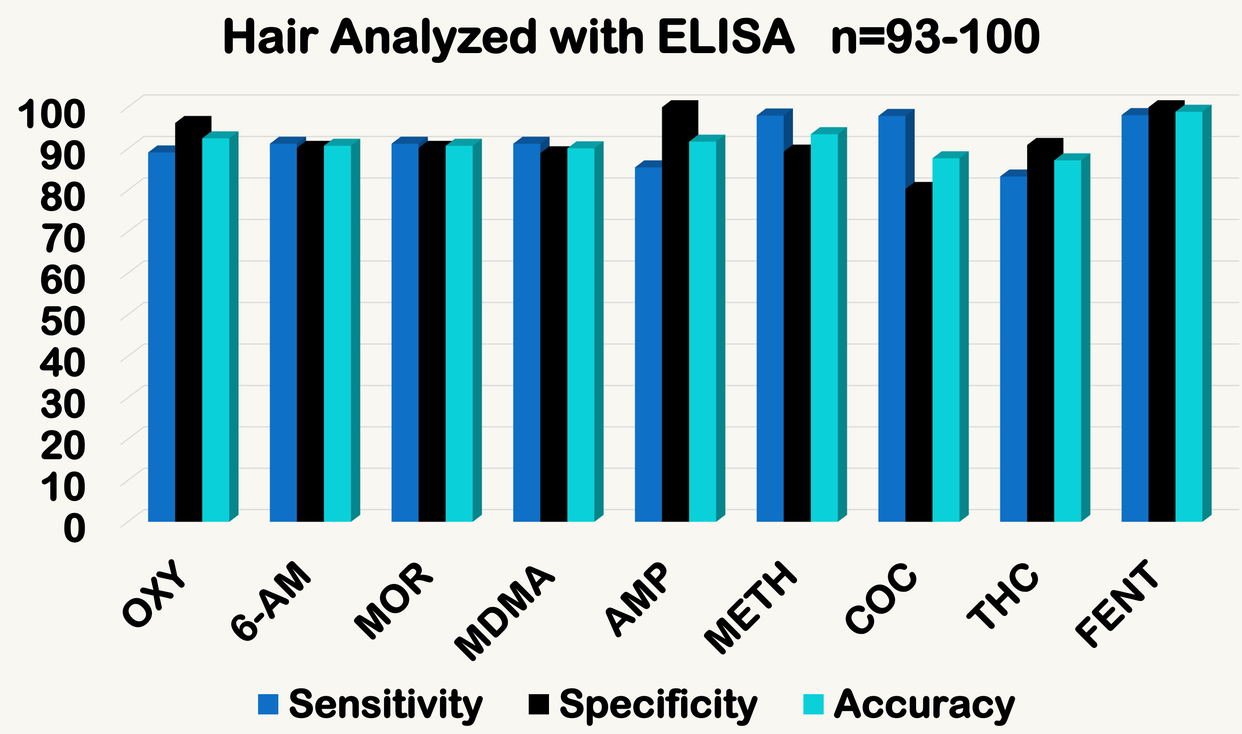
Background and Objective

This study compared Wondfo SAFElife™ Multi-Drug Rapid Hair Test utilizing competitive lateral flow with Neogen® ELISA (Enzyme-Linked Immunosorbent Assay) response for the initial screening of drugs of abuse in previously tested donor samples. The following drugs were tested utilizing both screening methods with their corresponding cutoff values: Amphetamine (500 pg/mg), Methamphetamine (500 pg/mg), MDMA (500 pg/mg), Oxycodone (200 pg/mg), Fentanyl (40-Wondfo™, 100 pg/mg-Neogen® ELISA), Cocaine (500 pg/mg), Opioids (200 pg/mg (target is morphine)), 6-Monoacetylmorphine (200 pg/mg), THC (100 pg/mg-Wondfo™, THCA-1.0 pg/mg-Neogen® ELISA). Donor samples were re-evaluated with Gas Chromatography Mass Spectrometry (GC/MS) or Liquid Chromatography with Tandem Mass Spectrometry (LC-MS/MS) to determine quantitative values of drugs in each specimen. Our objective is to evaluate the rapid hair test to a proven laboratory-based screening test method currently utilized by Omega Laboratories Inc. for insurance and workplace testing.

Accuracy Wondfo SAFElife™ Multi-Drug Rapid Hair Test with Spiked Controls

Conc.	Opiates		Amphet		Meth		MDMA		Cocaine		Fentanyl		Oxycodone		THC		6-AM	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
-100% cutoff	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-75% cutoff	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-50% cutoff	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-25% cutoff	14	6	17	3	15	5	19	1	13	7	12	8	12	8	16	4	13	7
CUTOFF	7	13	7	13	7	13	8	12	8	12	7	13	6	14	7	13	7	13
+25% cutoff	0	20	2	18	3	17	2	18	3	17	1	19	1	19	3	17	5	15
+50% cutoff	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
+75% cutoff	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20
+100% cutoff	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20





Sensitivity (*correctly identifying a true positive*) = true positives/(true positives + false negatives)

Specificity (*correctly identifying a true negative*) = true negatives/(true negatives + false positives)

Accuracy (*the proportion of true results*) = (true positives + true negatives)/ total

Discussion

The sensitivity, specificity and accuracy of the Wondfo SAFElife™ was calculated for donor samples using the above formulas for each drug class in comparison with GC/MS or LC-MS/MS quantitated results. Sensitivity ranged from 98 to 100% for all assays. Specificity ranged from 79.1 to 100% for all assays except delta-9-THC which was lower at 69.8%. Accuracy was between 87.7 and 100% for all analytes with delta-9-THC again being lower at 73.1%. Neogen® ELISA had the corresponding ranges for donor samples: sensitivity= 83.3 to 98.1%, specificity= 80.3 to 100%, accuracy= 87.2 to 98.9%.

No significant differences were observed for any assays when comparing hair color and type.

The Wondfo SAFElife™ accuracy around the cut-off with spiked controls ranged from 95% to 98%. All false negatives and false positives were within +/-25% of the cut-off for the spiked controls.

Conclusion

Both the Wondfo SAFElife™ and Neogen® ELISA yielded low false negatives when compared to the confirmatory quantitative values. The Wondfo SAFElife™ appears to have a low rate of false positives, except for THC, which may be due to the cross-reactivities to delta-8-THC, carboxy-delta-9-THC and cannabinol which were not measured by LC-MS/MS. This may also account for the lower specificity and accuracy response with the THC assay. Excluding THC for the Wondfo SAFElife™, the rate of detection of drug usage in hair samples were comparable for both testing methods. Future studies may include identifying other marijuana constituents and metabolites as a possible explanation for the THC false positives.