BIOCARTIS

IDYLLA™ MSI TEST

GOING MOLECULAR HAS NEVER BEEN EASIER

OUR MISSION

ENABLE UNIVERSAL ACCESS TO PERSONALIZED MEDICINE FOR PATIENTS AROUND THE WORLD

BY MAKING MOLECULAR TESTING CONVENIENT, FAST, AND SUITABLE FOR ANY LAB.

MSI TESTING BACKGROUND

The Idylla™ MSI Test is a CE-marked IVD in Europe and validated for detection of MSI status in colorectal cancer.

TRADITIONAL MSI TESTING PITFALLS

The traditional way of MSI testing is not suitable to the modern, fast-paced clinical needs, as it is:

Complex

- It requires visual result interpretation
- It often calls for paired normal tissue for comparison, which might not be available

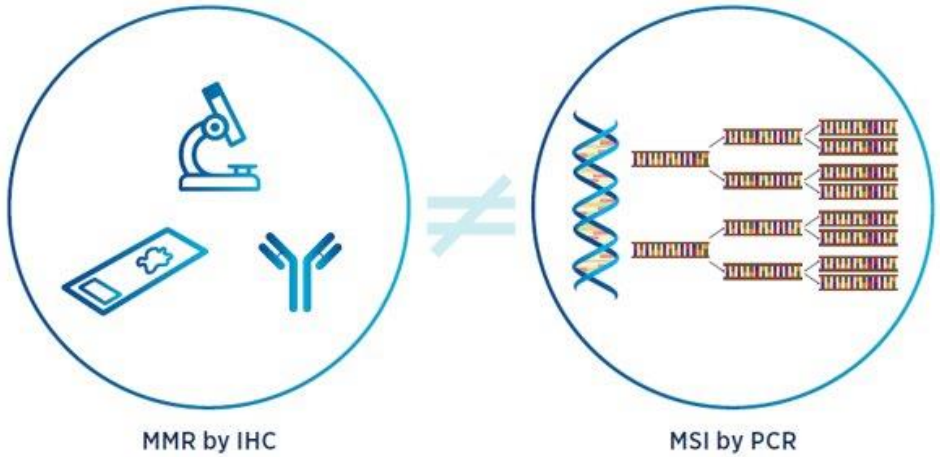
Technically demanding

- Traditional methods rely on highly trained staff
- Selection of appropriate tumor and normal tissue samples may be challenging
- A manual interpretation of test results is often needed

Slow

- Long turnaround time especially for molecular methods
- Cumbersome, lengthy workflows
- Batching of samples

DIFFERENCE BETWEEN MMR AND MSI DETERMINATION



MMR by IHC: measures the presence of four proteins (MLH1, MSH2, MSH6, PMS2) involved in the Mismatch Repair pathway in an FFPE sample. Lack of expression means that the pathway is compromised, and therefore there's a reduced capability for the cells to faithfully replicate DNA, possibly leading to tumorigenesis.

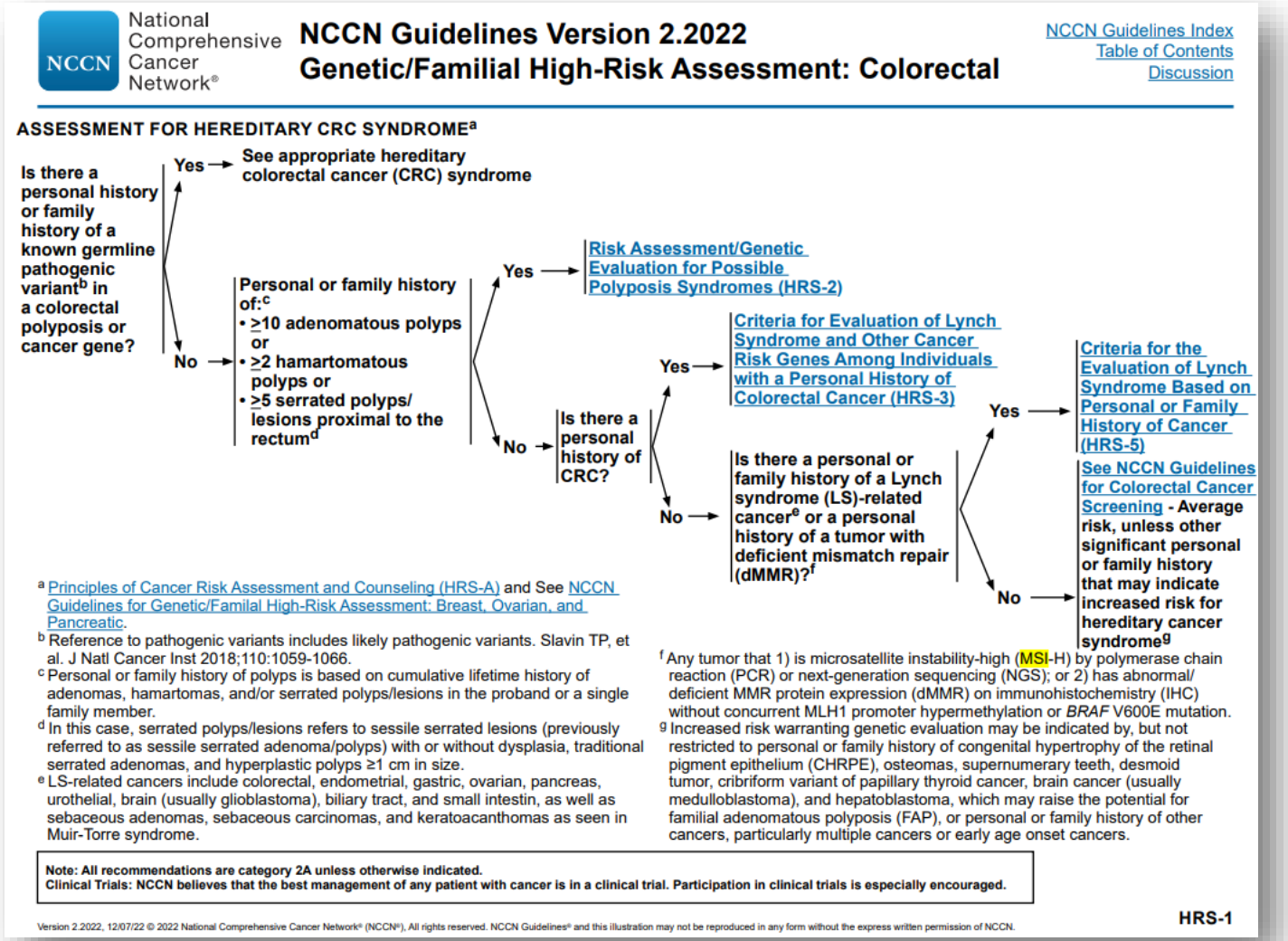
MSI by PCR: measures the length of homopolymeric biomarkers (microsatellites) present in the genome. An increased variability of the microsatellites lengths is a direct indication of an incorrect DNA replication, likely caused by a deficient ability of the cell to competently repair mismatches occuring during the DNA replication.

