

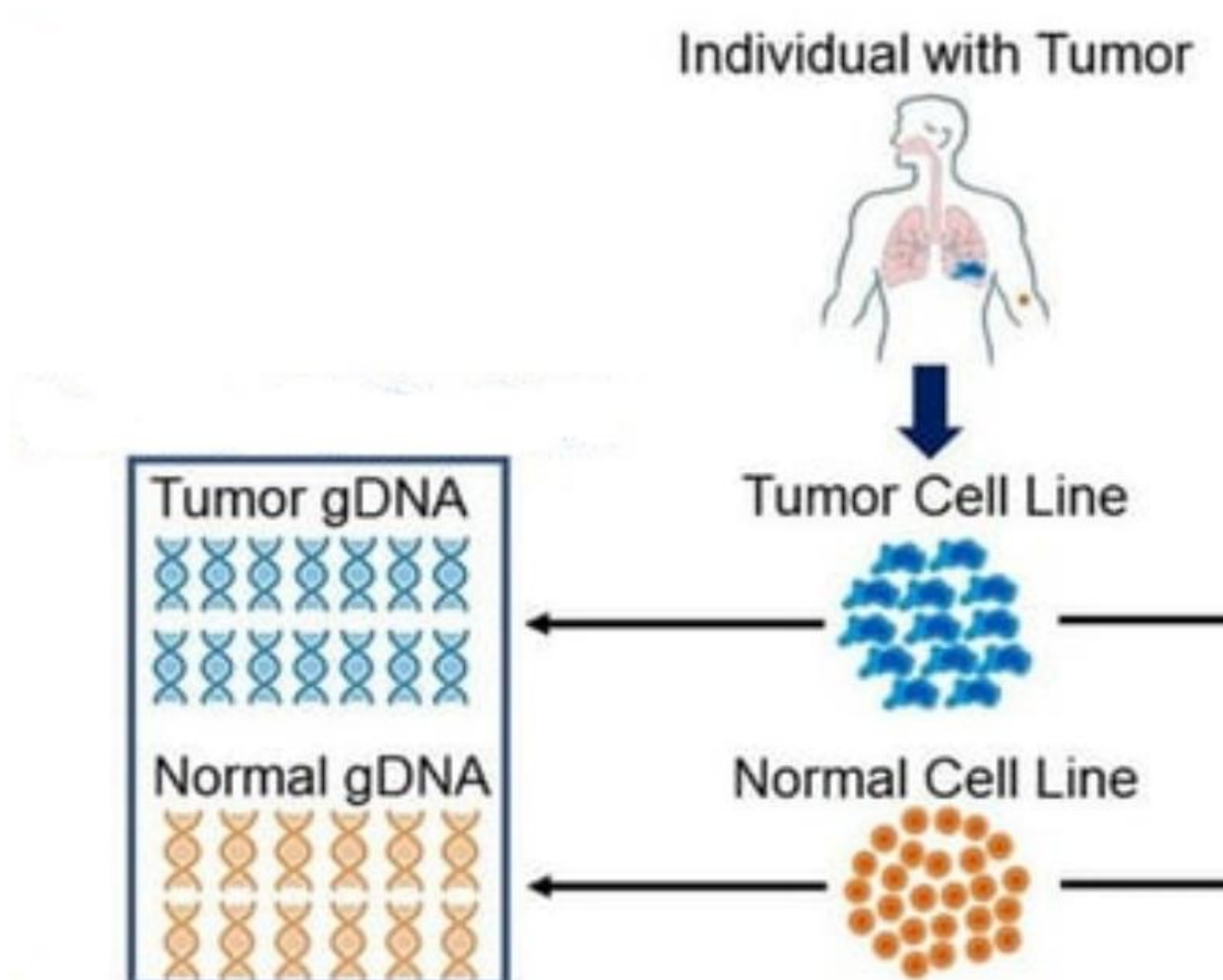
# MSI Reference Standard--CBP80001

## BACKGROUND

Microsatellite instability (MSI) is a molecular scar resulting from a defective mismatch repair system (dMMR) and associated with various malignancies. MSI tumours are characterized by the accumulation of mutations throughout the genome and particularly clustered in highly repetitive microsatellite (MS) regions. MSI/dMMR status is routinely assessed in solid tumours for the initial screening of Lynch syndrome, the evaluation of cancer prognosis, and treatment decision-making. Currently, pentaplex PCR-based methods and MMR immunohistochemistry on tumour tissue samples are the standard diagnostic methods for MSI/dMMR. Other tissue methods such as next-generation sequencing or real-time PCR-based systems have emerged and represent viable alternatives to standard MSI testing in specific settings.

