From: OC GCP Questions
To: [redacted]
Subject: Collection of CLIA Waived Certification for Urine Pregnancy Tests
Date: Friday, January 24, 2014 9:30:43 AM

Good morning –

I spoke to a colleague here in my office for a response to your question. While we don't think it is an FDA requirement to collect CLIA waivers in your files, it would be up to the sponsor to decide and it is better to have more documentation rather than less. It is well known that the pregnancy tests you are referring do have CLIA waivers but it might be best to speak to someone in the Office of In Vitro Diagnostics in CDRH. Please see their web page link below. There is a phone number at the bottom right.

In Vitro Diagnostics

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Thursday, January 23, 2014 1:06 PM
To: OC GCP Questions
Subject: Collection of CLIA Waived Certification for Urine Pregnancy Tests

I was wondering what the FDA's position was on collecting the CLIA waiver for urine pregnancy tests in clinical trials?

Would a sponsor be required to document the type of urine pregnancy test used for each subject's urine pregnancy test and have the CLIA waiver in their files for each and all tests used?

Or, since urine pregnancy tests are universally CLIA waived would we not be required to have that documentation in our files?

I am referring to the stick tests that are done by the study subject, not a laboratory test.

Thanks