From: OC GCP Questions
To: [redacted]
Subject: CLIA Waiver Requirement
Date: Wednesday, August 13, 2014 11:13:30 AM

Good morning –

We recently had a similar question regarding pregnancy testing and CLIA waivers. Please see our previous answer below.

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,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, August 12, 2014 6:41 PM
To: OC GCP Questions
Subject: CLIA Waiver Requirement

Hello,

We are doing a study that requires a urine pregnancy test that is being done locally (the tests are being provide by a central lab) and I was wondering if we would REQUIRE a CLIA waiver certificate for each site?

Thank you!
[redacted]