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From: Jack V. Smith, CEO
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RE: Comments to "Notice of Revisions"

Background:
Sciteck Clinical Laboratories, Inc., a subsidiary of Sciteck, Inc., has conducted studies in the past with the Probation & Parole Testing Facilities in Florida directly aimed at determining a reasonable cutoff for general oxidant screening on inmates (particularly women during their menstrual cycle).

The studies were conducted over a period of months. The findings indicated that there was a very high positive rate for the presence of oxidants using a 5 mg/dL Chromate (50 mcg/mL) calibrator. Upon further investigation, it was determined that a cutoff of 10 mg/dL (100 mcg/mL) prevented false positives for women during their menstrual cycle. Several commercial oxidant adulterants were purchased and samples were spiked at the suggested concentration. All samples were well above the 10 mg/dL cutoff.

Therefore, the suggested revision for LOD (20 mcg/mL chromate or 200 mcg/mL nitrite) for oxidizing adulterants is confusing and has no scientific or analytical support and is not legally defensible. For example only: using the general oxidizing reagent used in our laboratories the following are absorbance values at 600 nm for each suggested LOD: 100 abs @ 600 nm for the 20 mcg/mL chromate; 1,000 abs @ 600 nm for the 200 mcg/mL Nitrite. That is a 1:10 ratio for the suggested LOD on the same assay. Why would there be two (2) different LODs for the same assay? This would be an alert for all of the companies that makes adulterants. Find out if your laboratory uses a 20 mcg/mL Chromate cal or a 200 mcg/mL Nitrite cal. If it is the latter then use chromate and pour it in. Use twice the amount for good measure because the cutoff for a positive oxidants so high. This had already been done with the initial suggested SAMHSA for pH and other

assay cutoffs being way to spread out. The Adulterant manufacturers quickly designed assays that could easily get inside of the cutoff and still have an effective adulterant.

There is an easy answer that would solve this problem and enhance the overall process by adding another level of confidence. Run the general screen, reflex the positives to assays for specific adulterants. Then, run a third assay if found necessary by the MRO. Therefore, run the general oxidant assay with the lower sensitivity LOD (chromate 10 mg/dL (100 mcg/mL). Any positive could be reflexed for chromate, nitrite and halogen and peroxidase specific assays. If any these are positive then further testing by an alternative method would be the choice. There are commercially available assays for specific adulteration analytes that do not cross interfere with each other. In other words, the chromate cutoff calibrator will not show a positive response on the nitrite, halogen or peroxidase assays. The nitrite cutoff calibrator will not show a positive response on the chromate, halogen or peroxidase assays. The halogen cutoff calibrator will not show a positive response with the nitrite, chromate and peroxidase assays. The peroxidase cutoff calibrator will not show a positive response with the chromate, nitrite or halogen assays.

Best Regards,

Jack V. Smith, CEO
Sciteck, Inc.