

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** 1572 box 4: Single use lab  
**Date:** Wednesday, August 12, 2015 7:06:34 AM

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Good morning –

With the scenario you describe, the local lab would not have to be listed on the 1572 form.

Kind regards,

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**From:** [REDACTED]  
**Sent:** Tuesday, August 11, 2015 4:36 PM  
**To:** OC GCP Questions  
**Subject:** 1572 box 4: Single use lab

Good Afternoon,

I found the following on your website:

***28. What qualifies as a clinical laboratory facility for Section #4?***

Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

***29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4?***

It is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

If a patient goes to a local lab (i.e. they are unable to make it to clinic, a test was not drawn, etc.), for a study procedure and it is deemed that this lab will not be used repeatedly, is it required to be listed on the 1572 and credentials collected?

Thank you,

[REDACTED]