

**Reliability study of Roche Diagnostic Systems' TesTstik screening for amphetamine, cocaine, marijuana and morphine in urine.** Bogema, S.C., Forensic Testing, Inc., Clifton, VA. Testing for drugs of abuse in urine has become commonplace in the US criminal justice system. The technology of immunoassay has expanded from reagent systems for laboratories to disposable devices for point of care testing. On-site drug testing allows immediate identification of presumptive positive and negative specimens. The Roche Diagnostic Systems' (RDS) OnTrak TesTstik™ is an immunoassay device intended for on-site screening for individual drug classes at DHHS/DOT cutoffs in urine. The objective of this study was to determine the reliability of the TesTstik for initial screening of amphetamine (AMP), cocaine metabolite (COC), morphine (MOR) and marijuana metabolites (THC). The study consisted of two parts: 1) a precision study to determine the accuracy of the stated cutoffs, and 2) a clinical study of negative and positive patient specimens to determine specificity.

The precision study consisted of testing calibrator urine solutions at 50, 75, 125 and 150% of the DHHS/DOT cutoffs (N=20). Results below are percent negative results for each cutoff:

<u>CUTOFF</u>	<u>AMP</u>	<u>COC</u>	<u>MOR</u>	<u>THC</u>
50%	100%	85%	100%	100%
75%	95%	55%	100%	85%
125%	30%	5%	30%	0%
150%	10%	0%	5%	0%

The clinical study showed 0% false positives for all drug classes (N=50). The clinical study showed 0% false negatives for all drug classes (N=50). The RDS OnLine immunoassay was used for laboratory comparison. All positive specimens for amphetamines were confirmed by GC-MS for amphetamine greater than the DHHS cutoff of 1000 ng/ml.

TesTstik provides the screen result in several minutes and is simple to use. The TesTstik is dipped into the urine specimen, removed after ten seconds and a cover pulled over the dipped portion of the device. A Test Valid window indicates when the test is complete. The presence of a blue line in the Test Result window indicates a negative result.