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FR Doc # 04-7985
Public Comment 8500009

June 13th, 2004

Walter F. Vogl, Ph.D.
Division of Workplace Programs
CSAP
5600 Fishers Lane, Rockwall II, Suite 815
Rockville, MD 20857

Dear Dr. Vogl:

Re: FR Doc 04-7985

These comments are being submitted on behalf of all the Quest Diagnostics Incorporated certified SAMHSA laboratories. These comments are germane to the revision of the Mandatory Guidelines For Federal Workplace Drug Testing Programs relative to the SVT standards that are to be implemented effective October 1, 2004. Though the instructions indicated that this revision is subject to further comment only on the creatinine criterion, we feel compelled to make other comments on issues that we believe will have an impact on the implementation of these SVT standards.

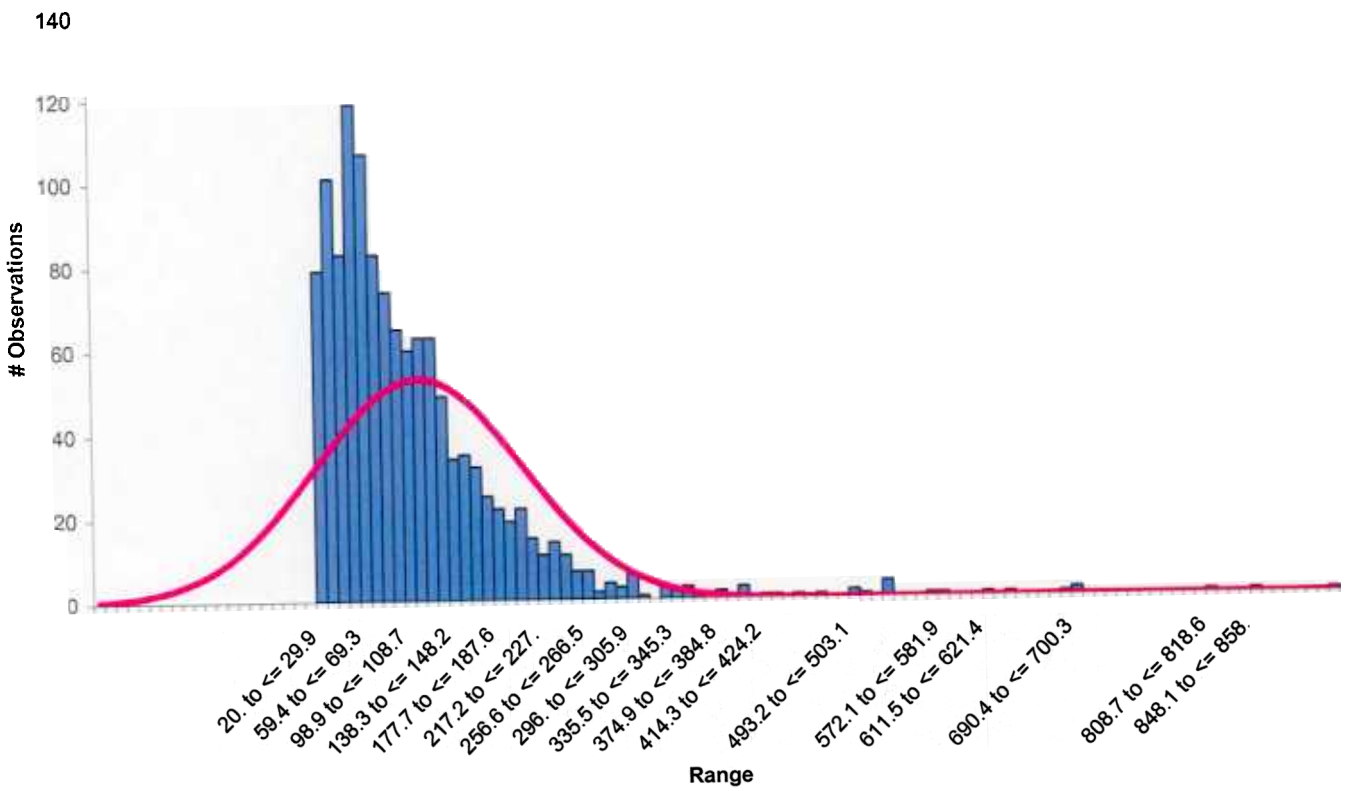
Section 2.4(g)(5): It is unclear what specimen validity tests would be considered appropriate to satisfy the conditions articulated in (i) through (iii). It appears as though laboratories are being given authority to perform specimen validity tests without established criteria for determining and further reporting the findings in a standardized manner. This section also does not specify what tests would be required versus optional to respond to the observed indicators.

Section 2.4(h)(4)(iii): Quest Diagnostics believes that the cutoff of 50 µg/mL of chromium (VI) on the initial screen and confirmatory is too high. Quest Diagnostics has been performing quantitative chromium (VI) assays since 2001 and has used 20 µg/mL as the screening cutoff. If the cutoff is increased to 50 µg/mL, many specimens that are in

fact adulterated will be reported as negative. Data below is from a preliminary analysis of chromium (VI) positive specimens by our certified laboratories from 2002 to 2004. The Histogram indicates that of 1251 specimens that were positive, 263 or 21% would have been reported as negative instead of as adulterated. A subset of this data that were Federally regulated specimens also provided the approximate percentage of specimens that would have been reported as negative with the 50 µg/mL cutoff. We believe that this is a significant issue and certainly a departure from our commitment to identify and report drug testing subversions. Increasing the cutoff to 50 µg/mL will encourage further adulteration of specimens using a lesser amount of the adulterant to achieve the same purpose. We are in the process of performing a study to document the concentration of chromium(VI) that will create a false negative for marijuana and other analytes. Upon completion, we will be very willing to share this data with you.