The Idylla™ MSI Test

Cleared by FDA as a 510(k)
Class II devicet

The Idylla™ MSI Test is a CE-marked IVD in Europe and validated for detection of MSI status in colorectal cancer.

NCCN GUIDELINES FOR LYNCH SYNDROME



National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2022
Genetic/Familial High-Risk Assessment: Colorectal

NCCN Guidelines Index
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Discussion

ASSESSMENT FOR HEREDITARY CRC SYNDROME[a]

Is there a personal history or family history of a known germline pathogenic variant[b] in a colorectal polyposis or cancer gene?

- **Yes** → **See appropriate hereditary colorectal cancer (CRC) syndrome**
- **No** → **Personal or family history of:[c]**
  - **≥10 adenomatous polyps or**
  - **≥2 hamartomatous polyps or**
  - **≥5 serrated polyps/ lesions proximal to the rectum[d]**

  - **Yes** → Risk Assessment/Genetic Evaluation for Possible Polyposis Syndromes (HRS-2)
  - **No** → **Is there a personal history of CRC?**
    - **Yes** → Criteria for Evaluation of Lynch Syndrome and Other Cancer Risk Genes Among Individuals with a Personal History of Colorectal Cancer (HRS-3)
    - **No** → **Is there a personal or family history of a Lynch syndrome (LS)-related cancer[e] or a personal history of a tumor with deficient mismatch repair (dMMR)?[f]**
      - **Yes** → Criteria for the Evaluation of Lynch Syndrome Based on Personal or Family History of Cancer (HRS-5)
      - **No** → See NCCN Guidelines for Colorectal Cancer Screening - **Average risk, unless other significant personal or family history that may indicate increased risk for hereditary cancer syndrome[g]**

[a] Principles of Cancer Risk Assessment and Counseling (HRS-A) and See NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.

[b] Reference to pathogenic variants includes likely pathogenic variants. Slavin TP, et al. J Natl Cancer Inst 2018;110:1059-1066.

[c] Personal or family history of polyps is based on cumulative lifetime history of adenomas, hamartomas, and/or serrated polyps/lesions in the proband or a single family member.

[d] In this case, serrated polyps/lesions refers to sessile serrated lesions (previously referred to as sessile serrated adenoma/polyps) with or without dysplasia, traditional serrated adenomas, and hyperplastic polyps ≥1 cm in size.

[e] LS-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, urothelial, brain (usually glioblastoma), biliary tract, and small intestin, as well as sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas as seen in Muir-Torre syndrome.

[f] Any tumor that 1) is microsatellite instability-high (MSI-H) by polymerase chain reaction (PCR) or next-generation sequencing (NGS); or 2) has abnormal/ deficient MMR protein expression (dMMR) on immunohistochemistry (IHC) without concurrent MLH1 promoter hypermethylation or *BRAF* V600E mutation.

[g] Increased risk warranting genetic evaluation may be indicated by, but not restricted to personal or family history of congenital hypertrophy of the retinal pigment epithelium (CHRPE), osteomas, supernumerary teeth, desmoid tumor, cribriform variant of papillary thyroid cancer, brain cancer (usually medulloblastoma), and hepatoblastoma, which may raise the potential for familial adenomatous polyposis (FAP), or personal or family history of other cancers, particularly multiple cancers or early age onset cancers.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

HRS-1

BIOCARTIS

IDYLLA™ MSI TEST – INTENDED USE

For in vitro diagnostic use.

For use on the Biocartis Idylla™ System only.

The Idylla™ MSI Test, for use on the Idylla™ System, uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of seven monomorphic biomarkers (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) and subsequent melt-curve analysis. The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid.

The Idylla™ MSI Test is indicated for use by healthcare professionals for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors, indicative of mismatch repair deficiency, and as an aid in the identification of probable Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome.

The results from the Idylla™ MSI Test should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data. The Idylla™ MSI Test should not be used for diagnosis of CRC. The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

IDYLLA™ MSI TEST – AT A GLANCE

- Detection of a proprietary panel of seven biomarkers in one cartridge
- In average, less than **3 minutes** hands-on time (HOT)
  Assay turn-around time (TAT) of approx. **150 minutes**
- Limited sample input: at minimum **1 FFPE** slice with no need for paired non-tumor samples
- Fully automated molecular walk-away system for on-demand testing

MINIMAL SPECIMEN REQUIREMENTS

- 62.5 mm² when 4 µm FFPE tissue sections are used.
- 50 mm² when 5 µm FFPE tissue sections are used.
- 25 mm² when 10 µm FFPE tissue sections are used.
- Multiple FFPE tissue sections (up to 5) can be used to meet this requirement
- ≥ 33% neoplastic cell content

IDYLLA™ MSI TEST – FULLY AUTOMATED FFPE SAMPLE TO RESULT

- No sample pre-treatment
- No molecular infrastructure required
- All reagents pre-loaded in the cartridge

IDYLLA™ MSI TEST – A PROPRIETARY SET OF BIOMARKERS

☑ The 7 Idylla™ MSI biomarkers are homopolymers that are frequently mutated in MSI-H colorectal cancer

