

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Lab Drawing stations
Date: Thursday, January 09, 2014 9:00:15 AM

Good morning –

I can refer you to FDA's FAQ guidance on the 1572 Form –

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> -- It states --

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY

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.

Based on the limited information in your email, it appears that the secondary lab does not need to be listed on the 1572. Question #29 appears to answer your question.

I hope this information is helpful. Please contact us again at gcp.question@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
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From: [Redacted]
Sent: Wednesday, January 08, 2014 6:10 PM
To: OC GCP Questions
Subject: re: Lab Drawing stations

To Whom It May Concern:

Is a lab drawing station required to be listed in box #4 on the 1572 along with the Main lab it falls under jurisdiction if they do not perform any analysis ?

The drawing station does not have a CLIA and falls under the Main lab which we have listed on the 1572 , the CRO is indicative that the drawing station needs to be listed per FDA.

Please advise if this is indeed so. Thank you.

Cheers,

[Redacted]