

510k Submission for  
**QuikPac II One Step Amphetamine Test**  
Syntron Bioresearch, Inc.

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## Summary of Safety and Effectiveness

The sponsor, Syntron Bioresearch, Inc. (2774 Loker Ave. West, Carlsbad, California, 92008), has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Amphetamine and its metabolites in a screening format.

The trade name of the device is QuikPac II One Step Amphetamine Test having a designated common name of Amphetamine Test System and a classification as a class II device per 21 CFR ¶ 862.3100. This device is intended for professional medical/forensic screening of urine.

Syntron's QuikPac II One Step Amphetamine Test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody:antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 500 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

In-house testing of Syntron's QuikPac II One Step Amphetamine Test yielded a relative sensitivity and specificity of 1.00 and an accuracy of 100% when tested against Syva EMIT® II on samples documented to be positive by GC/MS. A clinical trial consisting of 308 samples was run and the combined data yielded a relative sensitivity of 100%, a relative specificity of 100%, and an accuracy of 100% when compared to Emit® II.

All positive samples by either screening method were confirmed by GC/MS. The results on the 13 discrepant samples clearly demonstrate the same errors by both. Thirteen (13) of the samples were positive for Amphetamine by either Emit® II or QuikPac II, but negative for Amphetamine by GC/MS. Of these 13 false positives twelve (12) were positive for Ephedrine by GC/MS and one (1) was positive for Phenyl Propanolamine (PPA) by GC/MS.

Additional information pertaining to this submission may be obtained by contacting Dr. Cleve W. Laird, President, Drial Consultants, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.