IDYLLA™ biomarkers

ACVR2A
BTBD7
DIDO1
MRE11
RYR3
SEC31A
SULF2

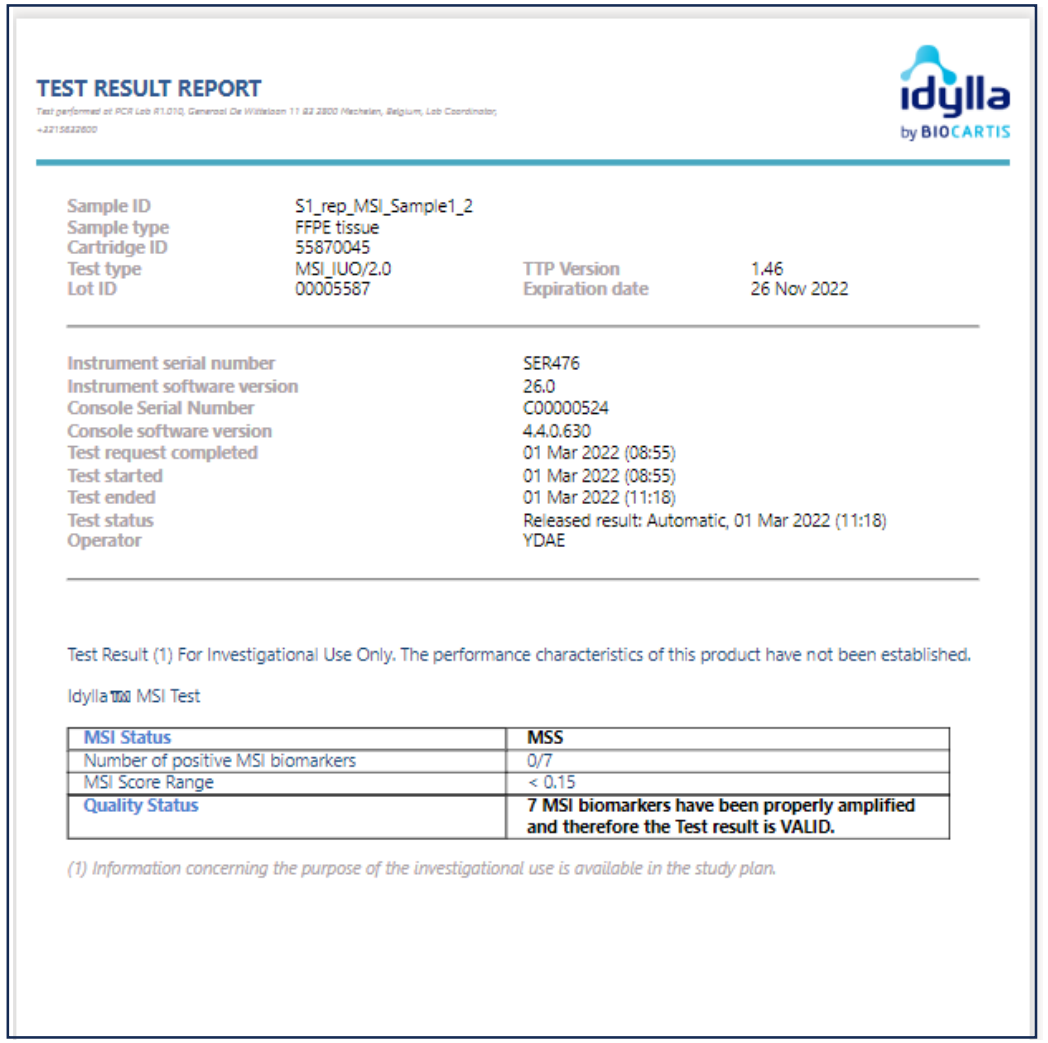
- Stable markers in multiple cancer types and across different ethnicities[1] – no need for normal samples
- High mutation frequency in MSI-H colorectal, gastric and endometrial cancers
- Short PCR amplicons for a high valid rate, even with low quality DNA samples

(1) Maertens G. et al. ESMO 2017, 138P

IDYLLA™ MSI TEST - UNBIASED RESULT REPORT

- Idylla™ MSI reports the overall call with 3 possible results:
  - VALID result if 5 or more biomarkers are amplified
    - MSS if <2 biomarkers mutant
    - MSI-H if >=2 biomarkers mutant
  - INVALID result if more than 2 biomarkers are invalid

- Idylla™ MSI reports a Quality Status indicating the validity of the Idylla™ MSI Test



TEST RESULT REPORT

Test performed at PCR Lab R1.010, Generaal De Wittelaan 11 B3 2800 Mechelen, Belgium, Lab Coordinator, +3215622600

idylla by BIOCARTIS

Sample ID	S1_rep_MSI_Sample1_2		
Sample type	FFPE tissue		
Cartridge ID	55870045		
Test type	MSI_IUO/2.0	TTP Version	1.46
Lot ID	00005587	Expiration date	26 Nov 2022

Instrument serial number	SER476
Instrument software version	26.0
Console Serial Number	C00000524
Console software version	4.4.0.630
Test request completed	01 Mar 2022 (08:55)
Test started	01 Mar 2022 (08:55)
Test ended	01 Mar 2022 (11:18)
Test status	Released result: Automatic, 01 Mar 2022 (11:18)
Operator	YDAE

Test Result (1) For Investigational Use Only. The performance characteristics of this product have not been established.

