
From: OC GCP Questions
Sent: Thursday, January 08, 2015 10:44 AM
To: [REDACTED]
Subject: CLIA waived tests FU question

Good morning –

I don't really know the answer to your specific question. However, we recently had a similar question regarding pregnancy testing and CLIA waivers. Please see CDRH's previous answer below.

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

I hope that helps. 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. (<http://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](#)

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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From:
Sent: Thursday, January 08, 2015 9:13 AM
To: OC GCP Questions
Subject: CLIA waived tests FU question

Hello again,

[REDACTED]

I guess the better question is does the specific urine pregnancy test used by the site such as First Response need to be on the list for it to be okay. There are many different urine pregnancy tests on the list and just want to clarify that if you can't find the one that you're using, do you need to use a test that is on the list. Thanks again.