The DOT Plot below further illustrates the frequency of specimens with chromium (VI) concentrations that were below 50 µg/mL in our preliminary analysis of chromium data.

Normal Distribution
Mean = 110.21
Std Dev = 92.63
KS Test p-value = .0000



Section 2.4(h)(5) and (6): Quest Diagnostics supports the change to the creatinine criterion for substitution.

Section 2.4(h)(7): Quest Diagnostics recommends that a provision be included to report specimens invalid when creatinine and SG values are consistent with drinks or juice substitutions that have the physical appearance of urine. Note: Some, but not all, may also be detected by pH.

Lemon Lime Powerade, for example, exhibits creatinine values in the range of 2-3 mg/dL and SG of 1.032. We suggest the use of **Creatinine < 2 mg/dL and Specific Gravity >1.0010 as Invalid criteria** and drop the upper bracket of a specific gravity of <1.0200 criteria. Sample data generated on just some of these products is included below.

		Ginger Ale	Diet Mountain Dew	Mountain Dew	Mountain Dew Red	Lemon Lime Gatorade	Lemon Lime Powerade
Creatinine Screen (AU5200)	11/4/2003	2.6	0.0	4.3	4.3	1.3	2.0
	11/4/2003	3.0	0.1	4.1	4.1	1.0	2.1
	11/6/2003	2.7	0.0	4.3	4.4	1.1	2.3
	11/6/2003	2.5	0.0	4.1	4.3	0.9	1.7
Creatine Confirm (AU800)	11/4/2003	9.0	0.0	34.1	35.2	1.0	2.7
	11/4/2003	9.4	0.0	41.2	37.5	1.1	2.9
	11/5/2003	9.4	0.0	36.4	34.3	1.1	2.8
	11/5/2003	8.3	0.0	39.1	39.0	1.1	3.7
Specific Gravity	11/4/2003	1.038	1.002	1.047	1.047	1.026	1.032
	11/4/2003	1.038	1.002	1.047	1.047	1.026	1.032
	11/5/2003	1.038	1.002	1.048	1.048	1.026	1.032
	11/5/2003	1.038	1.002	1.048	1.048	1.026	1.032

NOTES:

1. Only Lemon lime Gatorade meets current regulatory guidelines for substituted sample
2. Ginger Ale, Mountain Dew and Mountain Dew Red exhibit significantly different creatinine readings based on methodology. The low level Creatinine method, utilizing a larger sample size, provided higher readings.

Section 2.4(h)12: Quest Diagnostics believes that the responsibility for consultation of the results should be shifted to the MRO. As written, the laboratory would be responsible to contact the MRO before reporting an invalid result to the MRO. This presents operational hurdles and would delay resulting until the MRO can be reached. Other important questions that beg answers are: How many times should the laboratory attempt to have a dialog with the MRO before releasing the result? Should a prescribed interval be established before releasing of invalid results?

Given that current verbiage used for invalid reporting is already fairly specific in identifying the issue on the report, we believe that a more effective approach would be for the laboratory to report the invalid results that would then trigger a consultation between the MRO and laboratory if the MRO feels it necessary.

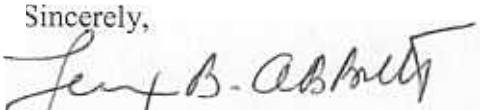
Section 2.4(k)(1): Quest Diagnostics believes that the retest criteria should include an interval around the adulteration cutoff for Nitrite. If for example the result from LAB A was 520 µg/mL and the Lab B result was within 20% of the cutoff or 400 µg/mL, this should be reported as reconfirmation of the presence of nitrite. With the current guidance this scenario would be reported as "Failed to reconfirm" when in fact the presence of nitrite can be documented and is far greater than normal physiological values even in the presence of any disease state.

If this is not an option for consideration, an alternative approach would be to issued instructions to the MROs that in cases where a nitrite fails to re-confirm because the reconfirmation value is less than 500 but greater than 200, the final report of adulteration should be downgraded to **invalid** since the revision provides for the reporting of invalid in specimens that have nitrite concentrations greater than 200 but less than 500 µg/mL.

Section 3.19(a)(7)(iii): This outlines the requirement to report Specific Gravity values on PT samples within ± 0.0003 Specific Gravity units of the calculated reference group means. We do not believe that there is currently sufficient data on urine Specific Gravity samples to assess realistic reproducibility between labs when testing to 4 decimal places on urine. In our recent evaluation of 3 different instruments with the ability to read to 4 decimal places, we have seen reproducibility between saline based standards to be tighter than reproducibility on urine based standards. Quest Diagnostics believes that acceptance criteria for Specific Gravity performance should be established only after true urine data has been evaluated in the field.

For further clarification on any issue or comment cited above, please do not hesitate to contact me at 412-920-7926 or by email at Lenox.B.Abbott@questdiagnostics.com.

Sincerely,



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