Idylla™ MSI Test

MSI Status	MSS
Number of positive MSI biomarkers	0/7
MSI Score Range	< 0.15
Quality Status	**7 MSI biomarkers have been properly amplified and therefore the Test result is VALID.**

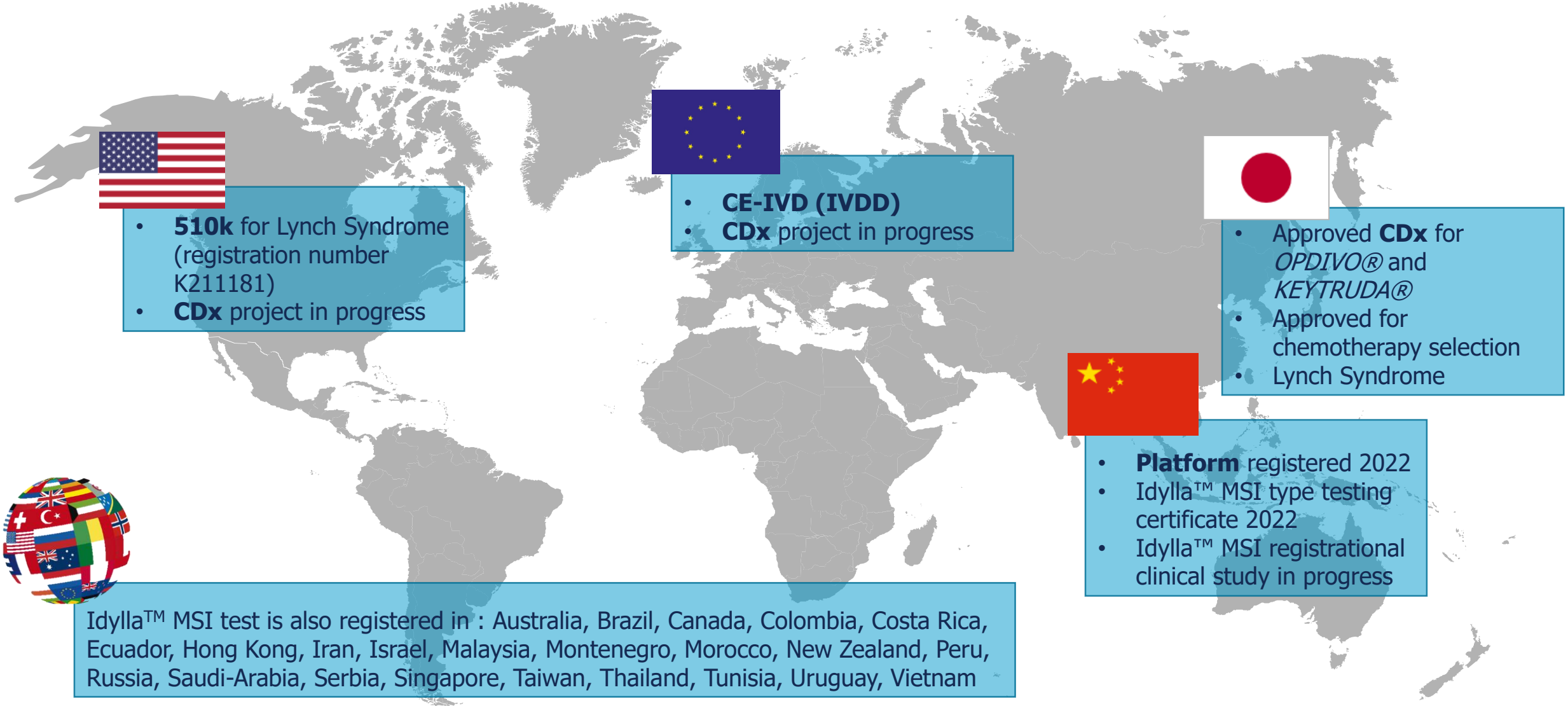
(1) Information concerning the purpose of the investigational use is available in the study plan.

World leading performance

GOING MOLECULAR HAS NEVER BEEN EASIER

The Idylla™ MSI Test is a CE-marked IVD in Europe and validated for detection of MSI status in colorectal cancer.

THE IDYLLA™ MSI TEST – WORLDWIDE CLINICAL RECOGNITION



- **510k** for Lynch Syndrome (registration number K211181)
- **CDx** project in progress

- **CE-IVD (IVDD)**
- **CDx** project in progress

- Approved **CDx** for *OPDIVO®* and *KEYTRUDA®*
- Approved for chemotherapy selection Lynch Syndrome

- **Platform** registered 2022
- Idylla™ MSI type testing certificate 2022
- Idylla™ MSI registrational clinical study in progress

Idylla™ MSI test is also registered in : Australia, Brazil, Canada, Colombia, Costa Rica, Ecuador, Hong Kong, Iran, Israel, Malaysia, Montenegro, Morocco, New Zealand, Peru, Russia, Saudi-Arabia, Serbia, Singapore, Taiwan, Thailand, Tunisia, Uruguay, Vietnam

IDYLLA™ MSI TEST – WORLD LEADING PERFORMANCE

Reliable results

Various studies showed excellent concordance against IHC and other PRC techniques

Low input

Successful results can be obtained when sample is limited or after NGS failures

IDYLLA™ MSI TEST – WORLD LEADING PERFORMANCE

Proven concordance against IHC

A study by Velasco et al. tested 1075 CRC cases comparing Idylla™ with immunohistochemistry in 44 different centers across the globe.

Idylla™ \ IHC	dMMR	pMMR	Invalid	Doubtful	Total
MSI-H	501	12	1	10	524
MSS	25	487	6	30	548
Invalid	2	1	0	0	3
Total	528	500	7	40	1075

Positive agreement 501/526 = 95.24% (CI: 93.08–96.76%)

Negative agreement 487/499 = 97.59% (CI: 95.84–98.62%)

Overall agreement 988/1025 = 96.39% (CI: 95.06–97.37%)

