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Blind Specimen Acceptability

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11/17/2014 11:58:12 AM

hrcah

2 posts

Blind Specimen Acceptability

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Our QA team went to ElSohly laboratory last week in support of the NEI audit. The following question was raised: Looking at 10 CFR 26.168(h) (3) If your manufacture sends you a positive cocaine blind specimen at 131% of the cutoff, 393ng.mL (acceptable by regulation) and your HHS laboratory report it as positive for Cocaine at 129% or 387 ng/mL would you reject that specimen and discard the samples from that lot and not use any further samples from that lot? These results would certainly fall witin normal standard deviation protocol and I am struggling with this issue. Your input would be appreciated.

12/8/2014 9:37:34 AM

JNielsen

3 posts

Re: Blind Specimen Acceptability

Quote

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12/8/14 -- The lot is acceptable, as long as the test results by the provider and the testing lab are within appropriate/expected range and the specimen is not past its expiration date.. In my discussions with Lab Directors, Responsible Persons, and others involved with the National Lab Certification Process that there is an acceptable deviation of +/- 20%. This deviation is allowable because of various acceptable test methods, associated reagents, etc. as long as the results are certified and the labs/facilities are HHS-certified. long story short - we accept HHS-certified lab audits and this is part of their audit scope.

In the scenario you describe, the difference between 387 ng/ml by one HHS-certified lab and the 393 ng/ml from the provider, also an HHS-certified lab, is 6ng/ml. This is definitely within the 20% range (+/- 39) for the substance being tested.

This has been a question asked by many since 2009. The overall certified results (positive; substituted; dilute; etc) must be the same, not the laboratory quantitative results. Our concern should be when the blind is certified for one thing and when we submit that blind for testing, the results do not agree.

Please feel free to contact me if you have any questions. John Nielsen, INPO, 770-644-8808 or [nielsenja@inpo.org](mailto:nielsenja@inpo.org)