From: Harris, Paul
Sent: Friday, June 17, 2016 2:45 PM
To: Sample, Barry X <Barry.X.Sample@questdiagnostics.com>
Subject: RE: RE: RE: Invalid Specimen

Barry,

As we discussed on the telephone.

Based on the sequence of events implemented by the licensee, for this case, the licensee is not now allowed to send the first (invalid pH) to another lab for another test. Therefore, the testing process was completed under 26.185(f)(3): (1) the invalid specimen was dispositioned by a direct observed (DO) collection and (2) due process was afforded to the individual. The DO result was negative (as a note, 26.185(l) does not allow a negative test result to be retested). The licensee needs to disposition their authorization determination based on the 2nd test result (the DO test result) and any other potentially disqualifying FFD information, 10 CFR 26.5.

Other thoughts

See NRC Statement of Considerations (73 FR 17112; March 31, 2008): "This provision requires the licensee… to rely on the test results from the directly observed collection in authorization decision-making because the result from the invalid specimen would be neither negative or positive, adulterated, substituted, or invalid and could not meet the requirements for granting authorization…"

Part 26 establishes a reasonable testing process for the licensees and labs to follow, but it also protects the individual from unreasonable testing when a negative test result has been obtained from a valid Part 26 test.

Hypothetically, the licensee's MRO could have made a "subversion attempt" determination based on two specimens having different physiological characteristics (etc.). It appears that the licensee did not do this.

I will place this email in the NRC's document management system as publicly available.

Paul

Paul Harris

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From: Sample, Barry X [mailto:Barry.X.Sample@questdiagnostics.com]
Sent: Thursday, June 16, 2016 3:04 PM
To: Harris, Paul <Paul.Harris@nrc.gov>
Subject: [External_Sender] RE: RE: Invalid Specimen

We simultaneously screen for drugs and SVT. SVT includes pH, Oxidizing Adulterants and creatinine. Since the creatinine was low (<20) we also performed a specific gravity test. On the initial SVT testing, only pH and creatinine were abnormal requiring additional testing.

Barry

From: Harris, Paul [mailto:Paul.Harris@nrc.gov]
Sent: Thursday, June 16, 2016 2:42 PM
To: Sample, Barry X
Subject: RE: RE: Invalid Specimen

Hey, one more question… did Lexana only get creatinine (10 CFR 26.161(b)(1)), then SG (10 CFR 26.161(b)(2)), and then pH (10 CFR (b)(3)) and then never got to test for any adulterants?

Paul

From: Sample, Barry X [mailto:Barry.X.Sample@questdiagnostics.com]
Sent: Thursday, June 16, 2016 11:04 AM
To: Harris, Paul <Paul.Harris@nrc.gov>
Cc: Hahn, Dawn M <Dawn.M.Hahn@questdiagnostics.com>; Samano, Kimberly L <Kimberly.L.Samano@questdiagnostics.com>
Subject: [External_Sender] RE: Invalid Specimen

Thanks!

From: Harris, Paul [mailto:Paul.Harris@nrc.gov]
Sent: Thursday, June 16, 2016 11:03 AM
To: Sample, Barry X
Cc: Hahn, Dawn M; Samano, Kimberly L
Subject: RE: Invalid Specimen

Barry I just got back from vacation – let me read this now …

From: Sample, Barry X [mailto:Barry.X.Sample@questdiagnostics.com]
Sent: Tuesday, June 14, 2016 11:45 AM
To: Harris, Paul <Paul.Harris@nrc.gov>
Cc: Hahn, Dawn M <Dawn.M.Hahn@questdiagnostics.com>; Samano, Kimberly L <Kimberly.L.Samano@questdiagnostics.com>
Subject: [External_Sender] Invalid Specimen
Importance: High

Paul:

Our Lenexa laboratory, after screening and confirmation, reported a specimen as Invalid (a low pH). Due to the fact that the specimen had an abnormal pH, it was determined after discussions with the MRO (per 10 CFR 26.169(c)(4) & 10 CFR 26.185(f)(1)) that no further testing would be fruitful in identifying a potential adulterant. The specimen also had a creatinine <20 mg/dL but a normal specific

gravity and did not satisfy the “dilute” criteria. Consequently, it also did not meet the requirements for LOD testing.

The donor was subsequently recollected under observed conditions and the results of that specimen were negative (with normal SVT).

We have now received a request (per 10 CFR 26.185(l)) from the operator to send out the specimen for retesting (screening and confirmation) at another laboratory. Based on our conversations with them, they don’t seem to be questioning the “scientific accuracy” of the Lenexa test results. However, they are concerned that this individual may have tried to manipulate his specimen and want to ensure they remain compliant with NRC regulations.

Is retesting permitted under this situation or are there any additional tests that may be permitted?

The donor is currently removed from duty pending the completion of the process and we would appreciate an expedited review of this inquiry.

Thanks and let me know if we need to discuss via phone.

Barry

R. H. Barry Sample, Ph.D.
Director of Science and Technology, Employer Solutions

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