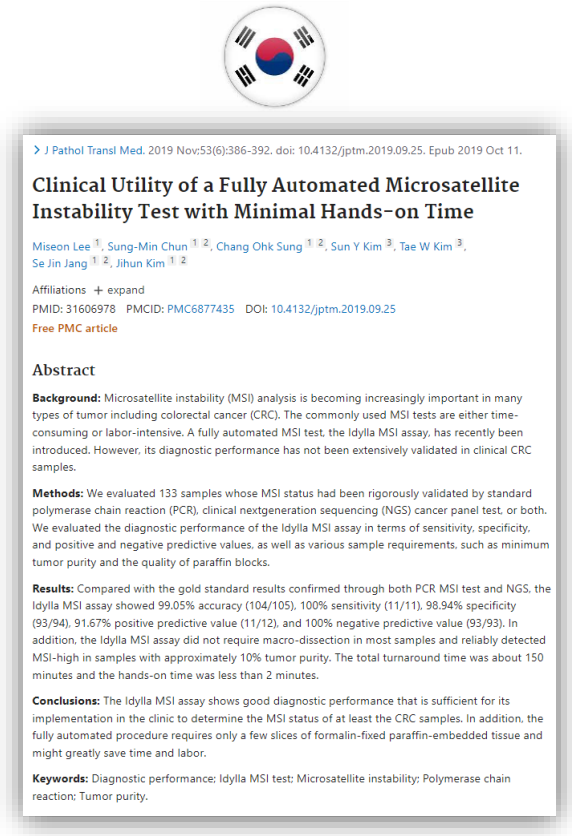
THE ADVANTAGE OF A COMPLETELY AUTOMATED RESULT CALLING

- In the study by Velasco, IHC was not correctly interpretable in around 3,7% of cases.

Similar results were obtained by Zwaenepoel et al, with a 98.7% concordance on 330 CRC samples against IHC

Velasco A et al, Virch Arch 2020
Zwaenepoel et al J Mol Diagn 2020

IDYLLA™ MSI TEST – FASTEST TURNAROUND TIME



J Pathol Transl Med. 2019 Nov;53(6):386-392. doi: 10.4132/jptm.2019.09.25. Epub 2019 Oct 11.

Clinical Utility of a Fully Automated Microsatellite Instability Test with Minimal Hands-on Time

Miseon Lee [1], Sung-Min Chun [1,2], Chang Ohk Sung [1,2], Sun Y Kim [3], Tae W Kim [3], Se Jin Jang [1,2], Jihun Kim [1,2]

Affiliations + expand

PMID: 31606978 PMCID: PMC6877435 DOI: 10.4132/jptm.2019.09.25

Free PMC article

Abstract

Background: Microsatellite instability (MSI) analysis is becoming increasingly important in many types of tumor including colorectal cancer (CRC). The commonly used MSI tests are either time-consuming or labor-intensive. A fully automated MSI test, the Idylla MSI assay, has recently been introduced. However, its diagnostic performance has not been extensively validated in clinical CRC samples.

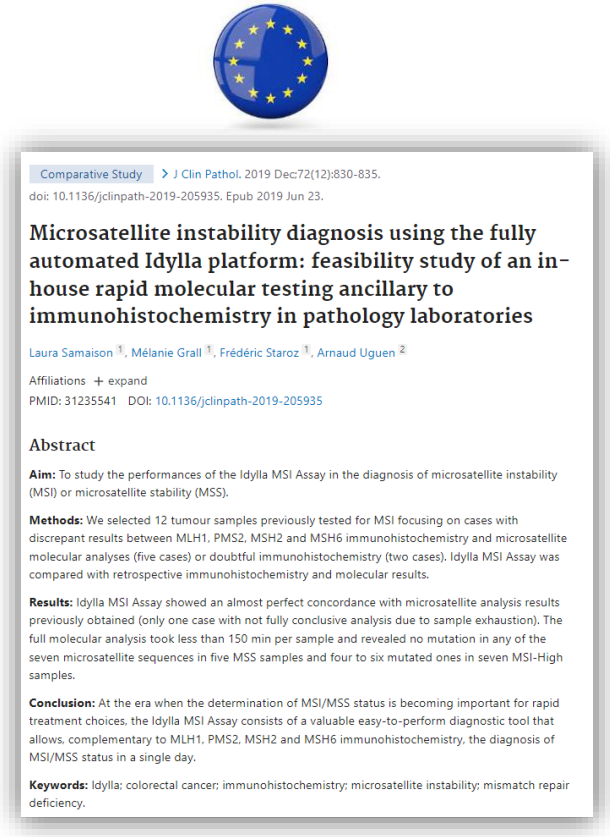
Methods: We evaluated 133 samples whose MSI status had been rigorously validated by standard polymerase chain reaction (PCR), clinical nextgeneration sequencing (NGS) cancer panel test, or both. We evaluated the diagnostic performance of the Idylla MSI assay in terms of sensitivity, specificity, and positive and negative predictive values, as well as various sample requirements, such as minimum tumor purity and the quality of paraffin blocks.

Results: Compared with the gold standard results confirmed through both PCR MSI test and NGS, the Idylla MSI assay showed 99.05% accuracy (104/105), 100% sensitivity (11/11), 98.94% specificity (93/94), 91.67% positive predictive value (11/12), and 100% negative predictive value (93/93). In addition, the Idylla MSI assay did not require macro-dissection in most samples and reliably detected MSI-high in samples with approximately 10% tumor purity. The total turnaround time was about 150 minutes and the hands-on time was less than 2 minutes.

Conclusions: The Idylla MSI assay shows good diagnostic performance that is sufficient for its implementation in the clinic to determine the MSI status of at least the CRC samples. In addition, the fully automated procedure requires only a few slices of formalin-fixed paraffin-embedded tissue and might greatly save time and labor.

Keywords: Diagnostic performance; Idylla MSI test; Microsatellite instability; Polymerase chain reaction; Tumor purity.

‘greatly save time and labor’



Comparative Study > J Clin Pathol. 2019 Dec;72(12):830-835. doi: 10.1136/jclinpath-2019-205935. Epub 2019 Jun 23.

Microsatellite instability diagnosis using the fully automated Idylla platform: feasibility study of an in-house rapid molecular testing ancillary to immunohistochemistry in pathology laboratories

Laura Samaison [1], Mélanie Grall [1], Frédéric Staroz [1], Arnaud Uguen [2]

Affiliations + expand

PMID: 31235541 DOI: 10.1136/jclinpath-2019-205935

Abstract

Aim: To study the performances of the Idylla MSI Assay in the diagnosis of microsatellite instability (MSI) or microsatellite stability (MSS).

