

**From:** Brown, Sheila (OGCP)  
**To:** [REDACTED]  
**Subject:** RE: FDA Regulations - Laboratory Testing  
**Date:** Monday, September 24, 2018 8:19:00 AM

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Dear [REDACTED],

We recommend using laboratory tests that are cleared or approved by FDA, when available. More information about in vitro diagnostic testing can be found on FDA's website at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm> . If you have questions about specific testing for a study, we recommend that you contact the review team for your submission.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) .

Best regards,

Sheila

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-----Original Message-----

**From:** [REDACTED]  
**Sent:** Thursday, September 20, 2018 2:40 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** FDA Regulations - Laboratory Testing

I have a question with regards to the regulations that pertain to a CLIA laboratory participating in clinical trials. I understand the FDA recognizes CLIA, as overseen by CMS. More specifically, are there any additional requirements for the following types of laboratory testing in support of a clinical trial?

- primary and secondary endpoint/efficacy
- safety
- patient inclusion/stratification
- pharmacodynamic (PD)
- exploratory

Thank you for your time and clarity on this matter.