

Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 1 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

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Title: Primary Sample Manual: Molecular Biology – Genetic Testing

Changes made since previous version: *Added sentence to 'COLOSAFE: METHYLATED SDC2 GENE' information, stating that the test is not diagnostic. Changed the consultant responsible to Dr. Michael Louw.*

Note: *Please refer to the document record on IQM/Q-Pulse for the revision history of this document.*

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Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 2 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

CONTENTS:

INTRODUCTION.....	3
TEST INFORMATION TEMPLATE.....	3
REFERENCES.....	4
REASONS FOR REJECTION OF SAMPLES/NON-REPORTING OF TESTS.....	4
COLOSAFE: METHYLATED SDC2 GENE	5

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Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 3 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

INTRODUCTION

This is a list of the Genetic tests performed in the Molecular Biology Department at Eurofins Biomnis' Dublin Laboratory. For a searchable list of tests performed by Eurofins Biomnis in France, in our laboratories in Lyon and Paris, [here](#).

If you cannot find details of a test you require, please contact our Client Services department on Free Phone 1800-252-966 or 01 295 8545, or e-mail clientservices@ctie.eurofinseu.com.

For sample collection, please contact our Logistics department on Free Phone 1800-252-967, or e-mail logistics@ctie.eurofinseu.com.

TEST INFORMATION TEMPLATE	
Brief information on clinical background, indications for test and interpretation of test results.	
Preparation of Patient: any special preparation required, such as fasting. Precautions: any special circumstances, conditions etc. to be aware of.	
Accredited	Whether or not the test is accredited by INAB to ISO 15189. If the test is accredited (Yes), this section is colour-coded in green; if the test is not accredited (No), this section is colour-coded in orange.
Method	Test method. Standard Operating Procedure reference for this test.
Sample Requirements	Type of tube required and other information.
Turnaround Time	The maximum turnaround time in working days from receipt of the sample in the laboratory's Pre-Analytics Department to the authorisation of the result. Working days are Monday to Friday 08:00 to 18:00.
Stability	Sample stability under various conditions.
Laboratory Sample Storage	Conditions under which samples are stored following testing, and the length of time for which the samples are stored.
Results and Source	Units and reference range(s) for the test. Source of the reference ranges: 1. Test manufacturer's Method Sheet.
Limitations of Test	The Limitations of the test as provided by the test manufacturer.
Notes	Any additional relevant information (e.g. notifiable diseases)

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Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 4 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

REFERENCES

1. Creative Biosciences Colosafe Methylation Detection Kit for Human SDC2 Gene (Real Time PCR) Instructions for Use Rev.03, 25/07/2023

REASONS FOR REJECTION OF SAMPLES/NON-REPORTING OF TESTS

1. Samples received beyond the stability limits and/or not at the correct temperature indicated below for each test.
2. Samples received in the incorrect tube.
3. Samples received without the correct media.
4. Samples that are too heavy (i.e. contain too much stool).
5. Samples that do not contain enough stool.

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Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 5 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

COLOSAFE: METHYLATED SDC2 GENE

Aberrant DNA hypermethylation is associated with the development of cancer. A number of studies have analysed the methylation levels of cancer tissues and adjacent non-tumour tissues in patients with colorectal cancer, leading to the discovery of the involvement of a highly methylated SDC2 gene. Compared with normal tissues, where almost no methylation of the SDC2 gene is seen, the hypermethylated SDC2 gene shows a high level of expression in patients with colorectal cancer and adenomas. This makes it an excellent marker for the diagnosis of colorectal cancer.

The Creative Biosciences Colosafe Methylation Detection (Colosafe) Kit for the Human SDC2 Gene is intended for the qualitative detection of SDC2 gene methylation in human stool samples. The Colosafe test is recommended for patients who have been referred for colonoscopy, to be used in conjunction with colonoscopy for the diagnosis of colorectal cancer. The results of the Colosafe test alone cannot be used for the diagnosis of colorectal cancer.

The Colosafe Methylation Detection Kit for the Human SDC2 Gene is **not** a diagnostic test.

Preparation of patient: Patient should empty their bladder immediately prior to sample collection

Precautions: None.

Accredited	No
Method	The Colosafe test consists of two steps: DNA extraction and conversion, and Real-Time PCR. During the extraction and conversion step, DNA is extracted from stool samples using magnetic bead technology. The extracted DNA is then treated with bisulphite, which converts unmethylated cytosines to uracil, while having no effect on methylated cytosines. Real-Time PCR is then performed on the bisulphite-converted DNA, to detect the methylated SDC2 gene, as well as the ACTB gene, which is used as an internal control. The methylated SDC2 gene is amplified by specific primers, and the amplification signal is emitted by a FAM-labelled fluorescent probe in the presence of methylated SDC2. The amplification signal for the ACTB gene is emitted by a Texas Red-labelled fluorescent probe. SOP: MB71 & MB72
Sample Requirements	Sample Type: Stool collected using the Colosafe Sample Collection kit. The total volume of sample and preservation solution in the tube should be approximately 20ml.
Turnaround Time	10 working days from sample receipt.

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Document number: PSM MOLECULAR BIOLOGY GENETIC TESTING Issue number: 1.02	Effective date: 05/10/26	Page 6 of 6
Title: Primary Sample Manual: Molecular Biology – Genetic Testing		

Stability	Specimens in Colosafe collection tubes must be received into the laboratory within 5 days of the sample being collected. The samples may be sent to the laboratory at 2-30°C.
Laboratory Sample Storage	Primary Sample Tubes: 3 weeks at 2-8°C Supernatant (post-processing): 1 month at -20°C DNA Extractions: 3 months at -20°C
Results and Source	Methylated SDC2 Gene (Colosafe) Detected Methylated SDC2 Gene (Colosafe) Not Detected Methylated SDC2 Gene (Colosafe) Borderline Invalid Source: Creative Biosciences Colosafe Methylation Detection Kit for Human SDC2 Gene (Real Time PCR) Instructions for Use Rev.03, 25/07/2023
Limitations of Test	- The Methylation Detection Kit for the Human SDC2 Gene (Real Time PCR) can only be used for stool samples collected using the Stool Collection Device produced by Creative Biosciences (Guangzhou) Co., Ltd. Stool samples collected by other means are not applicable for use with this kit. - The collection and storage of samples, as well as the DNA extraction and bisulphite treatment, should be carried out as described. Otherwise, the test results may be affected, leading to false negative and false positive results. - The test results of the Methylation Detection Kit for the Human SDC2 Gene (Real Time PCR) are for clinical reference only and should not be used as the basis for clinical diagnosis. The test results should be judged in combination with other clinical diagnostic results. For patients with positive results and borderline/grey zone results, colonoscopy is recommended for diagnosis. Patients with negative results cannot rule out the possibility of illness. For invalid samples, repeat sampling is recommended.

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