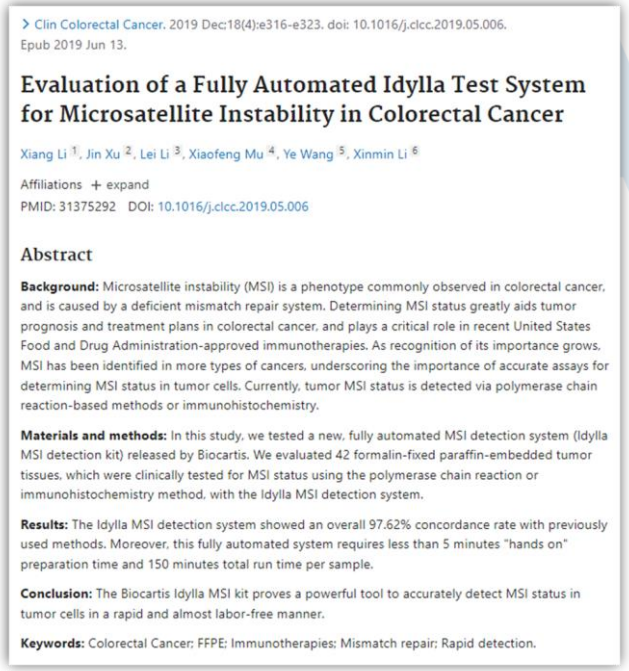
Methods: We selected 12 tumour samples previously tested for MSI focusing on cases with discrepant results between MLH1, PMS2, MSH2 and MSH6 immunohistochemistry and microsatellite molecular analyses (five cases) or doubtful immunohistochemistry (two cases). Idylla MSI Assay was compared with retrospective immunohistochemistry and molecular results.

Results: Idylla MSI Assay showed an almost perfect concordance with microsatellite analysis results previously obtained (only one case with not fully conclusive analysis due to sample exhaustion). The full molecular analysis took less than 150 min per sample and revealed no mutation in any of the seven microsatellite sequences in five MSS samples and four to six mutated ones in seven MSI-High samples.

Conclusion: At the era when the determination of MSI/MSS status is becoming important for rapid treatment choices, the Idylla MSI Assay consists of a valuable easy-to-perform diagnostic tool that allows, complementary to MLH1, PMS2, MSH2 and MSH6 immunohistochemistry, the diagnosis of MSI/MSS status in a single day.

Keywords: Idylla; colorectal cancer; immunohistochemistry; microsatellite instability; mismatch repair deficiency.

‘diagnosis of MSI + MMR in one single day’



Clin Colorectal Cancer. 2019 Dec;18(4):e316-e323. doi: 10.1016/j.clcc.2019.05.006. Epub 2019 Jun 13.

Evaluation of a Fully Automated Idylla Test System for Microsatellite Instability in Colorectal Cancer

Xiang Li [1], Jin Xu [2], Lei Li [3], Xiaofeng Mu [4], Ye Wang [5], Xinmin Li [6]

Affiliations + expand

PMID: 31375292 DOI: 10.1016/j.clcc.2019.05.006

Abstract

Background: Microsatellite instability (MSI) is a phenotype commonly observed in colorectal cancer, and is caused by a deficient mismatch repair system. Determining MSI status greatly aids tumor prognosis and treatment plans in colorectal cancer, and plays a critical role in recent United States Food and Drug Administration-approved immunotherapies. As recognition of its importance grows, MSI has been identified in more types of cancers, underscoring the importance of accurate assays for determining MSI status in tumor cells. Currently, tumor MSI status is detected via polymerase chain reaction-based methods or immunohistochemistry.

Materials and methods: In this study, we tested a new, fully automated MSI detection system (Idylla MSI detection kit) released by Biocartis. We evaluated 42 formalin-fixed paraffin-embedded tumor tissues, which were clinically tested for MSI status using the polymerase chain reaction or immunohistochemistry method, with the Idylla MSI detection system.

Results: The Idylla MSI detection system showed an overall 97.62% concordance rate with previously used methods. Moreover, this fully automated system requires less than 5 minutes "hands on" preparation time and 150 minutes total run time per sample.

Conclusion: The Biocartis Idylla MSI kit proves a powerful tool to accurately detect MSI status in tumor cells in a rapid and almost labor-free manner.

Keywords: Colorectal Cancer; FFPE; Immunotherapies; Mismatch repair; Rapid detection.

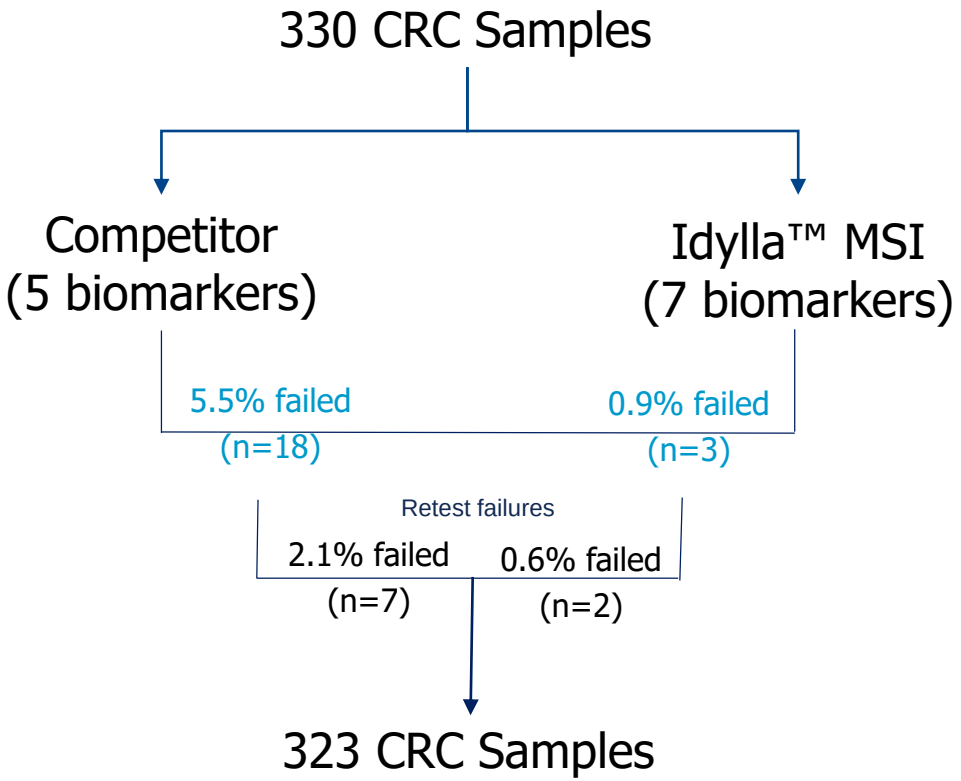
‘rapid and almost labor-free manner’

