



Massachusetts General Hospital Department of Pathology 55 Fruit Street, Bigelow 510 Boston, Massachusetts 02114-2696 Phone: 617-726-3635 Fax: 617-726-9206

11/05/2012

Jacob Hafter, Esq. 7201 W. Lake Mead Blvd, Suite 210 Las Vegas, NV 89128

Subject: Blood Collection/Testing Performed on Michael L. Langan, MD on July 1, 2011

Dear Sir:

I write you to provide my professional opinion regarding the quality and validity of testing performed on Michael Langan's (MLL) blood drawn on July 1, 2011 by a Quest Diagnostics specimen collector, at the request of Mary Howard of Physician Health Services, Inc (PHS).

As background, I have directed the MGH Chemistry and Toxicology Laboratories for nearly thirty years, and have both a clinical and academic interest in drug and drug-ofabuse testing. I have implemented many serum, urine, and oral fluid drug-of-abuse testing programs at MGH, including ones that dealt with "chain-of-custody" and Medical Review Officer issues. Much of my clinical work involves drug-of-abuse test interpretation for MGH clinicians.

I reviewed the documents MLL provided me relating to the July 1, 2011 testing. I was astonished at the large number of errors (including so-called "fatal" ones) and out-of-SOP events that occurred during the blood collection, processing, and transportation between 7/1 and when the specimen was finally received (seven!) days later by USDTLabs (where testing was actually done several days later). This is a very unusual delay; how the specimen was stored by the clinical (not forensic/"chain-of-custody") lab at Quest is not documented. This represents a serious, if not fatal flaw in the testing of MLL's blood. As a comparison, recall a recent very public case involving Major League Baseball vs. a league MVP. A positive urine performance-enhancing drug test was invalidated because there was only a 2-3 day explainable delay (because of a weekend transportation issue) in sending a sample to the testing lab. I think the seven day delay here is indefensible and will result in the overturning of any decisions based on MLL's very-flawed 7/1/2011 testing.

The many other errors in sample collection, processing, and transportation to USDTLabs include:



- 1. PHS directed Quest to use a chain-of-custody form (CCF) twice in PHS's order that initiated the 7/1/11 testing. The Quest specimen collector did not use the required form.
- 2. The collector then incorrectly used the PHS-to-Quest test order form, instead of a CCF. This resulted in fatal/significant errors noted in 3 below.
- 3. The documentation received by USDTLabs with the specimen on 7/8/11 did not have a date and time of specimen collection, proper ID of the collector, signature of the sample donor, or a tamper-proof seal affixed to the specimen.
- 4. On 7/1-7/2 someone (the 7/1 specimen collector?) incorrectly directed the sample to the clinical (not forensic/"chain-of-custody") QUEST lab in Cambridge, despite the clear instructions on the PHS order form. There the specimen sat for several days without documentation of its storage conditions.

By their own policy, upon receipt USDTLabs should have rejected the specimen because of the several fatal flaws involving chain-of-custody. They did not. Additionally, the Medical Review Officers (MROs) at both PHS and USDTL evidently ignored the fatal flaws and allowed the positive Phosphatidylethanolamine (PEth) result to be reported without any comment. As a standard of care, an MRO needs to investigate positive results to try and determine if there is an explanation(s) for them. The PHS MRO had an opportunity to clarify the 7/1/11 results when reviewing them. PEth is detectable for up to four weeks after exposure to ethanol, given its 4 day half-life. A repeat test drawn in the 7/15-7/20/2011 period, if negative for PEth, would have clarified the 7/1/11 result as a false-positive. Evidently the PHS MRO did nothing to clarify the situation, as PHS did not request a blood PEth test again on MLL until August, when it was too late to clarify the 7/1/11 test.

The actions PHS did take in July 2011 included requesting that Dr Langan's ID number be added to the already positive sample (19 days after specimen collection). They also requested that the lab report be updated to reflect that chain of custody was maintained. This second request is highly irregular. "Chain-of-Custody" never existed for MLL's 7/1/11 sample, and updating a report to say it did exist, many days after the fact, is wrong. Why PHS requested that chain of custody be added when there is not one is suspicious.

In conclusion, it appears from these documents that there is a purposeful and intentional act by PHS to show MLL's 7/1/11 test as valid when in reality this test was invalid, and

involved both fatal laboratory errors and lack of adequate MRO review of results. Anything based on MLL's 7/1/11 test as a confirmatory positive should be reversed, rectified, and remediated.

Dr. James G. Flood, PhD

Director, Chemistry Laboratory

James 6. Flood PhD

Massachusetts General Hospital

Assistant Professor of Pathology Harvard Medical School