

**From:** [Lias, Courtney H](#)  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: CLIA waiver for research testing?  
**Date:** Wednesday, April 16, 2014 11:55:53 AM

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Hello [redacted] –

Thank you for your question. If you are performing testing on people, that testing must be done in a lab that has and 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/>)

Regards,

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**From:** [Redacted]  
**Sent:** Monday, April 14, 2014 3:36 PM  
**To:** OC GCP Questions  
**Cc:** [Redacted]  
**Subject:** CLIA waiver for research testing?

Hello,

We have developed a protocol for a pilot study (privately funded) of oral [redacted] as a treatment for self-injurious behavior, and have planned to conduct periodic urine pregnancy testing, for safety reasons only, using a test approved for at-home use. Must these tests be conducted under a CLIA waiver? Or can they simply be performed by research study staff since the testing is primarily for a research purpose

rather than primarily for patient care?

Thank you for your assistance!

[Redacted]