Lee et al. 2019; Samaison et al, 2019; Li et al, 2019

IDYLLA™ MSI TEST VALIDATION STUDY

EXCELLENT PERFORMANCE AND LOW FAILURE RATE VS REFERENCE METHODS

COMPARISON STUDY VERSUS PCR COMPETITOR



99.7%
Concordance
(322 / 323)

CRC Samples		Competitor	
		MSI-H	MSS
Idylla™ MSI Test	MSI-H	**75**	0
	MSS	1*	**247**

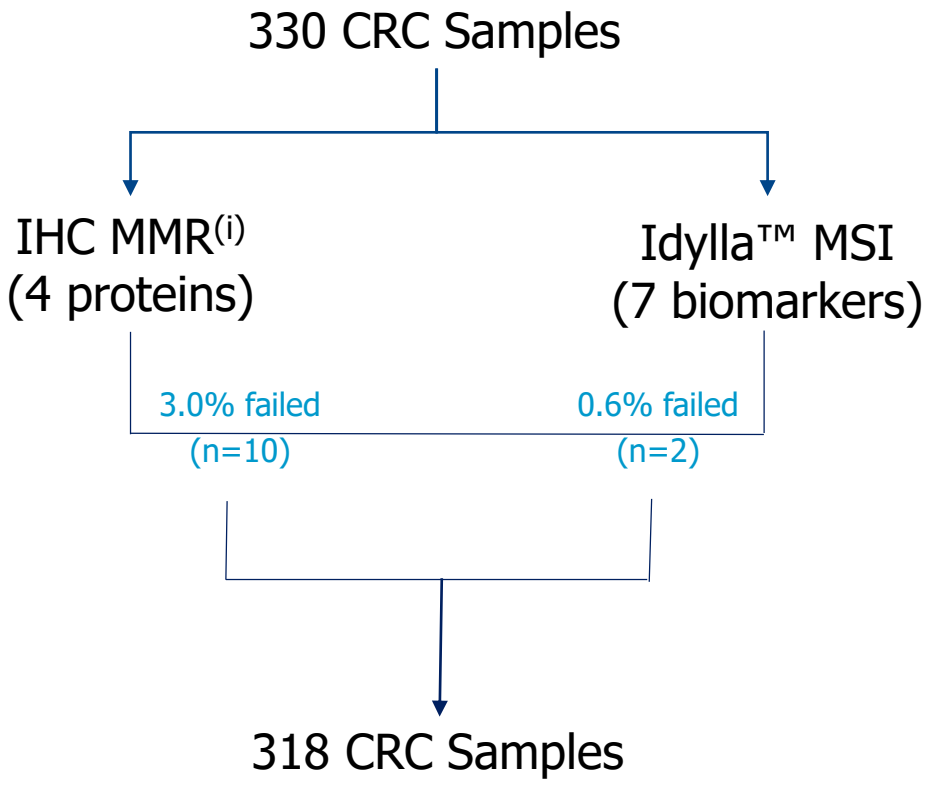
* Failed in 1st competitor run; MSI-H in 2nd competiror run, and dMMR with IHC.

BIOCARTIS

IDYLLA™ MSI TEST VALIDATION STUDY

EXCELLENT PERFORMANCE AND LOW FAILURE RATE VS REFERENCE METHODS

COMPARISON STUDY VERSUS IMMUNOHISTOCHEMISTRY



97.5%
Concordance
(310 / 318)

CRC Samples		IHC MMR	
		dMMR	pMMR
Idylla™ MSI Test	MSI-H	**72**	0
	MSS	8*	**238**

- 7 confirmed as MSS by Promega MSI Analysis System v1.2
- 1 reported as MSH by Promega MSI Analysis System v1.2

Peer-reviewed publications

GOING MOLECULAR HAS NEVER BEEN EASIER

The Idylla™ MSI Test is a CE-marked IVD in Europe and validated for detection of MSI status in colorectal cancer.

SCIENTIFIC VALIDATION: IDYLLA™ MSI PRODUCT PUBLICATIONS

Technology supported by evidence is driving adoption

85%

7.5%

7.5%

27

papers published in peer-reviewed journals using the Idylla™ MSI Test/Assay

Disease Area	# papers	Reference methods	Outcome
	14 papers	IHC, NGS, Bethesda markers	Excellent performance Lowest failure rate Fastest TAT and shortest HOT[1,2,3]
	7 papers	IHC, NGS, Bethesda markers	Good concordance Lower sensitivity vs IHC Excellent specificity Rescue inconclusive IHC cases[4] at least 30-40% TC[4,5]
	1 papers	IHC	Good concordance Rescue inconclusive IHC cases[6]
	5 papers	IHC, Bethesda markers	Good concordance Rescue inconclusive IHC cases[7] Lowest failure rate[7]

Updated JAN 2023

PERFORMANCE OF IDYLLA™ IN COLORECTAL CANCER

CRC

93% to 100% concordance with IHC
94% to 100% concordance with Molecular Methods

Study	# CRC cases	Concordance, OPA	Reference method
Velasco A et al Virch Arch 2020	1301	96.4% 98.0%	IHC routine molecular PCR tests
Gilson P et al Sci Rep 2020	15	100% 100%	IHC Promega
Mindiola-Romera et al *Exp Mol Path 2020*	47	100% 100%	IHC Promega
Malapelle et al Cells 2020	73	93.1%	IHC
Pécriaux et al J Clin Path 2020	53	94%	PentaPlex
Zwaenepoel et al J Mol Diagn 2020	330	98.7% 99.7%	IHC Promega
Lee et al J path Trans Med 2019	115	99%	NGS
Li et al Clin Col Can 2019	42	97%	Conventional PCR

