

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: CLIA waiver
Date: Wednesday, October 01, 2014 10:28:48 AM

Good morning –

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/>)

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: ~~TYXUM~~XQ
Sent: Tuesday, September 30, 2014 12:22 PM
To: OC GCP Questions
Subject: CLIA waiver

Hello,
I have a question regarding CLIA waivers and sites.....

Does the FDA require sites to obtain CLIA Waivers even if they only perform UPTs for clinical research study? Just to clarify, the site does not perform any lab testing other than urine pregnancy tests. Thank you.

]tgfcvzf_