

INVESTIGATOR INITIATED STUDY (IIS) APPLICATION

CONTACT DETAILS			
Date of proposal:			
Laboratory/Institute:			
City:			
Country:			
Principal Investigator:	Name: Email address: Phone number:		
Curriculum vitae enclosed?	☐ Yes ☐ No		
Current Idylla™ user?	☐ Yes ☐ No		
Primary Idylla™ user contact details	Name: Email address: Phone number:		
Do you use Idylla™ Explore?	☐ Yes ☐ No		
Is the Idylla™ System connected?	☐ Yes ☐ No		
STUDY DETAILS			
Project/Study Proposal/ Scientific Abstract			

 \square See attachment



		☐ Prospective ☐ Retro	ospective	
		☐ Observational ☐ Oth	ner	
		☐ Single center ☐ Mu	ulti center (sites)	
Aim of the project		Primary objective:		
		Secondary objective:		
Do you plan to publish?		☐ Yes ☐ No		
			Estimated time of submi	ssion:
Product ¹ / labeling ¹	□ RUO		GFR	☐ HepatoPredict ^{3,5}
	□ IVD	□к	RAS	☐ APIS Breast Cancer Subtyping Kit ^{3,5}
		□N	RAS-BRAF	☐ APIS ESR1 Mutations Kit ^{3,5}
		□N	RAS-BRAF-EGFR S492R	
		□м	SI	
		□м	SI 510(k)	
		□в	RAF	
		□G	eneFusion	
			DH1-2	
		□ ct	:KRAS	
		□ ct	:NRAS-BRAF-EGFR S492R	
		□ ct	:EGFR	
		□ Se	eptiCyte® RAPID²	
			P-GEP ^{3,4}	
			hyroidPrint®³	

In markets where available.

²Biocartis NV is the exclusive distributor in Europe.

³Biocartis NV is the exclusive distributor in Europe and selected other countries.

⁴Idylla™ CP-GEP (Clinicopathological Gene Expression Profiling) Assay.

⁵Not designed to be run on the Idylla™ System.



Sample type	☐ Core needle - tissue (FFPE)
	☐ Resected - tissue (FFPE)
	☐ Cell block - cytological
	☐ Smear - cytological
	☐ Monolayer - cytological
	☐ Fresh (non-fixated)
	☐ Plasma
	□ Blood
	☐ Extracted DNA from tissue
	☐ Extracted DNA from cytological
	☐ Touch Prep
	☐ Urine
	☐ Saliva
	☐ Nasopharyngeal swabs
	☐ Oropharyngeal swabs
	☐ Other, specify:
Disease area:	
Total sample size (number):	
Target patient population:	
On an increasely	
Open remark:	
If applicable, Reference technology	
Examples: - NGS; the Ion AmpliSeq Cancer Hot Spot panel v2 (Illumina) - NGS; the Oncomine Solid Tumor DNA Kit (ThermoFisher) - RT-PCR; the cobas® EGFR Mutation Test v2 (Roche)	



If applicable, Monitoring test scheme (eg ctDNA) Example of three time points: - Plasma and tissue testing before surgery (baseline) - Plasma testing after surgery 3 months - Plasma testing after surgery 12 months	
If applicable, Clinical Trial number	
If applicable, EC/IRB approvals Informed Consent approvals	EC/IRB approval: ☐ yes ☐ no ☐ ongoing ☐ not applicable
	Informed consent* approval: ☐ yes ☐ no ☐ ongoing ☐ not applicable *capturing data and material

REQUEST FOR MATERIAL NEEDED FOR THE STUDY			
Requested number of Idylla™ cartridges			
Requested number of Idylla™ systems	Idylla [™] Console: Idylla [™] Instrument:		
Timing (start/end)	Estimation start date: Estimation end date:		
Other Examples: - Publication cost - Support for medical writer - Cost of discordant analysis			

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