OPA: overall percent agreement
The table does not include all papers published, it excluded for example the papers with a sample size <10 and papers that assessed solely subgroups (i.e. mucinous adenocarcinoma)

PERFORMANCE OF IDYLLA™ IN ENDOMETRIAL CANCER

EC

87% to 100% concordance with IHC
Equal diagnostic performance within Molecular Methods

Study	# EC cases	Concordance (OPA)	Reference method	Additional information
Libera et al. Hum Path. 2022	56	ND	IHC	Retrospectieve selection: 31 EC dMMR and 25 EC pMMR 4 molecular methods vs. IHC: Oncomate Promega best in class with AUC of 0.98 and sensitivity of 96.8%, followed by Idylla™ (0.86 and 71%), Easy PGX of Diatech (0.82, 63.3%) and Tapestation4200 (0.7, 48.4%).
Gatius et al Virchow Archive 2022	242	87.5% 89.9%	IHC Promega	Invalid cases: 7% for IHC, 5.37% for Promega and 2.47% for Idylla Concordance Promega vs IHC: 88.6%
Samaison and Uguen Pathol Int 2022	16	94.3%	IHC + Bethesda	Pancancer (18 GC, **16 EC**, 8 OC, 3 PaC, 9 other) Retrospective: selected 28 pMMR/MSS and 26 dMMR/MSI, concordant Bethesda and IHC 3 disordant: sebecaus adenoma, gastric cancer and uterine corpus
Gilson P et al Sci Rep 2020	15	100%	IHC	OPA NGS *versus* IHC was 93%.
Malapelle et al Cells 2021	33	94% pMMR 77% dMMR	IHC	Pancancer (40 PrC, 39 GC, 38 OC, 35 PaC, **33 EC**) OPA Tapestation 4200 *versus* IHC (91% for pMMR and 68% for dMMR)
Pécriaux et al J Clin Path 2020	15	94%	Pentaplex PCR	Pancancer (53 CRC, 7 SI, 15 PaC,16 GC, **15 EC**, 5 OC, 4 UTC) Extracted DNA used in Idylla™ cartridge
Rafaniello-Raviele et al J Clin Path 2021	174	91.4%	IHC	3rd test Promega for 20 discordant cases: 90% (18/20) concordance Idylla with Promega
Siemanowksi et al Cancers (Basel) 2021	100	88%	IHC	Same diagnostic performance within molecular test methods (vs IHC) Molecular test can rescue invalid IHC results Recommendation more neoplastic cells (≥40%) and higher amount of tissue for EC (vs CRC)
Dedeurwaerdere et al Scientific Reports 2021	21	PPA 58% NPA 100%	IHC	NGS vs IHC: 75% PPA and 100% NPA Same diagnostic power (AUC) of all molecular tests
Ukkola et al Virchow Archive 2021	141	87.2%	IHC	Recommendation more neoplastic cells (≥ 30%) for EC (vs CRC)

OPA: overall percent agreement. PPA: positive percent agreement. NPA: negative percent agreement. ND: not determined.
Use of the Idylla™ MSI test on endometrial cancer samples to be considered for research use only

PERFORMANCE OF IDYLLA™ IN GASTRIC CANCER

GC

90% to 100% concordance with IHC

Study	# GC cases	Concordance (OPA)	Reference method	Additional information
Samaison and Uguen Pathol Int 2022	18	94.3%	IHC + Bethesda	Pancancer (18 GC, 16 EC, 8 OC, 3 PaC, 9 other) Retrospective: selected 28 pMMR/MSS and 26 dMMR/MSI, concordant Bethesda and IHC 3 disordant: sebecaus adenoma, gastric cancer and uterine corpus
Malapelle et al Cells 2021	39	94% pMMR 77% dMMR	IHC	Pancancer (40 PrC, 39 GC, 38 OC, 35 PaC, 33 EC) OPA Tapestation 4200 *versus* IHC (91% for pMMR and 68% for dMMR)
Pécriaux et al J Clin Path 2020	16	94%	Pentaplex PCR	Pancancer (53 CRC, 7 SI, 15 PaC,16 GC, 15 EC, 5 OC, 4 UTC) Extracted DNA used in Idylla™ cartridge
Farmkiss et al	50	98%	IHC	Retrospective observational study demonstrating Idylla™ less subjective than IHC

OPA: overall percent agreement
Use of the Idylla™ MSI test on gastric cancer samples to be considered for research use only

Take home messages

The Idylla™ MSI Test is a CE-marked IVD in Europe and validated for detection of MSI status in colorectal cancer.

IDYLLA™ MSI TEST- AN IDEAL OPTION FOR YOUR LAB

Excellent performance

- Excellent concordance with IHC and molecular methods
- Reduced invalid rate compared to standard molecular methods

Unmatched ease of use

- In average less than 3 minutes hands-on time, at minimum 1 FFI
- Automated sample to result in ~150 minutes
- No need for batching or paired normal tissue sample

Used by top laboratories

- More than 27 peer reviewed publications, covering colorectal, en

Solid regulatory status

- CE-IVD marked in Europe
- 510(k) clearance in US
- Approved CDx status in Japan

IDYLLA™: A SOLUTION FOR EVERY LAB

FASTER LOCAL TESTING DRIVES QUICKER TREATMENT AND MAY LOWER HEALTHCARE COSTS

Large hospitals Reference labs Cancer centers	Fast turnaround-time Complementary to NGS Directly actionable
Regional hospital labs & specialized group practices	Decentralized Ease-of-use No technical lab skills required
Community setting hospitals & medical offices	Fully automated Allows in-house MDx testing Sample retention

Idylla™ provides strong economic incentive for customers to retain MDx testing in-house

THANKS FOR YOUR TIME

THINK IDYLLA™
BECAUSE TIME MATTERS