From: Harris, Paul
Sent: Thursday, July 31, 2014 3:12 PM
To: 'Bonthron, David'
Subject: A Fumble Occurred : Blind Sample Question

David,

I have no record of myself responding to you about this question of yours. I am sorry that I dropped the ball.

As stated in the Statement of Considerations (73 FR 17105, dated March 31, 2008) for the 2008 Rule, "The NRC has made these changes in § 26.168(b)-(g) to increase the ability of licensees and other entities to independently monitor the ability of their HHS-certified laboratories to consistently identify positive, adulterated, dilute, and substituted specimens and hold false negatives to a minimum." We get many 30-days reports on blinds that occur without resolution because the blind supplier says one thing and the lab says another and the a second lab says something different.

R,
Paul

Paul Harris

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From: Bonthron, David [mailto:David.Bonthron@fpl.com]
Sent: Wednesday, May 21, 2014 4:10 PM
To: Harris, Paul
Subject: Blind Sample Question

Paul,

I hope all is well with you and that you will be able to join us in Columbus.

I have no current or past issues with the below but more of a question at the moment on blind specimens and in particular, "negatives" believe it or not. Since I am not a scientist or involved in the day to day activity of supplying blinds, what is the reason for conducting "confirmatory testing" as it states in 26.168(g)(1) as seen below on a negative? Just curious …

26.168

(g) Licensees and other entities shall use only blind performance test samples that have been certified by the supplier to be—

(1) Negative. A negative blind performance test sample may not contain a measurable amount of a target drug analyte and must be certified by immunoassay and confirmatory testing

Thank you,

David

David J. Bonthron
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