## INTRODUCTION

CB-Gene has launched MSI standard product, involving 12 pairs sample gDNA (one is from tumor sample,the other one is from paired normal sample). Some paired samples are from the same individual and some are from different individual.



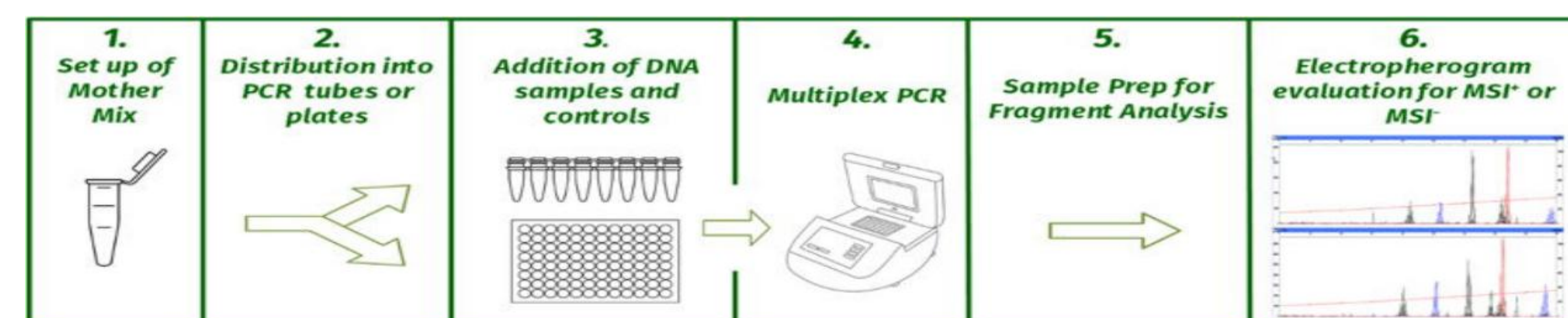
These paired references are analyzed in PCR-CE MSI analysis system : containing 6 nucleotide markers (BAT-25, BAT-26, MONO-27, NR-21, NR-24 and NR-27) for MSI typing . The MSI status could also be inferred using NGS data from whole-genome, whole-exome, gene targeted , or RNA sequencing that were not originally developed for MSI diagnosis . We further validated these standards using 50 genes NGS panel .

## PRODUCT DATA

We provide 12 pairs Reference Standard with confirmed MSI status by PCR-CE assay and NGS assay.

Name	Cat.No.	Background	Status	Comments
MSS-P1 Reference Standard	CBP80002-1T	Breast Cancer, Female	MSS	Same individual
	CBP80002-1N	B lymphoblast, Female	/	
MSS-P2 Reference Standard	CBP80002-2T	Ductal breast carcinoma, Female	MSS	Same individual
	CBP80002-2N	B lymphoblast, Female	/	
MSS-P3 Reference Standard	CBP80002-3T	Ductal breast carcinoma, Female	MSS	Same individual
	CBP80002-3N	B lymphoblast, Female	/	
MSS-P4 Reference Standard	CBP80002-4T	stage 4, adenocarcinoma Lung, Female	MSS	Same individual
	CBP80002-4N	B lymphoblast, Female	/	
MSI-H-U1 Reference Standard	CBP80002-5T	Colon Carcinoma,Female	MSI-H	Different individual
	CBP80002-5N	B lymphoblast, Female	/	
MSI-H-U2 Reference Standard	CBP80002-6T	colon Carcinoma, Male	MSI-H	Different individual
	CBP80002-6N	B lymphoblast, Female	/	
MSI-H-U3 Reference Standard	CBP80002-7T	Colon adenocarcinoma, Male	MSI-H	Different individual
	CBP80002-7N	B lymphoblast, Female	/	
MSI-H-U4 Reference Standard	CBP80002-8T	Prostate carcinoma, Male	MSI-H	Different individual
	CBP80002-8N	B lymphoblast, Female	/	
MSI-H-U5 Reference Standard	CBP80002-9T	Endometrial adenocarcinoma, Female	MSI-H	Different individual
	CBP80002-9N	B lymphoblast, Female	/	
MSI-H-U6 Reference Standard	CBP80002-10T	Colon adenocarcinoma, Male	MSI-H	Different individual
	CBP80002-10N	B lymphoblast, Female	/	
MSI-H-U7 Reference Standard	CBP80002-11T	Colon adenocarcinoma, Female	MSI-H	Different individual
	CBP80002-11N	B lymphoblast, Female	/	
MSI-H-U8 Reference Standard	CBP80002-12T	Colon adenocarcinoma, Female	MSI-H	Different individual
	CBP80002-12N	B lymphoblast, Female	/	

