



Investigator Initiated Studies (IIS) Study Concept Form	
Proposed Study Title	
Study Title	
Request Date	
Principal Investigator Contact Information	
Name	
Title	
Institution	
Address	
City, State, Zip (Country)	
Phone/Fax	
Email	
QIAGEN Contact (if applicable)	
Name	
Email	
Diagnostic Area Provide the diagnostic area of the IIS	
If other, please specify	
Background/Rationale Provide background on unanswered question the study is attempting to answer (limit to 1 page)	

Investigator Initiated Studies (IIS) Study Concept Form
Objectives List the aims to correspond directed with the listed hypothesis
Hypothesis List the clinical hypothesis in order of priority
Study Design/Clinical Plan Provide a concise overview stating the type of experimental design and include key inclusion/exclusion criteria

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Statistical Plans	
Include justification for sample size and primary hypothesis testing	
Include description of data collection and analysis	
Support requested	
Describe the kind of support requested	
Describe the number of cartridges, kits, instruments, etc.	
If financial, please specify breakdown of budget (reagent, overhead costs, etc.)	
If other, please specify	
Timelines and Study Plans	
Number of Sites	
Site Names	
Study Start Date	
Study End Date	
Number of Subjects	
Enrollment/Testing Period	
Ethics committee (EC) or institutional review board (IRB)	



Investigator Initiated Studies (IIS) Study Concept Form	
Publication Plan	
Where are you planning on submitting for publication?	
Are you planning to present this data at a scientific congress?	
References	