



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **3M 01/18-05/17**

Renewal decision dated: **07-04-2021**

Expiry date: **18-05-2025**

The Company:

**3M Health Care**

Microbiology Products

2501 Hudson Road – Building 275 5W05

MN 55144, St PAUL, USA

Is authorized to affix the NF VALIDATION mark on the alternative analysis method cited below, in accordance with the NF VALIDATION general rules and the certification rules NF102 - Validation of alternative analysis methods (Application to the food industry):

## Test 3M™ Molecular Detection Assay 2 - *E. coli* O157

Validated for the detection of *Escherichia coli* O157 (including H7)

Technical sheet reference's

34-8720-4565-2

This decision attests that the alternative analysis method has been assessed by AFNOR Certification and found to conform to the standards cited in page 2/2 and complementary requirements, as specified in the certification reference document. The **principal certified characteristics** are the "analytical performances" as defined in the associated validation study summarized report (sensitivity, relative level of detection), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 21-12-2017). This NF VALIDATION certificate, included 2 pages, is valid until **18<sup>th</sup> May 2025**. It is subject to the results obtained upon regular controls carried out by AFNOR Certification. Appropriate decision is made by AFNOR Certification in accordance with the NF VALIDATION general rules and certification rules NF102 - Validation of alternative analysis methods (Application to the food industry).



Managing Director  
Julien NIZRI



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Renewal decision dated: **07-04-2021**

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The alternative analysis method:

## Test 3M™ Molecular Detection Assay 2 - *E. coli* O157

Validated for the detection of *Escherichia coli* O157 (including H7)

Manufactured by:

**3M Columbia Plant**  
5400 Paris Road  
COLUMBIA  
65202, MISSOURI, USA

Has been certified according to the reference documents and the application scope specified here after:

Validation protocol	<b>NF EN ISO 16140-2</b> (September 2016): Microbiology of the food chain. Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
Reference method(s)	<b>NF EN ISO 16654</b> (July 2001) and its <b>amendment A1</b> (2017) : Microbiology of food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157 - Amendment 1 : annex B : result of interlaboratory studies
Scope	Raw beef meats, raw dairy products, raw fruits and vegetables
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the 3M™ Molecular Detection instrument and its software version 2.2 or later versions.

Please send any queries concerning the performances of the certified alternative method to AFNOR Certification.

You may download the validation study **summarized report** on <http://nf-validation.afnor.org/en>.