## PCR-CE DETECTION PROCESS



## MSI-H-U1 SHOWCASE DATA

PCR-CE Assay data:

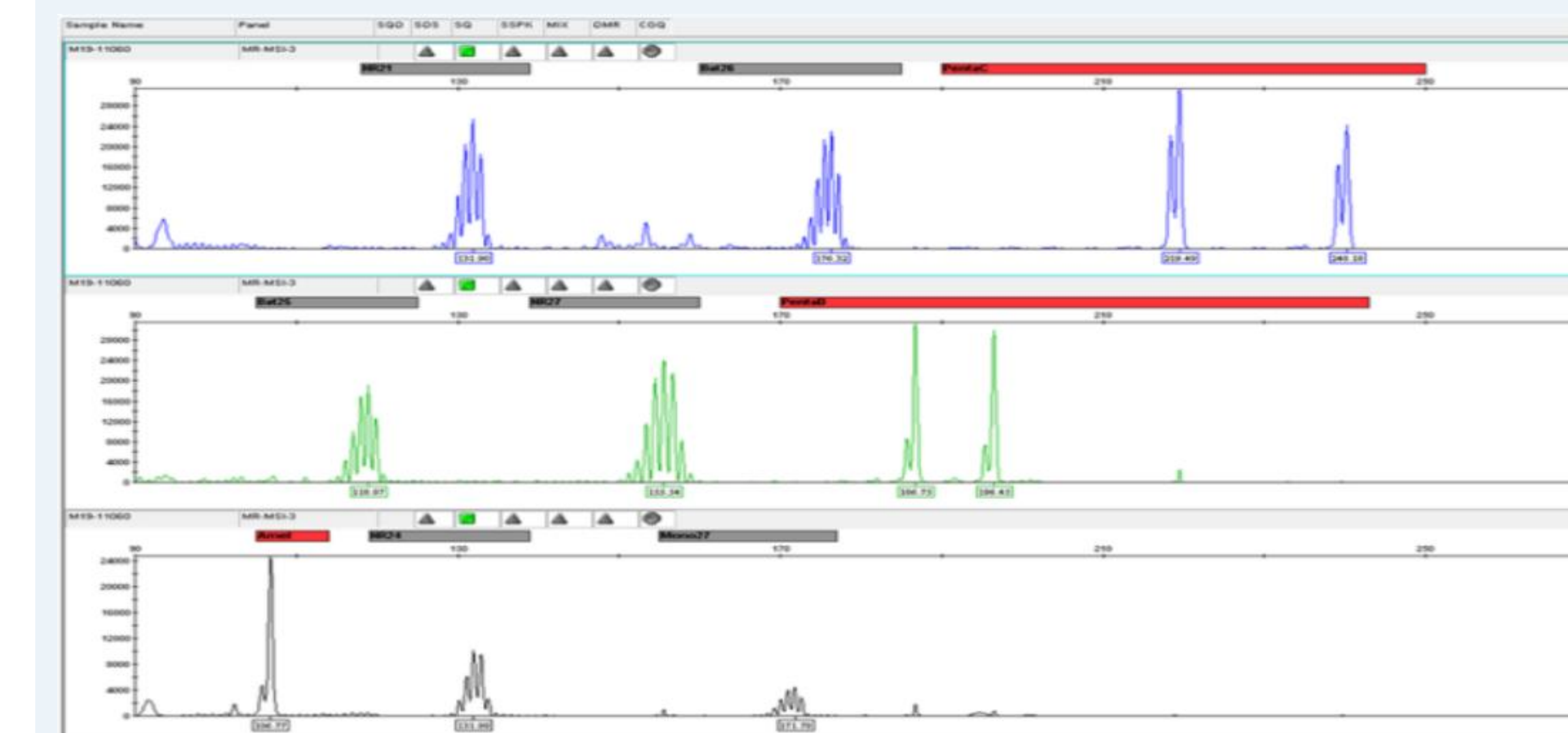
CBP80002-5N			CBP80002-5T		
Marker	Size 1	Size 2	Marker	Size 1	Size 2
NR21	131.9		NR21	120.92	
Bat26	176.32		Bat26	166.04	
Bat25	118.87		Bat25	109.62	
NR27	155.54		NR27	143.22	
NR24	131.99		NR24	125.79	
Mono27	171.78		Mono27	161.65	

NGS Assay data:

Item	Results	Method	Percentage
MSI Status	MSI-H	NGS-Panel	100.00%

## TYPING ATLAS

### CBP80002-5N



### CBP80002-5T

