From: OC GCP Questions
To: [redacted]
Subject: CLIA waivers
Date: Thursday, April 19, 2018 9:23:00 AM
Attachments: [redacted]

Good morning –

If you are performing testing on people (subjects), that testing must be done in a lab that has and appropriate CLIA certificate (e.g., a waived certificate to use waived tests).

If you have additional questions about CLIA testing or laboratory requirements, I recommend that you contact the CLIA group at CMS who regulates such testing. (www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/)

Additionally, it is well known that the pregnancy tests 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

Kind regards,

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

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From: [redacted]
Sent: Thursday, April 19, 2018 8:12 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: CLIA waivers

Hello,

It's my understanding that a clinical trial site performing protocol-required urine pregnancy tests on trial subjects in their office would be considered a lab for this purpose and would need a CLIA waiver certificate.

Could you please confirm if that's correct?

Thanks,