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Memorandum

Kroll

To: Dr. Walt Vogl

From: Pat Pizzo

Date: 7/7/04

RE: **Proposed Guidelines**

My concerns with the proposed guidelines are listed below:

1 EDUCATION – I believe a considerable amount of education should be provided prior to the introduction of alternative matrix and POCT. The education should be directed to collectors, MRO's, TPA's and the end user the industry clients. Many of the companies using urine drug screen testing still do not understand the result of positive, adulterated and invalid test. Although these guidelines are for federal employees, they will be accepted by non regulated industries and mandated for government agencies. SAMHSA has become the standard of excellence and any procedure endorsed by HHS will be implemented by states and non-regulated industries. Non-regulated industries frequently do not use MRO's which makes the education of the interpretation of results for POCT and alternative matrix testing critical.

2. HAIR – The issue of Racial Bias is still unresolved. The Hair proficiency test results were below the standards achieved by urine based proficiency testing. Collection issues such as extensions, bald/shaved body, claims of contamination by collector or collection device are a concern. Is ADA an issue? With a 90 day detection window will reformed drug users be subject to discrimination?

3. SALIVA – Why do saliva if you have to do a urine collection to detect marijuana. Education of clients of the half-life of drugs in saliva.

4. CONFIDENTIALITY - How can you maintain the high degree of confidentiality that currently exists in the program if POCT is allowed? The person performing the test not only knows the donors name and SS#, but also what they look like. How do you control the POCT provider from determining the outcome of the test to benefit his friends or a candidate he really wants to hire?

CONSISTENCY – How can a program such as the DOT have any consistency when companies would have the option of using different matrix for testing? Many companies do not have a standardized program and allow each division to determine testing criteria. Currently this may mean multiple labs. Under the new proposed guidelines this may mean a donor in location one is using hair and a donor in location two is using urine.

NEGATIVE MIGRATION – Historically the employee who is a drug user has migrated to the company that does not have a drug policy. Because the detection windows for the various matrixes are so different, a donor could migrate to the industry that suited his purpose for testing.

REGULATION OF POCT LOCATIONS – The certification and inspection process for the current 50 labs in the National laboratory Certification Program (NLCP) is a major project for SAMHSA. If POCT and Screening labs are approved the number of inspections could reach thousands. This would require major operational and monetary issue to implement an inspection program equal to the current NLCP.

POCT -The standards for the POCT are less stringent than those for laboratories. The industry clients will require education on the interpretation of the results of POCT devices. The have a high failure to confirm rate and often screen positive significantly below the listed cut off levels. Will the screen positive impact a company's decision to hire? Is thi discrimination?

SVT – What studies have been performed to indicate the effects of adulterants on alternative matrix samples? Is the testing that has been done sufficient?

believe it is too soon to introduce POCT and Alternative matrix testing to an industry that still acquiring knowledge in urine drug testing.