

GENVASC
SITE VISIT LOG

SITE	DATE
STUDY PERSONNEL PRESENT	
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	YES	NO	N/A	N/D
STUDY DOCUMENTATION				
Signed current Protocol on file?				
Protocol amendments on file?				
R&D approvals on file?				
REC approvals on file?				
Initiation visit log on file?				
Signed Practice Study Pack on file?				
Current CV's on File?				
SOP'S AND WORK INSTRUCTIONS				
Are all current versions of SOP'S and Work Instructions on file? *Consent (witnessed process + associated WI) *Consent (Un-witnessed process + associated WI) Sampling process (+ associated WI)				

TRAINING				
Current version of presentation on file?				
Current Practice Personnel Log on file?				
Are all current versions of study information on file? *Patient Information Leaflets (Full and Abbreviated) *Consent (Witnessed and Un-witnessed) *Withdrawal Form *GP Letter *Poster *Sample Labels				
STUDY CONDUCT				
Have there been any recruitment difficulties?				
Are correct consent procedures in place?				
Have correct version of consent template been used?				
Are all consent forms present and correctly completed?				
PROTOCOL ADHERENCE				
Were any protocol deviations recorded?				
If yes, have they been correctly documented?				
ADVERSE EVENTS				
Have any adverse events occurred?				

Were they reported on the Deviation Log and to the study team?				
SAMPLE PROCESS				
Have samples been taken and processed in accordance with protocol?				
If no, were they reported in the Deviation Log?				

Comments:

Summary of findings:

Action	Responsibility

Signature:	Date:
Name:	

